

New Paradigms In Healthcare

Jacopo Martellucci
Francesca Dal Mas *Editors*

Towards the Future of Surgery

 Springer

New Paradigms in Healthcare

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In the first two decades of this new millennium, the self-sufficiency of Evidence-Based Medicine (EBM) have begun to be questioned. The narrative version gradually assumed increasing importance as the need emerged to shift to more biologically, psychologically, socially, and existentially focused models. The terrible experience of the COVID pandemic truly revealed that EBM alone, while being a wonderful scientific philosophy and containing the physician's paternalistic approach, has its limitations: it often ignores both the patient's and physician's perspectives as persons, as human beings; it pays relentless attention to biological markers and not to the more personal, psychological, social, and anthropological ones, removing the emotions, thoughts, and desires of life, focusing on just the "measurable quality" of it.

Health Humanities, Medical Humanities and Narrative Medicine are arts intertwined with sciences that allow to broaden the mindset and approach of healthcare professionals, helping them to produce better care and more well-being.

Aim of this series is to collect "person-centered" contributions, as only a multidisciplinary and collaborative team can meet the challenge of combining the multiple aspects of human health, as well as the health of our planet, and of all the creatures that live on it, in a common effort to stop or reverse the enormous damage committed by humans during our anthropocentric era: a new paradigm of healthcare, education and learning to create a sustainable health system.

Jacopo Martellucci • Francesca Dal Mas
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Towards the Future of Surgery

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Preface

Why should we need a book to collect ideas about the future of surgery? And why should it be co-edited by a surgeon and management scholar?

As many more industrial fields, the healthcare sector is facing some grand challenges that are disrupting the current scenario. These urgent issues are calling for sound solutions.

The global demand for healthcare services is increasing, especially taking into consideration an aging population with chronic diseases. Budget cuts and the need for long-term financial sustainability are being imposed in most countries. Technological innovation is running fast, and the fourth industrial revolution characterized by paradigms like robotics, artificial intelligence, additive manufacturing, and the blockchain is being replaced by new solutions aiming at deep tech, quantum computing, and space economy. While technological developments are relevant, sometimes research and development activities still struggle to be translated from a lab scale to pharmaceutical products, clinical protocols, diagnostic or surgical techniques, leaving important unmet medical needs. Therefore, solutions should be found elsewhere. The COVID-19 pandemic has exacerbated all these challenges, underlining some relevant organizational and knowledge gaps to be addressed and resolved.

Most of these issues are affecting surgery as well. Technologies like artificial intelligence, mixed and augmented realities, and robotics are offering new surgical solutions, but they are also unveiling new ethical questions and educational paradigms.

The relationship with the patient is changing, calling for a more effective surgeon-patient dialogue and shared decision-making, which often requires adequate tools to translate knowledge and information, even at a distance with e-health instruments.

Multidisciplinarity is a key paradigm, especially in surgical oncology, and the clinical expert panel comprises new specialities and professionals for integrated care. Surgeons will need to act as “hybrid managers,” with their responsibilities running beyond pure surgical practice.

Global trends like environmental sustainability are stepping into the operating room, affecting the way surgeons will carry on their decision-making processes.

Diversity and inclusion represent top priorities in medicine and in the management of surgical teams.

That is why the surgical profession and the surgeon's figure will need to take all of these challenges and trends into account. An exciting scenario awaits, but big changes are expected. Our book, comprising contributions from surgeons but also other professionals (healthcare executives, policymakers, academics, clinicians with different expertise, ...), wishes to inspire the international surgical community to face these exciting challenges.

Florence, Italy
Venice, Italy

Jacopo Martellucci
Francesca Dal Mas

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Part I
Introduction

Chapter 1

How to Create a Surgeon: The Surgical Leaders of Tomorrow



Jacopo Martellucci  and Francesca Dal Mas 

“From time to time predictions about the future of surgery have been made that subsequently proved to be both fallible and foolish. Indeed, most such predictions now serve the classic purpose of indicating the folly of those who made them.”

Debakey ME. The future of surgery. *Ann Surg.* 1963.

In these times of rapid changes, the evolution of surgery only partly reflects developments in surgical technique or in physiopathological knowledge. The greatest influence is received from changes in fields supposedly unrelated to human health, such as technology, business, society.

Until now the major changes in surgical practice have been related to advancements in medical science, such as asepsis, anesthesia, blood transfusion, or organ transplantation. However, the progressive evolution from open surgery to minimally invasive surgery and from demolitive/reconstructive surgery to interventionalism marked the crossing of an irreversible limit: surgery of the future can no longer be independent of technology.

In the near future, surgery is expected to become even more precise and less invasive, with fewer risks and side effects, even if not so much due to the technical skills of the surgeon (always essential). Robots or computer-guided tools will become commonplace in the operating room, allowing us to perform more complicated procedures, reducing surgical errors, and improving patients outcomes. As healthcare becomes increasingly personalized and data-driven, surgery will become tailored to the individual patient, using advanced analytics to determine the best course of

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action. The use of artificial intelligence, virtual reality, and machine learning algorithms could help surgeons to improve their training, their decision-making process and make surgery more efficient. Advances in technology may also lead to the development of stem cell therapies to repair damaged tissues, 3D printing to create personalized implants, as well as gene-editing techniques to treat genetic diseases.

Technological evolution will also mean that we will be able to explore more effectively the complex mechanisms that regulate our body, enabling us to improve our knowledge and answer many unanswered questions.

Unfortunately, technological surgery will have costs, and waste, and these will certainly be among the social challenges of our near future. Moreover, the progressive increase in technological interfaces between the surgeon and the patient could adversely affect what is the basis of our work: the patient–doctor relationship.

All these challenges will make the surgeon we have in mind when looking back at the past very different from the one we will be asked to be, but one thing is sure: the surgeon will continue to be the heart of this increasingly complex system.

Considering this, the surgical leader of Tomorrow will be:

Technological

“It has become appallingly obvious that our technology has exceeded our humanity.”

Albert Einstein.

Obviously. In a world increasingly filtered by technology and digital interfaces surgeons will need to be able to manage and sometimes to chase technological actualities and advances. This will influence their training, their profession, their research, their reputation.

The possibility to use simulators, to participate in events and distance learning courses, to network with referral centers, to access any existing scientific content through global databases are just some of the opportunities that will enable more accessible, comprehensive, and continuous training, very different from the traditional model of surgical school, where the content to be learned was not extracted from a shared global knowledge but from local experiences and habits.

It is unnecessary to say that artificial intelligence, robotics, cybernetics, and other bioengineered advances will change our approach to major surgery, such as endoscopic, radiologic guided or endovascular procedures will change our indications.

However, the surgeon’s main task will be not to passively submit to the various technological proposals, but rather to orient them according to his own needs, in order to have developments that are most closely relevant to the requirements of our profession.

Digital

“If you do not come up on a Google.com search you are a nobody.”

Moshe Schein.

Digital surgery may be defined as the use of technology for the enhancement of preoperative planning, surgical performance, therapeutic support, or training, to improve outcomes and reduce harm [1].

Nowadays, it is estimated that up to 60% of the global population uses internet and other digital channels, and this value increases by more than 90% in industrialized countries, with an average time per person daily spent using the internet of more than 6 h (about 2 h/day for social media), and about 50% of people have looked for health or medical information on the internet or have accessed a website that provides information about specific medical conditions [2].

With these considerations in mind, it is evident that the digital world holds significant opportunities for both professionals and patients. Eased professional networking and education but also organizational promotion (health care systems, hospitals, companies, professional societies, patients associations, etc.) and public health programs, or patients education and care are only some of the powerful examples to take advantage of.

However, the surgeon should manage these opportunities carefully because dangerous limitations must always be considered. These included often poor or unverified quality of information, potential damage to professional image, privacy issues (patient privacy, personal privacy, patient–hcp relationship, hospital–hcp relationship, etc.), and legal issues (constantly modified and updated).

Manager

“I would like to see the day when somebody would be appointed surgeon somewhere who had no hands, for the operative part is the least part of the work.”

Harvey Cushing, in a letter to Dr. Henry Christian, November 20, 1911.

In current and future organizational models, the surgeon is increasingly asked for numerous new skills, which are not part of the medical background, and for which professionals often have no training.

A skillful operation is 75% decision-making and 25% dexterity [3] and in about half of the errors in surgical operations (or in medical-legal disputes) there is a communication problem that contributes to the bad result [4].

Nontechnical skills such as decision-making, leadership, teamwork, team building, communication, or resilience are increasingly crucial in a multidisciplinary and multi-professional working context such as the surgical patient pathway, where surgery is often only one of the several therapeutic moments of more and more complex patients.

Moreover, organizational duties are now part of daily business, with the request of control and organization of resources, strategic and streamline management, problem solving, or participation in the budget programming.

Finally, the growing problem of waste produced by surgical activity, the associated energy-intensive processes, the consumption of resources, and the use of volatile anesthetic agents cannot be forgotten, as well as its economic and environmental sustainability.

It is therefore clear that for the surgeon the moment in the operating room will increasingly be a moment of serenity, which interrupts the need to deal with the multitude of non-surgical problems that plague him.

Woman

“The ideal surgeon should have the mind of Aesculapius, the eye of an eagle, the heart of a lion, and the hands of a woman.”

Attributed to fifteenth century English author.

The number of women entering medicine significantly increased over the last decades. Currently, more than 60% of the medical students are women and up to 50% are considering a surgical speciality for their profession. However, despite the increasing number of women in medicine and surgery, there are still low numbers of women in senior faculty and clinical roles and lack of mentorship, feelings of exclusion, demands of childrearing, and poor accommodations during childbearing years are still reported as potential barriers.

Anyway it is certain that this process is not only irreversible but also a great opportunity for the surgery of the future. In these times of rapid changes, with surgery that is less and less extreme and more technical and optimized, ideal scenarios can arise to offer attractive and rewarding professional situations also for women. This also means the improvement of working conditions and work–life balance accommodation. But most of all, it will mean no longer needing to call us male surgeon or female surgeon, but simply surgeon.

Amazing

The knife is not for pressing. It is for drawing across the field of skin.

Richard Selzer, *Esquire*, November 1, 1974.

Medical TV series and movies have accustomed us to an image of good-looking surgeons. Even if it has been suggested that male surgeons may be taller and better looking than other physicians, film stars who play doctors on screen are definitely better looking than both these groups of doctors [5]. Moreover, the era of surgeons presenting to patients and relatives in bloody scrubs is over. Today, surgeon’s appearance affects perceptions of the quality of medical care received, and white coat formal attire was almost always preferred by patients, even if perceptions of attire are influenced by age, setting, and context of care [6].

Over the last few years, there has been a growing interest in integrating arts and humanities in medicine to increase empathy and resilience, improve personal well-being, communication, and observational skills, enhance self-reflection, and promote professionalism. These desired skills and qualities are becoming increasingly important for the physicians and surgeons of tomorrow [7].

Surgery has always been technique, art, passion. The passion behind the choice of a surgical profession has usually been an indicator of a curious and creative personality. It is therefore not surprising that surgeons often take up other creative activities with equal passion, such as visual arts, writing, music, cooking, and many others [8].

It is also interesting to note that, for example, playing music and performing surgery have in common several cognitive skills that include great accuracy in motor performance, integration of multimodal sensory and motor information, coordination between eye and hand, spatial visualization, intense concentration, quick reaction time, and efficient mental rotation. Moreover, it has been shown that people who played a musical instrument performed laparoscopic tasks on a simulator significantly faster than those who did not and musical background is associated with better performance of fundamental surgical skills among surgical novices, particularly technique quality [9].

It is certain, therefore, that the surgeon of the future will not only be good-looking but will also retain the passion that has always characterized our profession, finding more and more alternative ways to improve himself and to keep intact the deeper meaning of surgery, which despite everything is not just profession, but art.

References

1. Lam K, Abràmoff MD, Balibrea JM, et al. A Delphi consensus statement for digital surgery. *NPJ Digit Med.* 2022;5(1):100. <https://doi.org/10.1038/s41746-022-00641-6>.
2. Fox S, Jones S. The social life of internet users. Washington, DC: Pew Internet & American Life Project; 2009.
3. Spencer FC. Teaching and measuring surgical techniques: the technical evaluation of competence. *Bull Am Coll Surg.* 1978;63:9–12.
4. Gawande AA, Zinner MJ, Studdert DM, et al. Analysis of errors reported by surgeons at three teaching hospitals. *Surgery.* 2003;133:614–21. <https://doi.org/10.1067/msy.2003.169>.
5. Trilla A, Aymerich M, Lacy AM, Bertran MJ. Phenotypic differences between male physicians, surgeons, and film stars: comparative study. *BMJ.* 2006;333(7582):1291–3. <https://doi.org/10.1136/bmj.39015.672373.80>.
6. Petrilli CM, Mack M, Petrilli JJ, Hickner A, Saint S, Chopra V. Understanding the role of physician attire on patient perceptions: a systematic review of the literature—targeting attire to improve likelihood of rapport (TAILOR) investigators. *BMJ Open.* 2015;5(1):e006578. <https://doi.org/10.1136/bmjopen-2014-006578>.
7. Mi M, Wu L, Zhang Y, Wu W. Integration of arts and humanities in medicine to develop well-rounded physicians: the roles of health sciences librarians. *J Med Libr Assoc.* 2022;110:247–52. <https://doi.org/10.5195/jmla.2022.1368>.
8. Martellucci J. Surgery and jazz: the art of improvisation in the evidence-based medicine era. *Ann Surg.* 2015;261(3):440–2. <https://doi.org/10.1097/SLA.0000000000000782>.
9. Sun RR, Wang Y, Fast A, Dutka C, Cadogan K, Burton L, Kubay C, Drachenberg D. Influence of musical background on surgical skills acquisition. *Surgery.* 2021;170(1):75–80. <https://doi.org/10.1016/j.surg.2021.01.013>.

Chapter 2

How to Create a Surgeon: History of Surgical Training



Donatella Lippi and Jacopo Martellucci 

Introduction

On the gravestone of William T. G. Morton (1819–1868), in the Cambridge cemetery (Middlesex County, Massachusetts) is written: “*Inventor and Revealer of Inhalation Anesthesia: Before Whom, in All Time, Surgery was Agony; By Whom, Pain in Surgery was Averted and Annulled; Since Whom, Science has Control of Pain*” [1].

On October 16, 1846, in fact, Dr. Morton had practiced the first general narcosis, marking the birth of modern anesthesia. It was an epochal turning point, a new chapter in the history of surgery, which could suppress, in this way, pain and which would have learned to avoid infections and bleeding.

These had always been the obstacles against the affirmation of surgical practice, which remained for a long time, albeit in the articulation of its skills, in the hands of barbers and charlatans: until the nineteenth century, in fact, the evolution of surgery was limited by bleeding, infection, and pain [2].

History of surgery however has very ancient roots as documented by human remains and literary sources. Surgical interventions are attested by literary sources, in ancient times, throughout the Mediterranean basin.

Egyptian papyri, in particular that of Edwin Smith, deal with numerous cases of traumatological interest, and in the classical world, the group of surgical treatises traditionally attributed to the school of Hippocrates, constituted an unsurpassed model for the Hellenistic and Roman culture and then again in the Renaissance and beyond [1].

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The theater of these interventions were the battlefields, which offered the opportunity for decisions and operations, which went beyond the philosophical approach of medicine, to deal with the emergencies of the body.

The results of these interventions, however, denounced the limits of a practice governed by fate: “*Diaulus, lately a doctor, is now an undertaker: what he does as an undertaker, he used to do also as a doctor*” [3].

Military surgeons, on the contrary, were renowned. Eutyches, the surgeon of Ariminum, victim of the hordes of Alemanni and Iutungi invaders in the third century AD, possessed a box containing 150 surgical instruments: scalpels, knives, spring forceps, very sharp hooks, needles, probes and pincers [4].

Operative techniques and surgical interventions ranged, in fact, in the various anatomical districts and differed for various levels of severity: bruises, abscesses, fistulas, removal of arrows, head defects, eye, ear, and odontostomatological diseases, hernias, varices, stones, dislocations, fractures, and gangrene.

From the naïve lowering of cataracts, to paracentesis for ascites, to hernia operations and perineal incisions to remove bladder stones.

This patrimony of knowledge, which was systematized in the classical world, was transmitted to the medieval West, through the *Epitome*, in seven volumes, by Paul of Aegina (seventh century AD.), a compendium of medical texts, which, in the ninth century, was translated into Arabic and became the surgical text of reference for medical encyclopedists of the Islamic world.

Toward Surgical Education

The Roman Cornelius Celsus (25 BC–50 AD) was the author of the eight-volume compendium *De medicina libri octo*, which was the first medical treatise written in Latin and using Latin medical terminology, including two books about surgery (VII + VIII).

In this work, he divided medical knowledge into three parts: a part devoted to diseases cured by means of diet; diseases cured with medicine; diseases in which surgical intervention was necessary [5].

Also in the so-called Hippocratic Oath, the role of the surgeon was clearly distinguished by the role of the doctor, laying the foundations of medicine as an intellectual profession while surgery was considered a practical, banausic activity: “*I will not cut for stone, even for patients in whom the disease is manifest; I will leave this operation to be performed by practitioners, specialists in this art*” [6].

Ὁὐ τεμέω δὲ οὐδὲ μὴν λιθιῶντας, ἐκχωρήσω δὲ ἐργάτησιν ἀνδράσι πρήξιος τῆσδε: the expression πρήξιος confirms the practical approach, not supported by a theoretical attitude.

Although this separation of surgery from the practice of medicine was already present in early medieval times, this was emphasized in 1215 by the Fourth Lateran Council, when the Church forbade from performing surgical procedures, as contact with blood or body fluids was viewed as contaminating.

Dubious as it is, the bulla *Ecclesia abhorret a sanguine* is believed to have influenced the separation of surgery from medicine: as a result, the practice of surgery was downgraded to craft status with training by apprenticeship [7].

With the advent of specialized programs for education in medicine (physic), surgical training came to occupy an even lesser status in the curriculum. The manual nature of surgical work caused it to be viewed as a trade rather than an art.

In the midst of the fourteenth century, the famous surgeon Guy de Chauliac (d. 1368), while reconstructing the history of surgery, argued that an initial unity of the art of health was followed by a distinction between medicine and surgery.

However, he mentioned Ruggero di Frugardo (c. 1170), and Rolando da Parma (c. 1230), as the first to set surgery apart from medicine: he recognized their value as empiricists but underlined their role in writing works focused on surgery [8].

With Rolando and Ruggero, Bruno da Longobucco and Teodorico Borgognoni, the new surgical school of northern Italy was built, but there is no evidence that their books were expressions of oral teaching and connected with an academic training.

Guy claims general theoretical training for the surgeon as well: the ideal surgeon had to be a learned man (*litteratus*), expert in anatomy and trained in medicine, knowing the *sex res naturales*, *res contra naturam* and *the sex res non naturales*, which encompassed the habits of life of individuals [9].

Only with this general background, surgery could be brought to perfection (*perficitur*).

Guy de Chauliac's ideal was, however, an auspice that was not reflected in reality and contrasted with the general situation: surgery was not part of academic medicine and it was taught and learned privately, by attending the operations of a master.

In many cases, this competence was transmitted within the family: all the four sons of Ugo da Lucca, municipal surgeon in Bologna, for instance, became surgeons and one of them, Teodorico, was the author of a *Chirurgia*, where he shared his father's secrets with his public [10].

The abandonment of the secret can be considered another evidence of the surgeon's project to transform their activity into a learned discipline, which could and should have been transmitted, taught, and shared [10].

Surgeons knew they had an ancient tradition behind them, studded with the great names of the past, and this awareness gave them the impetus to accredit their discipline, in the shadow of the teaching of the greats of Classical and Arab medicine.

Guglielmo da Saliceto (thirteenth century AD), for instance, tried to emancipate surgery from the ancillary role to which it was relegated, because the surgeon-barber, a manual practitioner, had no academic dignity and was devoid of that baggage of theory and philosophical reflection, which constituted the difference from the physicus [11].

His *Chirurgia*, in which anatomy plays a pivotal role, demonstrates his aim at structuring surgical knowledge in the form of a *doctrina*, which could be taught and shared.

This process could have taken place at the University of Bologna, where there was a long tradition in medical and anatomical studies: the situation was more

complex in other European *Studia*, which, however, in the fourteenth century, provided for surgical instruction, more or less organized.

Just to give some examples: since 1339, the Pisan *Studium* had called a reader *ad lecturam cirugiae scholaribus* and, albeit in a discontinuous manner, teaching had been guaranteed over the centuries [12].

Even within the Florentine *Studium*, many Lectors of surgery were present, called to teach it as an autonomous subject, but Lorenzo the Magnificent in 1472 closed the Florentine *Studium* in favor of Pisa's, interrupting this academic tradition [12].

In Paris, the College de Saint Come, established in about 1210 AD, was the first to separate surgeons from barbers, by identifying the academic surgeons, those who had training or had attended the university, as surgeons of the long robe and the barber-surgeons as surgeons of the short robe.

To systematically instruct barbers in surgery, a school was set up in France in the middle of the thirteenth century by the Brotherhoods of St. Cosmas and St. Damian [13].

Thus, surgery could be offered either as part of the medical curriculum or as a separate subject, but it was considered inferior in status to medicine and left as latest resource: in many Universities, the license in surgery became a sort of second-class academic degree, deepening the gap with medicine and creating a hierarchy that excluded the surgeon from academic training [14].

For example, by the 1430s, the Paduan medical faculty had five lecturers in surgery among its sixteen members but there were more masters than students and between 1405 and 1434, not a single student completed the surgical degree [15].

The Renaissance of Surgery

Pietro d'Argellata himself (d. 1423) was a distinguished surgeon; a pupil of Guy de Chauliac, he was Chair of Logic, Astrology, and Medicine at the University of Bologna: Pietro himself suggested his readers to leave surgery to wandering empirics, maybe due to avoid the lethal risks which surgery inevitably implied [16].

Despite the objective problems implicit in the practice of surgery, during the Renaissance conditions were met to allow the development of surgery: the use of firearms, the greater anatomical knowledge, and the printed edition of Classic surgical works allowed the acquisition of fundamental techniques.

In particular, the arrival in Italy of the *Niceta codex* and the translation into Latin, by Guido Guidi (1544), of the surgical treatises attributed to Hippocrates paved the way for new experiments [1].

However, generally speaking, the fortune of surgery in the universities was not long-lasting and, at first redimensioned, it was progressively excluded from the academic path, addressing mainly health professionals exclusively surgeons.

For this reason, the teaching of surgery took place in hospitals.

The initial informal didactic function of hospitals was more and more disciplined and organized, giving rise to “real” Hospital schools that compensated for the absence of teaching university until the seventeenth-eighteenth centuries.

In Tuscany, for instance, the major city centers saw the rise, more or less simultaneously, of schools of this type: Florence in the Hospital of Santa Maria Nuova, Siena in that of Santa Maria della Scala, Pistoia in the Hospital of Ceppo and finally also in Pisa, when university teaching of surgery was cancelled from the university training offer [17].

The didactic vocation of the Hospital of Santa Maria Nuova, founded in Florence in June 1288 by Folco Portinari, father of Beatrice, the woman beloved by Dante, is confirmed since its origin.

By the will of the founder, foreigners and citizens were treated in the *Medicheria*, even if not recovered in the hospital: the most famous doctors and surgeons of the city operated there, assisted by three additional servants, who could learn the art of surgery.

When the School was officially founded is a thorny question: the real foundation of the School was traditionally attributed to Ferdinando I de’ Medici (1587–1609), but it was recently demonstrated that already in 1580 Santa Maria Nuova had a surgical *curriculum*, aimed at young students and lasting at least 4 years [12].

This feature is very important above all if compared to other situations.

In Lombardy, for instance, the license of minor surgery, yet in the mid-eighteenth century, required a 5-year of practical apprenticeship in a workshop and the exam was based on the mnemonic ability of answering a century of prepared questions.

Each hospital school and each university had its own rules, which involved also the relationship with other disciplines, in particular with the study of anatomy, which developed from the fourteenth century on.

From a didactic point of view, the teaching of surgery occurred contemporary to the affirmation of anatomy but they seemed not to be directly connected: Paracelso himself criticized anatomy, because it was a “dead discipline,” without any connection with clinics [18].

Anatomy and Surgery

In England, the reputation of the surgeons began to increase slowly during the Renaissance, as they gained the esteem of various kings and made technical innovations, but the rivalry with physicians continued until the king Henry VIII signed a charter in 1540 uniting barbers and surgeons in London.

This Guild of Barbers and Surgeons, forerunner of the Royal College of Surgeons, formalized a regulatory agency for training and certification of surgical practice, which set the stage for recognizing surgery as a profession, requiring unexperienced practitioners—aged from fourteen to twenty—to receive at least 7 years of training in the domestic shop of a senior surgeon [19].

This mode of instruction offered would-be surgeons basic practical training and inculcated in them the duties and tasks associated with company membership.

Along with the teaching of technical skills, the surgical apprenticeship established a clear patriarchal relationship with the senior surgeon and aimed at ensuring that there was uniformity of behavior and that the future surgeon would respect the rules, aligning himself with the tradition.

To strengthen the educational goals of the Barber-Surgeons' Company, the print medium was used, improving the professional skills and behavior of the young colleagues.

Thanks to these innovations, there was a significant change in the consideration of surgeons: the inclusion of surgical courses in some Universities, and the increasing availability of published texts on the topic of surgery determined a shift in the perception of surgery and surgeons.

Recent studies have maintained that this surgical training was often “multi-modal and included hands-on and oral instruction conducted in close master-apprentice relationships, in lectures and anatomical demonstrations organized by guilds, and in self-directed book-based learning” [20].

It was necessary to combine wisdom, experience, and technical competence to the study, according to the formula “the book and the art,” a merging of textual tradition, practical experience, and the capacity of treating, through direct manual manipulation, sick, and injured bodies [19].

“Eliminating the superfluous, reducing what has been displaced, separating what has been united, bringing together what has been separated, repairing the defects of nature”

Surgery also owes much to Ambroise Pare, regarded by many as one of the Renaissance's greatest surgeons [21].

All the sovereigns of Europe courted Ambroise Paré, who remained faithful to his status as a surgeon, rejecting the paludaments and honors of medicine.

He successfully applied rose oil, egg whites, and turpentine on gunshot wounds, which became one of his most widely used surgical techniques, substituting the moist treatment with the dry one.

He taught the ligation of vessels, used *Punctus aureus* in the treatment of hernia, inaugurated the dry treatment of wounds, refuting that pus was “*bonum atque laudabile*” and inventing prostheses to avoid phantom limb syndrome.

Surgery had already understood the importance of the “*restitutio ad integrum*,” anticipating the need for functional restoration.

Despite the evolution of techniques and the acquisition of new knowledge, it was only in the eighteenth century, however, that surgeons, who had always learned by “imitating,” were able to have access to a complete academic training course [22].

It was the year 1731, when the Académie Royale de Chirurgie was founded in Paris by Georges Mareschal, first surgeon of Louis XV, and by François de Lapeyronie, whom Mareschal had chosen as his successor: its motto was *Consilioque manique* (“By the reasoning and by the hand”), which paved the way for surgery as an academic discipline [23].

The way was thus opened for surgery as a clinical activity and for its definitive recognition as an academic discipline, paving the way for the fight against charlatanism, on the one hand, and the recognition of professionalism on the other.

In fact, the power struggles between the Company of Physicians and the Company of Barber Surgeons and the infighting between barbers and surgeons by the end of the seventeenth century in London occurred in many major cities all over Europe [24].

Women

Although mentions of women practicing surgery (in particular obstetric and gynecological procedures) are reported from the earliest times, the presence of women who performed surgery from the middle ages is very rare: in Florence, for instance, the first woman surgeon managed to obtain the possibility to work in 1788.

Among the Proceedings of the Florentine Medical College, a corporative institution dating back to the thirteenth century, empowered to give individuals permission to officially practice medicine and surgery in Tuscany from 1560 through the second half of the nineteenth century, many names of midwives occur, as every health care practitioner, not only physicians and surgeons, had to apply to take the qualifying examinations [25].

A striking element in this documentation concerns Maria Petrocini Ferretti (1759–1791), whose case documents which formative channels were still in the eighteenth century.

Maria Petrocini Ferretti had learned basic surgical skills from her husband, Francesco, who worked as a surgeon in Anghiari, a small town near Arezzo in the Tuscany region [26].

In 1788, she made a request to undergo the licensing examination administered by the Florentine Medical College, providing the necessary certificates, signed by the most important surgeons of the Florentine School of Surgery that attested to her skills.

The College refused to consider her request because, even though she had scientific knowledge, a woman could have neither steadfast hand nor boldness, which were essential requirements for a surgeon [27].

To support its thesis, the College brought illustrious examples, as the verdict of the Athenian Areopagus, which forbade women to practice medicine.

Thus, Petrocini Ferretti was forced to write a plea directly to Grand Duke Pietro Leopoldo d'Asburgo Lorena of Tuscany, confirming her long apprenticeship under her husband's guidance and her consistent attendance during lectures in anatomy, obstetrics, and surgery in the Hospital of Santa Maria Nuova in Florence, which housed the Florentine School of Surgery.

A Grand Ducal decree dated August 16, 1788, gave her the opportunity to take the examination.

Petrocini Ferretti took the exam and was passed with all votes in favor, obtaining the long-awaited permission to practice surgery on September 13, 1788. She and all

other surgeons had to strictly follow the rules in force; for instance, they were prohibited from castrating children to preserve their high-pitched voices for use in choirs.

The following year, Petrocini Ferretti left Florence and published a book in which she introduced new methods of bringing up children, such as the abolishment of swaddling in newborns [26].

Petrocini Ferretti's story remained an isolated case in Florence for a long time.

However, her example was followed by other women in the early years of the nineteenth century, including her daughter Zaffira, who received a degree in surgery from the University of Bologna in 1808 and the license to practice surgery in 1810, and Maria Dalle Donne (1777–1842), director of the School of Obstetrics for Midwives in Bologna.

In the rest of Europe, with the rise and predominance of the male dominated church, women were actively discouraged from the practice of surgery. In 1313, in Paris, a royal edict banned women from the practice of surgery unless examined by a competent jury. During the fourteenth and fifteenth centuries, no women were allowed to practice surgery except for widows or daughter of deceased surgeons. In the fourteenth century, King Henry VIII was quoted as saying "No carpenter, smith, weaver or women shall practise surgery." Moreover, when in 1540 he allowed the founding of the Company of Barber Surgeons, women were banned [28].

Despite all the attempts made to prevent women from practicing surgery, they continued to do it during this period, without formal training or recognition in Europe and North America for the next centuries.

The first recorded female surgeon in North America was Mary Edwards Walker, graduated at Syracuse Medical College in New York in 1855 (the second woman to graduate from an American medical school after Elizabeth Blackwell in 1849). At the beginning it is believed that her surgical practice failed because she refused to change her surname and practiced as a nurse. Only in 1863 she was recognized as the first female surgeon working for the US Army.

The first registered female general surgeon in Canada according to the Royal College of Physicians and Surgeons registrar was Jessie Gray (1910–1978). In 1934, she was the first female surgical graduate from the Gallie Program at the University of Toronto. In 1941, she was named Canada's "First Lady of Surgery" and she served, starting in 1946, as chief of surgery at the Women's College Hospital [29].

The first admitted woman by the American College of Surgeon was Florence Duckering, in 1913. In 1975, women represent less than 2% of ACS members. In 2018, of the approximately 82,000 members of the ACS, 16 percent were women (40% of residents).

The Revolution

Behind the surgical revolution which took place in the eighteenth century, there is a new bourgeois society, which, on the ruins of the Bastille, also broke the eighteenth-century practice of professional stereotypy, transmitted at the family or noble level.

It is not hazardous to affirm that special surgery affirmed before than general surgery, as orthopedics and other specialism responded to a social necessity which had arose from the philanthropic approach of the French revolution [2].

The way was paved for the rise of surgeons, who, in 1850, saw their discipline achieve academic dignity in much of Europe and the USA.

In 1745, English barbers and surgeons separated: the Company of Surgeons received its royal charter in 1800, expanding from the Royal College of Surgeons in London to the Royal College of Surgeons of England in 1843.

By the beginning of the nineteenth century, training had unified in England, so that surgeons and medical doctors went through the same medical school or university training, received the same degree authorizing them to practice medicine, and practiced in the same institutions.

For the most part, surgeons and internists are now both known as “doctors” [30].

The efforts of an entire scientific community converged, then, on the need to eliminate the other major obstacles, which stood in the way of the definitive affirmation of surgery: pain, infections, bleeding.

It was thanks to Joseph Lister (1827–1912) to have identified, on the basis of Pasteur’s experiences, two fundamental principles for the development of operative surgery: the germs responsible for putrefaction are present everywhere and the infection does not represent a normal stage in the process of wound healing [31].

However, theoretical and economic reasons were opposed to antisepsis and only starting from the 1870s, following the research of Koch, who provided the theoretical and experimental basis for the theory of germs and the specificity of wound disease, the surgeons dressed in white, used sterilized gowns, masks, and gloves.

Two surgeons were the first to receive the Nobel Prize, Theodor Kocher, in 1909, for his work on the physiology, pathology, and surgery of the thyroid gland and Alexis Carrel, in 1911, for his research on blood vessel suturing and transplants.

Still, at the beginning of the twentieth century, even the surgical amphitheaters, which had been the background to Billroth and Gross, closed the wings, to transform themselves into real operating suites, enriching themselves with the instruments useful for diagnostic and post-operative control, after the introduction of X-rays.

Surgery no longer needed the spectacularity of the theater and became practice, in close collaboration with the clinic and laboratory, invoking the fast track and the acceleration of times, including hospitalization.

This improvement in technology and the change in culture have been pivotal to the development of surgery from a set of skills into an accepted medical profession.

Consequently, apprentice style surgical training has developed, particularly rapidly in the twentieth century, including structured progressive exams: technical skills continued to be evaluated by senior supervising surgeons, but training occurred in departments with recognized mentors and senior specialists [32].

This apprenticeship system stimulated the “cult of the individual,” with the identification of masters who established competing “schools of surgery,” who identified themselves in a master, in his style, in his techniques.

The end of the nineteenth century and beginning of the twentieth marked the first major shift from the previous apprenticeship training models to more formalized and structured training.

The method currently in practice to train surgical residents in the USA is, in large part, due to the influence of William Halstead (1852–1922), who developed a novel residency training program at Johns Hopkins Hospital that, with some modifications, became the model for surgical and medical residency training in North America [33].

In 1904, Halstead delivered a momentous lecture at Yale on the training of surgeons, suggesting the adoption of a model of the German system of residency training, whereby trainees received increasing responsibility with each advancing year: the Halsted triad of educational principles included knowledge of the basic sciences, research, and graduated patient responsibility for the resident [34].

The model allowed for improved structure and standardization in training, but it also introduced the “pyramid” structure in residency training, in which candidates would be eliminated each year, until culminating in the graduation of a single chief resident.

The idea gained support and, in 1928, the American Medical Association House of Delegates approved the application of the underlying principles promoted by Halstead to approve residency programs and fellowships.

However, it was William Osler (1849–1919) to have started the first modern North American residency, introducing in 1893 the concept of clinical clerkships, and incorporating bedside rounds into student classes.

In fact, the history of surgical training in the last two centuries was particularly debated in the USA, where, in 1913, the American College of Surgeons (ACS) was founded: in 1939, the ACS published the Fundamental Requirements for Graduate Training in Surgery, which proposed criteria for hospitals that trained surgical residents, along with guidelines for achieving training criteria [35].

In the following decades, many specialist boards were formed, and in 1928, the American Medical Association published the “Essentials of Approved Residencies and Fellowships” [36] but there was a need to standardize practices, policies, and standards, so that in 1981, the Accreditation Council for Graduate Medical Education (ACGME) was born.

Since then, the initiatives have multiplied and surgery has undergone a deep transformation: technologic advances such as the emergent use of the electronic medical record (EMR), minimally invasive surgery (MIS), and efforts by the health care system to reduce hospital costs have led to what is called “fast track surgery,” circumscribing the surgical act, and depriving students of diagnostic and post-operative experience [37].

The operating room is no more the predominant location for the acquisition of technical skills: therefore, it is necessary to develop education methods for acquiring technical skills in other contexts and many different programs were developed, involving workshops focused on basic surgical skills, which are appropriate for all medical and surgical disciplines [38].

In the UK in 1976, the Association of Surgeons in Training (ASiT) was founded, an independent organization of the National Health Service (NHS), Surgical Royal Colleges, and speciality associations and has the aim at endorsing excellence in surgical training for the advantage of would-be surgeons and patients [39].

ASiT has recently published a list of 34 key recommendations to improve the content and the delivery of surgical training and education, fostering a debate with different stakeholders, in order to draw the most appropriate training program.

Present and Future

The apprenticeship model, exemplified from the phrase “see one, make one, teach one,” is no more valid.

The increase in complexity of surgical care and teaching constraints has made progressively difficult to use the apprentice model. There are three specific areas of concern: (1) skills assessment, (2) inefficiencies and time limits inherent in mentor-dependent teaching, and (3) credential methods [40].

Therefore, a new paradigm for surgical education is now required, in the frame of a new model for education that takes into account the new typology of student aspiring surgeons, transforming the assessment in surgical training from the apprenticeship model to a more objective workplace-based assessment pattern.

Today’s medical students and surgical residents were born into the Millennial generation [41] and their learning attitude is quite different from the ones of the “digital immigrants,” who are forced to adapt themselves to a continuously new approach: the surgical educator is challenged to adjust educational methods to meet the needs of the twenty-first century learner.

In recent decades, many new training opportunities have been created, thanks to e-learning, which has articulated in “flipped classroom,” “blended classroom,” and Massive Open Online Course, and today it seems established that e-learning is a more effective teaching method, because students acquire knowledge and skills faster than through traditional teacher-centered methods, leading to better motivation and performance [42].

However, for e-learning to be successful, there must be several elements: content management, course design, learning objectives and measurable outcomes, and communication [43].

With the development of technology and the reduction of working hours in surgical education, an increase in the use of simulation occurred, as students move forward the 4 stages of learning as they progress through the residence: the novice, the apprentice, the boy and, finally, the teacher [44].

The use of simulation was determined by the necessity to accelerate the acquisition of skills but the inadequate education and training of the surgeon caused many iatrogenic injuries, which the use of force multipliers tried to resolve: virtual learning and telementoring [31].

The expansion of knowledge, the lack of time, the increase in interventions, which do not always correspond to an increase in the number of professionals, have determined the progressively frequent use of innovative techniques, as virtual reality, including mechanical simulators, robotics and telesurgery, and animate models, which provide students with the opportunity to complete their training.

However, it is necessary to accept and assimilate the awareness that these methods are not part of the future, but are the reality that surgeons face every day [24].

The problem of time is therefore crucial: time for study, for practical exercise, for surgery. Even more than what happened in the past, today the motto of the Ancients is valid: “*Cito, tute, jucunde.*”

References

1. Lippi D. *Consilioque manue: surgery in the manuscripts of the Biblioteca medica laurenziana*. Florence: Mandragora; 2011.
2. Tröhler U. Il trionfo della chirurgia, in *Storia del pensiero medico occidentale*, a cura di M.D. Grmek, 3 voll., Roma-Bari 1993–1998: III. Dall’età romantica alla medicina moderna; 1998. p. 355–88.
3. Martial, Epigr. I, 47. Martial, Epigrams. Mainly based on Bohn’s Classical Library (1897). Preface to the online edition. <https://topostext.org/work/677>.
4. *Ars medica. I ferri del mestiere. La domus «del chirurgo» di Rimini e la chirurgia nell’antica Roma—9788880493921* st ed. by De Carolis S., Rimini, Guaraldi, 2009.
5. Köckerling F, Köckerling D, Lomas C. Cornelius Celsus—ancient encyclopedist, surgeon-scientist, or master of surgery? *Langenbeck’s Arch Surg*. 2013;398(4):609–16. <https://doi.org/10.1007/s00423-013-1050-0>.
6. Lippi D, Gensini GF, Conti AA. Charter on medical professionalism: putting the charter into practice. *Ann Intern Med*. 2003;138:852–3.
7. Berger YE. The specificities of surgical education in medieval Europe, *Istoriâ. Mediciny*. 2014;3(3):112–8.
8. Mc VM. Surgical education in the middle ages. *Dynamis*. 2000;20:283–304.
9. de Caulhiaco G. *Inventarium sive Chirurgia magna*, vol. 1. Leiden: Brill; 1997. p. 6–7. and ix-x (for the English translation) [ed. Michael R. McVaugh].
10. McVaugh M. When universities first encountered surgery. *J Hist Med Allied Sci*. 2017;72(1):6–20. <https://doi.org/10.1093/jhmas/jrw045>.
11. Agrimi C, Crisciani C. The science and practice of medicine in the thirteenth century according to Guglielmo da Saliceto, Italian surgeon. In: Ballester LG, et al., editors. *Practical medicine from Salerno to the black death*. Cambridge: Cambridge University Press; 1994. p. 60–87.
12. Baldanzi F. Nell’Ospedale di «Santa Maria Nuova di Firenze a imparare il cerusico»: origini e primo consolidamento della Scuola Medica e Chirurgica (XVI-XVIII secolo). *Archivio Storico Italiano*. 2019;CLXXVII(2):273–304.
13. Franzese CB, Stringer SP. The evolution of surgical training: perspectives on educational models from the past to the future. *Otolaryngol Clin N Am*. 2007;40(6):1227–35, vii. <https://doi.org/10.1016/j.otc.2007.07.004>.
14. Bagwell CE. “Respectful image”: revenge of the barber surgeon. *Ann Surg*. 2005;241(6):872–8; discussion 878. <https://doi.org/10.1097/01.sla.0000165185.88634.d0>.

15. SIRAI SI, Nancy G. *Medieval and Early Renaissance Medicine*, Chicago, University of Chicago Press, 1990, p. 64.
16. Russell K. The Cirurgia of Pietro d' Argellata. *Aust N Z J Surg.* 1952;21(3):230–2.
17. Coturri E. Le Scuole Ospedaliere di Chirurgia del Granducato di Toscana (secoli XVII-XIX) [Hospital School of Surgery of the grand duchy of Tuscany (17th & 18th centuries)]. *Minerva Med.* 1958;49(94):3–18.
18. Pagel W, Rattansi P. Vesalius and paracelsus. *Med Hist.* 1964;8(4):309–28. <https://doi.org/10.1017/s0025727300029781>.
19. Chamberland C. From apprentice to master: social disciplining and surgical education in early modern London, 1570–1640. *Hist Educ Q.* 2013;53(1):21–44.
20. Leong E. Learning medicine by the book: reading and writing surgical manuals in early modern London. *BJHS Themes.* 2020;5:93–110. <https://doi.org/10.1017/bjt.2020.7>.
21. Drucker CB. Ambroise Paré and the birth of the gentle art of surgery. *Yale J Biol Med.* 2008;81(4):199–202; PMID: 19099051; PMCID: PMC2605308.
22. Savoia P. Skills, knowledge, and status: the career of an early modern Italian surgeon. *Bull Hist Med.* 2019;93(1):27–54.
23. Peumery JJ. Georges Mareschal (1658-1736) the founder of the Académie de Chirurgie. *Hist Sci Med.* 1996;30(3):323–31.
24. Nebiolo M. Surgery as a science: the intellectual and practical evolution of European Surgery from the 16th to the 18th century. *Butl J Undergrad Res.* 2017;3(Article 7):101–27.
25. Registries of the Florentine medical college, Biomedical library, University of Florence. Series L, leaf no. 55, box 5; 1788.
26. Lippi D, Vannucci L. Maria Petrocini Ferretti, the first female surgeon in Florence, Italy. *Arch Surg.* 2011;146(11):1231–2. <https://doi.org/10.1001/archsurg.2011.276>.
27. Registries of the Florentine medical college, Biomedical library, University of Florence. Series V, file no. 77, manuscript shelf 1; 1788.
28. Pastena JA. Women in surgery. An ancient tradition. *Arch Surg.* 1993;128(6):622–6. <https://doi.org/10.1001/archsurg.1993.01420180020004>.
29. Wirtzfeld DA. The history of women in surgery. *Can J Surg.* 2009;52(4):317–20.
30. Aggarwal A. The evolving relationship between surgery and medicine. *Am Med Assoc J Ethics.* 2010;12(2):119–23.
31. Rosser J, Nitsche L, Yee G, Alam H. The evolution of surgical virtual education and telementoring: one surgeon's journey. *J Surg Oncol.* 2021;124:162–73. <https://doi.org/10.1002/jso.26563>.
32. Payne T, Toms JD, Zaidi A, Thrumurthy SG. The history of surgery and surgical training in the UK. *Pak J Med Sci.* 2021;37(5):1532–5. <https://doi.org/10.12669/pjms.37.5.4628>.
33. Wright JR Jr, Schachar NS. Necessity is the mother of invention: William Stewart Halsted's addiction and its influence on the development of residency training in North America. *Can J Surg.* 2020;63(1):E13–9. <https://doi.org/10.1503/cjs.003319>.
34. The training of the surgeon : the annual address in medicine delivered at Yale University, June 27, 1904 by Halsted, William, 1852–1922; Royal College of Surgeons of England, Reprinted from the Johns Hopkins Hospital Bulletin, No. 162.
35. American College of Surgeons. Centennial reprint: graduate training for general surgery and the surgical specialties. *Bull Am Coll Surg.* 2013; <http://bulletin.facs.org/2013/03/reprint-graduate-training/>.
36. Eisele CW. Essentials of a residency in general practice. *JAMA.* 1957;164:384–8.
37. Camison L, Brooker J, Naran S, Potts JR, Losee JE. The history of surgical education in the United States: past, present, and future. *Ann Surg Open.* 2022;3(1):e148. <https://doi.org/10.1097/AS9.000000000000148>.
38. Morris M, Caskey R, Mitchell M, Sawaya D. Surgical skills training restructured for the 21st century. *J Surg Res.* 2012;177(1):33–6. <https://doi.org/10.1016/j.jss.2012.03.060>.
39. Fitzgerald JE, Giddings CE, Khera G, Marron CD. Improving the future of surgical training and education: consensus recommendations from the association of surgeons in training. *Int J Surg.* 2012;10(8):389–92. <https://doi.org/10.1016/j.ijso.2012.03.012>.

40. Walter AJ. Surgical education for the twenty-first century: beyond the apprentice model. *Obstet Gynecol Clin N Am*. 2006;33(2):233–6, vii. <https://doi.org/10.1016/j.ogc.2006.01.003>.
41. Prensky M. Digital natives, digital immigrants. *Horizon*. 2001;9:1–6.
42. Clark D. Psychological myths in e-learning. *Med Teach*. 2002;24:598–604.
43. Evans CH, Schenarts KD. Evolving educational techniques in surgical training. *Surg Clin North Am*. 2016;96(1):71–88. <https://doi.org/10.1016/j.suc.2015.09.005>.
44. Dreyfus HL, Dreyfus SE. *Mind over machine: the power of human intuition and expertise in the era of the computer*. New York, NY: The Free Press; 1986.

Part II
Research and Knowledge

Chapter 3

E-Learning and Surgery: The Value of Sharing Knowledge



María Rita Rodríguez-Luna and Silvana Perretta

Introduction

E-learning consists of learning through an electronic format (where “e” stands for “electronic”). Vaona *et al.* define *e-learning* as any educational intervention disseminated via the Internet [1]. *E-learning* interventions in the medical field have been able to address healthcare system training students, professionals, and patients. In the pursuit of better healthcare equity, particularly in geographical regions with limited economic capital such as Africa, Asia, and Latin America, *e-learning* has played an essential role in confronting the shortage of specialists in such lower-income countries [2].

In both financial resources and market share of tele-education, *e-learning* is expected to exceed 315 billion USD in 2021 with a 20% compound annual growth rate predicted for 2022–2028 [3, 4]. This underscores the stakeholders’ (government, networks, universities) need for greater investment in strategic *e-learning* implementation.

The recent SARS-COV2 (COVID-19) pandemic had an enormous impact on healthcare systems. The pandemic drastically changed educational structures worldwide as it highlighted the need for innovative and enhanced approaches to addressing educational needs, especially in the complex field of surgery [5].

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Current Perspectives on E-Learning

Within the last two decades, medical education has progressed significantly in implementing competency-based training, as well as focusing on how adults learn “*andragogy*” [6, 7]. Taking generational differences into consideration, and embracing qualities of physicians on the front lines such as millennials, has helped to spur creative electronic-based dissemination of scientific knowledge including but not limited to the use of social media [8]. In addition, there is growing evidence in andragogy regarding the disadvantages of a teacher-centered approach: as students already have a learning foundation upon which learning strategies should be built to achieve their educational goals. The traditional role of educators is evolving from a *distributor of content* to a *facilitator*, enhancing the learner-centered characteristics of the educational programs [9]. *E-learning* has fostered innovative educational strategies such as the flipped classroom, team-based learning, just-in-time teaching, think-pair-share, and problem-based learning [10, 11]. Due to its positive impact on educational systems and well-known advantages for trainees and providers, including geographical coverage, self-paced learning, cost-effectiveness, targeting a large audience, and data availability for research purposes, *e-learning* is gaining popularity and online programs are rapidly increasing in the surgical field [3].

Recent studies suggest that students are more inclined towards the newer teaching method than traditional learning, and therefore *e-learning* could well facilitate continuing medical education (CME) and professional development.

The IRCAD Experience

E-learning has been a cornerstone of the Research Institute against Digestive Cancer (IRCAD, France). Launched in 2000, WebSurg, the online university of IRCAD, is a video-based platform with operative procedures, state-of-the-art lectures, and surgical technique videos, which provides surgical educational content by world-renowned experts in all fields of minimally invasive surgery, completely free of charge [12]. The WebSurg virtual university standards meet Health on the Net Foundation (HONCode) ethical requirements, guaranteeing high-quality and reliable content [13]. Importantly, this peer-reviewed process has helped WebSurg to become the primary online resource for many trainers [14, 15]. In light of the increasing demand to transfer knowledge remotely imposed by the COVID-19 pandemic lockdowns, an innovative and rapid transformation arose in the form of webinars, massive open online courses (MOOC), and conferences. Webinars share all the advantages of *e-learning*, such as addressing geographical coverage, self-paced learning, cost-effectiveness, and data availability for research purposes [16].

The rise of e-learning also created the need for secure, user-friendly platforms and communication tools to meet trainee expectations. Indeed, these technologies are essential to provide quality, engaging *e-learning* content that keeps students

committed to their follow-up educational modules [17]. To this aim, IRCAD webinars implemented strategies to improve participant satisfaction. One of these was having a key opinion leader (KOL) as a moderator to stimulate and optimize the interaction between speakers and participants during the Q&A panel. In fact, to ensure effective learning, most adult learners need an interactive environment [18]. Additionally, adult learners have superior performance in self-directed learning contexts rather than in conventional teacher-centered classrooms [19].

Since 2017, the European Accreditation Council for Continuing Medical Education (EACCME) has encouraged *e-learning* methodologies by providing accreditation for *e-learning* material provided by reputable educational institutions. Accreditation represents a major opportunity to standardize *e-learning* educational practices across the European Union by providing quality control and curriculum standards [20].

The COVID-19 pandemic has undoubtedly raised awareness of the importance of *e-learning* and sharing knowledge. Virtual international collaboration has been shown to improve confidence, knowledge, and basic laparoscopic skills, even in resource-limited settings during a health crisis [21]. In this context, WebSurg developed *e-learning* modules (ELMs) and comprehensive educational programs such as Basecamps. WebSurg's Hernia and Colorectal Basecamps are clear examples of standardized and accredited ELMs with lectures, operative videos, and learning resources with self-study activities (i.e., multiple-choice questionnaires) for knowledge evaluation for the learners. Hands-on courses in expert centers are also provided as a key part of any educational program.

Even though *E-learning* has represented an optimal solution to facilitate surgical learning strategies during the COVID-19 pandemic, there are obvious limitations in teaching and assessing the acquisition of technical motor skills.

Complete educational programs that can teach and assess both fundamental knowledge and technical skills are highly sought after. The Fundamentals of Laparoscopic Surgery (FLS) program is a case in point. It includes web-based didactic training, hands-on skills training, as well as an assessment. FLS proved to be so effective that the American Board of Surgery (ABS) considers it to be a prerequisite for eligibility [22].

As in the case of FLS, overcoming *e-learning* limitations can be accomplished with a flexible educational program that combines *e-learning* with mandatory participation in a live educational event including hands-on practice, also known as blended learning [23, 24].

To enhance surgical performance in the era of modern surgery, there is a strong need to investigate modalities that can support technical skills practice in a friendly environment. The combination of visual and tactile interfaces allows virtual reality (VR) simulators to present learners with situations that mimic reality. However, most of the platform's high cost limits its widespread use. In addition, the community of surgeons using VR simulators report recurrent concerns such as the fact that their use may be repetitive and boring, that they lack realism, and that they usually incur complex movements. Serious games as tools to train either basic laparoscopic skills or endoscopic skills to surgical novices are easy and low-cost alternatives to



Fig. 3.1 Screen view of the endoscopic serious game rescue in the deep. Objectives are expressed as game missions



Fig. 3.2 Overview of the endoscopic serious game rescue in the deep. Students can be trained in a friendly sea environment. Five training levels that allow navigation, targeting, and coordination are considered

existing simulators. In partnership with the INRIA (Institut national de recherche en informatique et en automatique/Institut national de recherche en sciences et technologies du numérique) and the University of Twente, we developed a “plug and play” portable simulator for flexible endoscopy with a serious game interphase. The current version consists of 5 levels of game play that allow training on navigation, targeting, and coordination. Delivering affordable skills training and education at home can support in filling the gap for trainees in low and remote resource areas, as well as making training more accessible in developed regions (Figs. 3.1 and 3.2).

In addition to the above mentioned *e-learning* modalities, telementoring has also helped to overcome geographical limitations. Defined as a relationship facilitated by telecommunications technologies, an expert (mentor) provides guidance to a less experienced learner (mentee) from a remote location during an operative procedure. Since 2015, the Society of American Gastrointestinal and Endoscopic Surgeons

(SAGES) has implemented Surgical Teleproctoring Project Six (P6) to summarize existing evidence, identify conceptual educational frameworks that may be used during Surgical Teleproctoring Project Six, and present a structured framework for an educational curriculum in the project [25]. Although several models were referenced, targeting guided and structured teleproctoring educational programs such as the ADDIE model (Analysis, Design, Development, Implementation, Evaluation), GROW model (Goals, Reality, Options, Wrap-up), and SSTAR model (Structured Training Trainer Assessment Report), there was a lack of high-level evidence regarding outcomes for each educational model, making it difficult to standardize teleproctoring systems. Undoubtedly, in the era of high-performance wireless communications, there are promising advantages that could facilitate teleproctoring such as 5G and Wi-Fi 6. Developments in real-time haptic feedback and Tactile Internet are increasing [26], and these improvements could potentially be adapted to teleproctoring in the near future, providing an immersive environment for both mentor and mentee.

Telepresence considered as the projection of oneself from a remote location to create a human-machine-human interface was the beginning of telerobotics. Since the first telesurgery performed by Jacques Marescaux who transatlantically operated on a patient in Strasbourg, France from New York, United States, in 2001, many technological advances occurred to support telepresence on a regular basis [27].

Telepresence platforms are highly needed to democratize surgical care in underserved areas in order to increase access to superior healthcare standards.

In this regard, metaverse has opened the gate to new ways of telepresence. In 1992, the metaverse concept was created by Neal Stephenson in his novel *Snow Crash*. It is a combination of the words “meta” and “universe,” which means transcendence reality [28]. Regarded as the next iteration of the Internet, metaverse is a VR space where multiple users can interact with a computer-generated graphically rich environment, as well as with other users. Metaverse allows to explore the operating room (OR) in ways that are impossible in the current physical world using an immersive shared tridimensional virtual space. As a result, surgical training using metaverse offers numerous benefits, including real-time interaction, access to complex cases, democratization of knowledge, a visually enriched learning experience, teleproctoring and supervision, among others. However, the routine use of metaverse in the OR and surgical training are still limited, mostly because of the need for specialized hardware, software, high-speed connectivity, as well as for the users’ acceptance. Currently, metaverse is still evolving, and future advances in mixed reality, 3D visual feedback, and tactile experience will have a critical impact on the implementation of such technologies in the OR and related educational environments [29].

There are alternative platforms that aim to transcend geographical boundaries. Proximie Ltd. (London, UK) is a case in point as it allows surgeons to communicate visually and verbally intraoperatively anywhere in the world, hence supporting telementoring [30]. It is a secure, trustworthy augmented reality platform compliant with General Data Protection Regulation (GDPR) and Health Insurance Portability

and Accountability Act (HIPAA) regulations. Proximie has been created to use both high- and low-speed Internet connections and can operate with low-speed Internet compatible with most electronic devices. The Proximie virtual telementoring platform was used as a proof of concept during hands-on training for hernia surgery at home during the pandemic [31]. It has also proven successful in supporting the teleproctoring of digital natives when performing exercises using the da Vinci™ (Intuitive Surgical, Sunnyvale, CA, United States) surgical robotic platform [32].

Immersive technologies may not only be beneficial for underserved areas but also for prolonged post-course mentorships, as well as for supervising surgical practice by supporting e-learning strategies.

The Quest for Standardization

E-learning has mostly focused on theoretical programs and classroom flipping. Facilitating motor skills proficiency still needs consistent development away from the screen. In addition, the current literature shows a low certainty of evidence, particularly when it comes to patient clinical outcomes. Much more robust data is necessary to determine the effectiveness of *e-learning* in this context [22]. There is a significant opportunity to improve *e-learning* strategies through robust studies with clear reporting outcomes and standardized metrics.

Surgical societies are shifting paradigms, promoting *e-learning* platforms in which they can support residents and surgeons through ELMs and CME [14, 33].

The difference between traditional learning and *e-learning* is defined not only by the intellectual content and academic programs but also by the use of technology and multimedia systems used towards this goal. Therefore, as stressed by Verona *et al.*, the quality assessment of *e-learning* programs involves more than evaluating the quality and educational design of the course content—it also involves an analysis of navigability, a multimedia approach, the degree of interactivity, and other key factors such as intervention duration, repetition, feedback, or layout impact in the development of an optimal *e-learning* framework [1].

The Future of E-Learning

Future perspectives on *e-learning* include the use of enhanced communications technologies such as 5G and Wi-Fi 6 and metaverse. As previously described, metaverse is considered to be a network of 3D virtual reality to enhance the connections between real and cyber spaces. Metaverse is gaining attention since promising results have been shown in the fields of education, gaming, training, rehabilitation, etc. Currently, research is underway to enable somatosensory sensation aimed at immersive VR experiences [34].

E-learning is currently playing a fundamental role in surgical curricula, which continue to grow at an exponential rate. The shift from the conventional on-site to online academic curricula involves competence assessments, particularly of hands-on technical skills as they are the linchpin of high-quality surgical performance. Long-term data, continuous monitoring, and optimization of educational systems are highly needed. Educators should be prepared to continuously implement innovative educational strategies. Undoubtedly, emerging communications technologies such as 5G and Wi-Fi 6 and metaverse will improve *e-learning*, promoting telementoring and teleproctoring via videoconferencing systems. Finally, AI-based technologies represent a promising application in facilitating high-quality and globalized surgical care.

As referred by Parks, an e-learning pioneer, the “e” of *e-learning* should be exciting, energetic, eager, emotional, extended, and educational. These very principles should be pursued when considering the new frontiers of surgical education [18].

At present, up to 5 billion people around the world do not have access to safe, affordable, and timely surgical care [35]. How to take up this challenge goes well beyond this chapter’s scope. However, we should consider that redefining *e-learning* could well play a critical role by training more physicians and proficiently promote high standards in surgical care.

References

1. Vaona A, Banzi R, Kh K, Rigon G, Cereda D, Pecoraro V, et al. E-learning for health professionals (review). 2018
2. Ionescu A, De Jong PGM, Drop SLS, Van Kampen SC. A scoping review of the use of e-learning and e-consultation for healthcare workers in low- and middle-income countries and their potential complementarity. *J Am Med Inform Assoc.* 2022;29(4):713–22.
3. Vazquez AG, Verde JM, Dal Mas F, Palermo M, Cobianchi L, Marescaux J, et al. Image-guided surgical e-learning in the post-COVID-19 pandemic era: what is next? *J Laparoendosc Adv Surg Tech A.* 2020;30(9):993–7.
4. E-learning market report.
5. Rusch VW, Wexner SD, Atala A, Atkinson JLD, Denny JC, Eberlein TJ, et al. The American College of Surgeons responds to COVID-19. *J Am Coll Surg.* 2020;231(4):490–6.
6. Szasz P, Louridas M, De Montbrun S, Harris KA, Grantcharov TP. Consensus-based training and assessment model for general surgery. *Br J Surg.* 2016;103(6):763–71.
7. Gutruf P, Utzinger U, Subbian V. Moving from pedagogy to andragogy in biomedical engineering design: strategies for lab-at-home and distance learning. *Biomed Eng Educ.* 2021;1(2):301–5. <https://doi.org/10.1007/s43683-020-00043-8>.
8. Wexner SD, Petrucci AM, Brady RR, Ennis-O’Connor M, Fitzgerald JE, Mayol J. Social media in colorectal surgery. *Color Dis.* 2017;19(2):105–14.
9. Wentling TL. E-learning: a review of literature e-learning; 2019. p. 1–60; https://www.researchgate.net/publication/331938876_E-learning_A_review_of_literature.
10. Koo A, Almeida BA, Kerluku J, Yang B, Fufa D. Teaching in orthopaedic surgery: effective strategies for educating the modern learner in a modern surgical practice. *JB JS Open Access.* 2022;7(3):e22.00005.
11. Hew KF, Lo CK. Flipped classroom improves student learning in health professions education: a meta-analysis. *BMC Med Educ.* 2018;18(1):1–12.

12. Mutter D, Vix M, Dallemagne B, Perretta S, Leroy J, Marescaux J. WeBSurg: an innovative educational web site in minimally invasive surgery-principles and results. *Surg Innov.* 2011;18(1):8–14.
13. Celentano V, Smart N, Cahill RA, Spinelli A, Giglio MC, McGrath J, et al. Development and validation of a recommended checklist for assessment of surgical videos quality: the LAParoscopic surgery video educational GuidelineS (LAP-VEGaS) video assessment tool. *Surg Endosc.* 2021;35(3):1362–9. <https://doi.org/10.1007/s00464-020-07517-4>.
14. Mahendran B, Celentano V, Soltes M, Popa D, Adamina M, Sanz CM, et al. EAES online educational resources: a survey of the membership of the European Association for Endoscopic Surgery (EAES). *Surg Endosc.* 2021;35(5):2059–66. <https://doi.org/10.1007/s00464-020-07602-8>.
15. Ferhatoglu MF, Kartal A, Filiz Aİ, Kebudi A. Comparison of new era's education platforms, YouTube® and WebSurg®, in sleeve gastrectomy. *Obes Surg.* 2019;29(11):3472–7.
16. Al-TaHER M, Okamoto N, Mutter D, Stassen LPS, Marescaux J, Diana M, et al. International survey among surgeons on laparoscopic right hemicolectomy: the gap between guidelines and reality. *Surg Endosc.* 2022;36:5840. <https://doi.org/10.1007/s00464-022-09044-w>.
17. Yekefallah L, Namdar P, Panahi R, Dehghankar L. Factors related to students' satisfaction with holding e-learning during the Covid-19 pandemic based on the dimensions of e-learning. *Heliyon.* 2021;7(7):e07628. <https://doi.org/10.1016/j.heliyon.2021.e07628>.
18. Verrier ED. The surgeon as educator. *Thorac Surg Clin.* 2019;29(3):227–32. <https://doi.org/10.1016/j.thorsurg.2019.03.001>.
19. Lim L, Lim SH, Rwy L. Measuring learner satisfaction of an adaptive learning system. *Behav Sci (Basel).* 2022;12(8):264; <https://www.mdpi.com/2076-328X/12/8/264>.
20. European Union of Medical Specialists. EACCME criteria for the accreditation of E-learning materials (Elm); 2016. p. 1–37; <https://eaccme.uems.eu/applywithus-accreditation>.
21. Harrell Shreckengost CS, Reitz A, Ludi E, Rojas Aban R, Jáuregui Paravicini L, Serrot F. Lessons learned during the COVID-19 pandemic using virtual basic laparoscopic training in Santa Cruz de la Sierra, Bolivia: effects on confidence, knowledge, and skill. *Surg Endosc.* 2022;1:0123456789; <https://www.absurgery.org/default.jsp?epahome>.
22. Zendejas B, Ruparel RK, Cook DA. Validity evidence for the fundamentals of laparoscopic surgery (FLS) program as an assessment tool: a systematic review. *Surg Endosc.* 2016;30(2):512–20.
23. Sonesson L, Boffard K, Lundberg L, Rydmark M, Karlgren K. The potential of blended learning in education and training for advanced civilian and military trauma care. *Injury.* 2018;49(1):93–6. <https://doi.org/10.1016/j.injury.2017.11.003>.
24. Halverson AL, Darosa DA, Borgstrom DC, Caropreso PR, Hughes TG, Hoyt DB, et al. Evaluation of a blended learning surgical skills course for rural surgeons. *Am J Surg.* 2014;208(1):136–42. <https://doi.org/10.1016/j.amjsurg.2013.12.039>.
25. Augestad KM, Han H, Paige J, Ponsky T, Schlachta CM, Dunkin B, et al. Educational implications for surgical telementoring: a current review with recommendations for future practice, policy, and research. *Surg Endosc.* 2017;31(10):3836–46.
26. Senk S, Ulbricht M, Tsokalo I, Rischke J, Li SC, Speidel S, et al. Healing hands: the tactile internet in future tele-healthcare. *Sensors.* 2022;22(4):1–16.
27. Marescaux J, Leroy J, Gagner M, Rubino F, Mutter D, Vix M, et al. Transatlantic robot-assisted telesurgery. *Nat Publ Gr.* 2001;413:379–80.
28. Kawarase MA, Anjankar A. Dynamics of metaverse and medicine: a review article. *Cureus.* 2022;14(11):1.
29. Onggirawan CA, Kho JM, Kartiwa AP, Anderies, AAS G. Systematic literature review: the adaptation of distance learning process during the COVID-19 pandemic using virtual educational spaces in metaverse. *Procedia Comput Sci.* 2023;216:274–83; <https://linkinghub.elsevier.com/retrieve/pii/S1877050922022153>.

30. Cheikh Youssef S, Hachach-Haram N, Aydin A, Shah TT, Sapre N, Nair R, et al. Video labeling robot-assisted radical prostatectomy and the role of artificial intelligence (AI): training a novice. *J Robot Surg*. 2022;0123456789:695. <https://doi.org/10.1007/s11701-022-01465-y>.
31. Greenberg JA, Schwarz E, Paige J, Dort J, Bachman S. At-home hands-on surgical training during COVID19: proof of concept using a virtual telementoring platform. *Surg Endosc*. 2021;35(5):1963–9. <https://doi.org/10.1007/s00464-021-08470-6>.
32. Patel E, Mascarenhas A, Ahmed S, Stirt D, Brady I, Perera R, et al. Evaluating the ability of students to learn and utilize a novel telepresence platform, proximie. *J Robot Surg*. 2022;16(4):973–9. <https://doi.org/10.1007/s11701-021-01330-4>.
33. SAGES TV: HOME OF SAGES SURGICAL VIDEOS. [cited 2022 Sep 26]. <https://www.sages.org/video/>.
34. Sun Z, Zhu M, Shan X, Lee C. Augmented tactile-perception and haptic-feedback rings as human-machine interfaces aiming for immersive interactions. *Nat Commun*. 2022;13(1):5224.
35. Raykar NP, Yorlets RR, Liu C, Goldman R, Greenberg SLM, Kotagal M, et al. The how project: understanding contextual challenges to global surgical care provision in low-resource settings. *BMJ Glob Health*. 2016;1(4):1–9.

Chapter 4

Network and Social Media: The Digital Surgeon



Gaetano Gallo , Marta Goglia, and Veronica De Simone

Definition of Digital Surgery

According to a recent Delphi consensus statement digital surgery is defined “as the use of technology for the enhancement of preoperative planning, surgical performance, therapeutic support, or training, to improve outcomes and reduce harm” [1].

Nowadays, the use of technology in the clinical practice is continuously increasing and providing effective tools in every field of medicine. In particular, for what concerns digital technology in surgery the purpose of introducing this discipline is basically to improve the quality of interventional healthcare and its value through the capture, organization, analysis, and modelling of data.

In the age of social media, information is just a click away and technology plays an important role as a powerful tool to share new and updated links to online resources, images/pictures, short videos, interactive polls, and tutorials. Therefore, medicine and surgery cannot be considered far from technology but must embrace it.

It is estimated that more than 55% of the global population uses the internet [2]. In Italy, as in other industrialized countries, the percentage reached 92%, with increasing trend over the last years. The average time per person spent using the internet and social media in a day is 6 h 4 min and 1 h 51 min, respectively [2, 3]. Internet is nowadays an indispensable tool, and it was intuitive that online platforms

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would have become an essential and useful also in medical sharing of information and practice, leading to better patients' self-management and self-care.

In fact, online health information may improve patient–physician relationship, increasing patient knowledge and engagement in the decision-making process with a higher probability of a better health outcome and also a higher awareness of the difficulties that patients and relatives may encounter facing some of the diseases. In addition, a recent study has shown that networks are tools widely used by patients before booking a medical visit, with the main purpose of being prepared for the medical diagnosis [3] and also to find out if there are other people, in forums for example, with whom they can compare and share their clinical condition. This type of attitude, particularly studied and detected in those patients with problems related to colorectal surgery, shows strong benefits in the support that patients may find on social networks. However, these online researches have also demonstrated the potential misunderstandings and errors that may arise by patient's autonomous research [3]. Nowadays, what was once done through word of mouth is now standardized in some blogs on the web where patients can leave comments and votes on the service and care received. However, online platforms are essential for medical doctors to share experiences, techniques, and also feelings about their job performances beyond the education that this technology may preserve. The advantages of these social media include immediacy of communication, dynamic digital discussions, high-quality educational content, and instant global reach. According to Gallo et al. [4] education in surgery may be strengthened through online training courses, e-learning platforms, or simply having the opportunity to take part to the best surgical meetings without any time or place related difficulty. Especially for residents, who generally have hard working hours, need authorization to take time off from work, and do not normally have sponsor for financial travel reimbursements, online platforms represent an effective solution. Indeed, these have the potentiality to reach everyone who is interested in the field and to disseminate new evidence, filling gaps of information between countries, and sometimes to identify pitfalls in the guidelines currently adopted.

However, the digital age has certainly stimulated the birth and development of the figure of the scientist surgeon, a type of health care professional engaged in translation research in a wide-range of fields [5, 6]. Although the figure of the surgeon involved in the research is now recognized and the constant updating and sharing of surgical experience are considered essential, the surgeon who is interested in research as well as in the clinic is still the most penalized medical figure. Indeed, the environment in which a health care professional operates is of fundamental importance. The evolving reimbursement landscape has made medical institutions more motivated to push surgeons to be clinically active rather than producing academic content. It is thought that burn-out in surgical field is often due to the strenuous work hours, lack of autonomy, and a perception of an unfulfilling career [5]. Establishing protected research time might help surgeons to protect their career path and to validate the importance of the surgeon-scientist. Kibbe et al. proposed an early exposure of the residents to research, in such a way as to immediately accustom the younger surgeon to the difficult search for a balance between clinical

duties and those of science and to provide the most experienced surgeons not only with a practical help, fresh mind, and new ideas but also with a stimulus for teaching, handing over, and becoming a mentor [5]. Keswani and colleagues, in their survey among physicians, demonstrated that surgeon-scientists feel the pressure to be clinically productive and the burden of excessive administrative responsibilities is too heavy to be bear. These factors both adversely affect their ability to be productive scientifically. They also identified the impact of basic research on work-life balance, especially among younger respondents, further limiting the time and motivation for research. Moreover, the difficulty of obtaining funding is today a major impediment in surgical fields which may question the surgeon-scientist motivation to pursue basic science [7]. However, the novel COronaVirus Disease (COVID-19) pandemic, despite the enormous impact on health care systems, has certainly brought to light many of these problems, highlighting the urgency of finding a solution.

The Role of Social Media

Social media is defined as all “websites and applications that enable users to create and share content, to interact with other users or to find people with similar interests to one’s own” [8]. They can be considered as the most powerful tools of communication and learning in the recent era. The term encompasses multiple platforms ranging from blogs/micro blogs (e.g. *Twitter*[®]) through to wikis, *YouTube*[®], and social network sites such as *Facebook*[®] [9].

Blogs are the equivalent of online diaries where the author shares contents in chronological fashion and can receive comments and replications to posts from the users that visit his page [9]. *Twitter* is considered to be a “microblog” as each post is limited to 140 characters (*Twitter*[®], San Francisco, CA). *Wikis* are similar to blogs with the exception that all users are allowed to edit the page. The most famous example is *Wikipedia*[®] (from “wiki” that means quick in Hawaiian language and “paideia” that means education in ancient Greek) with over 5.5 million published articles written in more than 300 languages [10]. Social network sites allow users to create personal profiles online, where they can share information, music, videos, thoughts, and opinions but also papers, and information of any subject going from politics to science. *Facebook* is the most widely used social network site (*Facebook*[®], Palo Alto, CA). Moreover, *YouTube*[®] represents another famous platform which allows users to create and upload videos to the site (*YouTube*[®], LLC, San Bruno, CA). People are allowed to comment and share ideas on the video. Therefore, every day millions of contents are uploaded to the web and shared for free by anyone interested in a particular topic, with the raise of discussion and comments on them. Furthermore, the figure of a user particularly able to communicate effectively with their audience, the so-called “influencer”, can direct their “followers”, the users who routinely visit and “follow” his page, towards an opinion or towards an event, a book, or an information channel.

Currently, with roughly 2.93 billion monthly active users as of the second quarter of 2022, Facebook is the most used online social network worldwide. People spend on average 33 min on Facebook, followed by TikTok with 32 min and Twitter with 31 daily minutes. Due to the COVID-19 outbreak in 2020, all major social media platforms saw an increase in daily usage, which then either plateaued or decreased in 2021.

For what concerns medical education, according to Cheston et al. [11] blogs are social media of choice. Different types of information can be shared through these social networking sites in the form of texts, videos, pictures, audios, and references (contacts). During COVID-19 pandemic the use of social media in teaching and learning has exponentially increased especially among the youngest population. Indeed, the new generations of surgeons have been exposed to digital technologies from a very young age and, for the majority, they use social media on a daily basis or even as their primary source of information [12, 13]. Furthermore, both students and educators use it for communication, education, sharing and expressing knowledge, and recreation. Therefore, today we should not discuss on the possibility to incorporate social media in the medical and therefore surgical education, but on how best we can use them.

Undoubtedly, social media and networks promote the speed of access of information and an almost instantaneous sharing of opinions on the most different topics. They are slowly becoming a mainstay of the medical profession. Therefore, it would be useful probably if medical students would be taught how to use it professionally. They could potentiate the benefits while simultaneously limiting the drawbacks [14]. Indeed, choosing the right platform, the amount, and quality of the information shared to ensure optimal benefit, providing ethical guides, and professional standards for social media use at institutional levels are the few challenges that need to be addressed. Moreover, enabling young medical students to recognize false and misleading information and explaining them how to behave to avoid such errors and/or to report such pages would be essential for a correct usage of the media.

Jaffar [15] investigated the use of Facebook among students demonstrating that the majority of them were belonging to the youngest group aged 16–25 and the percentage was diminishing proportionally with the increase of age. The author investigated how Facebook was used and he showed that 96% of students were looking for pages in which they could find anatomical tables, while the second most used item, in 94% of students, was multiple choice questions, followed by explanatory comments (88%). Some studies analysed the use of Facebook more as a means of communication that allowed them to keep in contact with students with updates on day-to-day requirements [16, 17]. Facebook is therefore one practical example of a multifunctional tool that would allow educators and students to adapt to their own teaching and learning styles. It can therefore be seen as a supplement to conventional teaching.

Regarding *twitter*, Hennessy [18] reported that this online platform is able to create an informal community where students could share their thoughts and concerns, which in turn encouraged learning. Students tend to use it for networking opportunities, mentorship, and learning.

YouTube represents a graphic platform in which users communicate through videos [19]. It is generally thought that it might be useful to visualize anatomical structures but especially for surgery this platform might be particularly useful to visualize surgical operations and innovative techniques.

Interestingly, many surgical journals, such as Colorectal Disease [20] or Diseases of the Colon and Rectum [21], have developed their own YouTube channel with videos that can be consulted by all users for free.

Barry et al. found that 78% of medical students participating in the study used YouTube as their primary source of information for anatomy with only 29% of them looking at recommended textbooks [22]. However, social media help to bring groups of people together and represent a tool of support for students but also a link between students and faculty. They might help and lead to a stronger sense of community, which in turns increases interactivity, productivity, and confidence.

Surely, surgeons have today more opportunities to meet up in online groups, to share techniques and results, or ideally to design and participate in projects together. We are facing a change in students' scientific development, in which new technologies can facilitate engagement in international projects or access to online resources. These factors have had a positive impact on training and education. Social networks, in the digital age, have certainly helped to create networks of relationships between young surgeons and students, extremely relevant for the professional growth of surgeons [23, 24].

Surgical Training and Artificial Intelligence

Surgical sciences, from general surgery to eye microsurgery, require a greater learning curve than clinical sciences. In fact, a young medical doctor who wishes to become a surgeon has not only to possess theoretical knowledge but also practical skills, knowledge of surgical instruments, and technical procedures rather than empathy and communications competencies [25]. It often happens that opportunities to practice a surgical procedure are limited and that residents complete their training still at the beginning of the learning curve. In addition, the same thing also happens frequently to new surgeons who find themselves having to face complex surgical cases, more frequently in an emergency setting, and for the first time with the entire responsibility of patient's outcomes. Technologies may offer a valid support during the residency programme to practice basic surgical procedures and acquire confidence and gestures in the operating theatre in order to become confident with the instruments and the operating times. The surgeon needs modern and efficient operating tools, but also sufficient training before being able to reach an adequate level of familiarity with the procedure. Indeed, technology is indispensable for a progression of the whole medical science, but this is even more true when it comes to surgery. In fact, surgery is a practical science where the physician must not only be able to make a diagnosis, identify the correct therapeutic indications, and manage the clinical aspects of pre- and post-operative course, but must also

demonstrate a marked dexterity and practical skills that undoubtedly improve exponentially with experience and exercise. Furthermore, the new generation surgical instruments that are used in the operating room have as their main purpose to reduce the operating risks for the patient (e.g. the risk of bleeding), to help the surgeon in the most complex procedures, and to progressively reduce the operating time in order to render the operations more bearable and less impacting on the general condition of the patients, especially the fragile ones. Geronto-surgery is particularly linked to the use of technology. Indeed, the intraoperative monitoring and the reduction of operating times and risks are themes that are certainly supported by the so-called digital surgery.

It is therefore clear that the practice of laparoscopic and robotic interventions in the operating room is an indispensable advancement of surgery, increasingly practised everywhere, and that it has to be supported by adequate training and exercise by physician in specialist training. Development of technical laparoscopic surgical skills (LTS) in General Surgery residents is of paramount importance. Notably, to develop laparoscopic ability in trainees under safety conditions, multiple tools have been implemented, such as video games, virtual reality (VR) training models, box simulators (BS), surgical simulation (SS) on synthetic, virtual, biological models, and human cadaveric models which have shown to be an effective educational method for surgeons. SS in VR offers an additional opportunity to measure skills of students and evaluate their progress objectively by evaluating time, number of movements, errors committed, among other variables. In this sense, technology plays a crucial role in the course of education and training of a surgeon. Unlike artificial intelligence (AI) in medicine, which hopes to use autonomously functioning algorithms to better analyse patient's data in an effort to improve patient outcomes, AI in surgery also involves movement. Unlike the clinical fields, surgery is an art that is also dynamic. Unfortunately, the medical community has already been shown to be resistant to any automation of medical tasks even simple computations. It is safe to say that automation of surgical tasks will have an even more deep degree of resistance [26–28].

Data Analysis, Collection, and Sharing Database

Nowadays, clinical trials and data analysis are at the base of the development of evidence-based medicine. No technique or innovation will be really supported and modified from the scientific community without a well-designed trial. For this reason, it is clear that data collection and data analysis have become a not negligible part of surgeon's daily life [29].

The economist stated that “the world's most valuable resource is no longer oil, but data” [30] and with the introduction of the modern electronic medical records, the amount of medical data has been exponentially expanded. This huge and sudden increase of data led to the confirmation of some results on a larger scale and the discovery of underestimated practices that greatly modified patient outcomes. The

recently very famous “Big Data” can be defined as extremely large datasets that may be analysed computationally to reveal patterns, trends, and associations, especially relating to human behaviours and interactions [30]. This mechanism is at the base of the AI application. Indeed, data collection is essential also for the advancement of AI models in which large volumes of videos that capture surgery procedures are required. This requires hundreds if not thousands of fully annotated videos for each specific type of surgery that can be used and shared within the research community. To meet this requirement, data collection, preparation, and annotation must be part of future medical practice [27]. The purpose of machine learning is to discover algorithms that give machines the ability to reason and perform cognitive functions such as problem solving, object and word recognition, and decision-making. Social media may represent a quick and effective vehicle of information, reaching different medical doctors who may be interested in participating to multi-centre trials also regarding AI. These online platforms have the potentiality to drastically reduce timing of communication putting general practitioners, residents, and the surgical community from all over the world in direct contact instantaneously. As well as society dedicated pages may reach surgeons and share preliminary research data or collect opinions, share databases or decisions on the design of some trials [31].

However, AI is not limitless, there are multiple important technical and ethical issues that must be well discussed within the scientific community. First of all, the issue of “big data” can be taken from mobile phone applications, wearable watches, and “omics” data, which not all patients wish to share. Moreover, to achieve large enough sample sizes to be interpreted we have to share sensitive data or images, particularly between hospitals. AI can be an attractive solution, but it is not always the answer where traditional methods may be more suitable [32].

Telemedicine and COVID-19 Age

Telemedicine (or telehealth) is the distribution of remote clinical services, including diagnosis, monitoring, and prescribing therapies by means of health-related services using information and communications technology.

COVID-19 pandemia raised the need of promoting this kind of activities which permit to reach distant and isolated people [33]. Worldwide, we assisted to a suspension of the in-person elective clinical activities for a long period. Surgeon had to promote the use of telemedicine in order to do not underestimate mild symptomatology or to not delay too much screening visits or examinations. This need promoted a further increase in the use of internet and social media, yet well-known powerful tools to increase engagement and participation of patients with colorectal diseases. Using smartphones or webcam-enabled computers physicians were allowed to communicate with patients 24/7, to follow their clinical course and to answer their questions making them feel not abandoned even though alone. In this

context, also modern machineries in the emergency intensive care unit helped monitoring multiple critically ill patients at distance.

International COVID-19 collaborations such as CovidSurg have been widely disseminated through social media [34–37]. They provided some research opportunities during the pandemic, and it seems that they started a new era in which trials are firstly announced and proposed through them.

Videoconference-based platforms, such as Zoom, Google Meet, and Microsoft Teams, among others proved to be efficacious tools of teaching and sharing documents. During this “social distancing-era” these mandatory ways of educating have expanded the traditional teaching and learning techniques since they provided the flexibility of recording and listening the lecture out of hours [28].

These platforms are easy to access through smartphones and tablets, they allowed to maintain the daily and weekly meetings among residents as well as they permitted to continue with the oncological multidisciplinary meeting on a surgery ward, giving the opportunity to present in- and out-patient cases and to raise the discussion on the best therapeutical strategy. They have been used for departmental meetings and for the reintroduction of journal clubs and exams. However, the impact of COVID-19 in healthcare systems globally has been detrimental [38].

The national health systems had to fight against the pandemic with low resources, few equipment, and frequently without any guidelines [39, 40]. Therefore, healthcare professionals have joined forces in a regional, national, and international level, and this was possible only by the use of internet, social media, and networks. In this chaotic scenario, it has been recently introduced a new kind of surgical live training: the telementoring. The intraoperative aid of a tutor at distance. In particular, augmented reality telementoring in surgery permits external communication with audio and visual input and telestration (graphical overlay on a live image). This can be established from a disparate site within the hospital or internationally. This technology could be utilized by trainees and trainers. By the mean of an integrated surgical command centre or experts in the field, data could be securely stored for developing technical skill and team performance metrics [41, 42].

Limitations of the Digital Surgeon

The first evident limitation of digital surgery are the current national health systems that are not yet ready for the spread of digital surgery. Indeed, significant investment into infrastructure is required. Nonetheless, the use of social media and network could be integrated in the routine of hospitals to collect data, spread information, convey patients to screening programmes or to the right specialists when and where the general practitioners are not able to intervein. Second, to make social media really effective they should be integrated into the normal practice; therefore, they should also be regulated by appropriate legal and commercial guidelines. Template

data sharing agreements and commercial models designed specifically for digital surgery applications should be considered as well as the bureaucracy and cost of standardizing the process. The development of a national health research hub in surgery should be considered.

The spread of social media should also raise concerns about privacy and professionalism. Indeed, it is reported that sometimes students had behaved in an unprofessional manner, sharing inappropriate statuses, uploading of unprofessional profile pictures as well as confidential information.

Efforts must be made to educate stakeholders to be aware of the evolving legal and regulatory landscapes. Social media platforms are dealing with data privacy law and include issues of competition law and intellectual property protection rights, as well as commercial considerations such as liabilities, indemnities, and data ownership. The German Chamber of Physicians released recommendations for physicians and medical students using social media as well as the American Medical Association (AMA) and many other international medical schools established guidelines and policies on the professional use of Facebook and social media in general [13]. Furthermore, modern operating theatres have the potential to generate extensive and heterogeneous datasets but the majority of hospitals, at present, lack the technical storage, network, and cybersecurity capabilities and funding required for advances in technology.

Public acceptability of digital surgery and sharing of information through online platforms is of fundamental importance too but the drawbacks of involving patients may lay in the “doctor google” phenomenon. This is the reason why it would probably be useful if the health care system and the hospital produce a system to recognize institutional and reliable pages.

Last but not least, the services provided by telemedicine should have the same requisites of professional liability and insurance as standard consultations. Teleconsultation should be regularly paid, with advice and prescriptions incorporated into a formal report sent by e-mail to the patient, along with a receipt [43].

Future Perspectives

Scientific community has to accept that the future surgeon will have to become a digital surgeon. This includes a deep understanding of AI and technology as well as has to show awareness around the legal, ethical, and data governance issues concerning their use. Surgeons living in the modern era have to embrace technologies and especially the modern ways of communication such as social media filling more and more the gap in surgeon–patients relationship. As physicians or healthcare professionals we should start thinking as a global community working together and sharing information and results for the progression of medicine.

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References

1. Lam K, Abràmoff MD, Balibrea JM, Bishop SM, Brady RR, Callcut RA, Chand M, Collins JW, Diener MK, Eisenmann M, Fermont K, Neto MG, Hager GD, Hinchliffe RJ, Horgan A, Jannin P, Langerman A, Logishetty K, Mahadik A, Maier-Hein L, Antona EM, Mascagni P, Mathew RK, Müller-Stich BP, Neumuth T, Nickel F, Park A, Pellino G, Rudzicz F, Shah S, Slack M, Smith MJ, Soomro N, Speidel S, Stoyanov D, Tilney HS, Wagner M, Darzi A, Kinross JM, Purkayastha S. A Delphi consensus statement for digital surgery. *NPJ Digit Med.* 2022;5(1):100. <https://doi.org/10.1038/s41746-022-00641-6>.
2. <https://wearesocial.com/au/blog/2022/04/more-than-5-billion-people-now-use-the-internet/>.
3. Sturiale A, Pata F, De Simone V, Pellino G, Campenni P, Moggia E, Manigrasso M, Milone M, Rizzo G, Morganti R, Martellucci J, Gallo G, ISMAEL working group. Internet and social media use among patients with colorectal diseases (ISMAEL): a nationwide survey. *Color Dis.* 2020;22(11):1724–33. <https://doi.org/10.1111/codi.15245>; Epub 2020 Aug 2. PMID: 32645247.
4. Gallo G, Sturiale A, De Simone V, Mayol J. Epistemic networks on twitter: a new way to learn. *J Investig Surg.* 2021;34(5):536–44. <https://doi.org/10.1080/08941939.2019.1656787>; Epub 2019 Sep 1. PMID: 31475634.
5. Kibbe MR, Velazquez OC. The extinction of the surgeon scientist. *Ann Surg.* 2017;265(6):1060–1. <https://doi.org/10.1097/SLA.0000000000002192>.
6. Alverdy JC. Surgeon as basic bench scientist: a play in three acts. *J Surg Res.* 2019;241:336–42. <https://doi.org/10.1016/j.jss.2019.04.016>.
7. Keswani SG, Moles CM, Morowitz M, Zeh H, Kuo JS, Levine MH, Cheng LS, Hackam DJ, Ahuja N, Goldstein AM, Basic Science Committee of the Society of University Surgeons. The future of basic science in academic surgery: identifying barriers to success for surgeon-scientists. *Ann Surg.* 2017;265(6):1053–9. <https://doi.org/10.1097/SLA.0000000000002009>; PMID: 27643928; PMCID: PMC5450912.
8. Waite M, Dictionaries O. Paperback Oxford English dictionary. 7th ed. Oxford: Oxford University Press; 2015.
9. Whyte W, Hennessy C. MedEdPublish. Systematic review open access social media use within medical education: a systematic review to develop a pilot questionnaire on how social media can be best used at BSMS. 1. <https://doi.org/10.15694/mep.2017.000083>
10. <https://www.wikipedia.org>.
11. Cheston CC, Flickinger TE, Chisolm MS. Social media use in medical education: a systematic review. *Acad Med.* 2013;88(6):893–901. <https://doi.org/10.1097/ACM.0b013e31828ffc23>.
12. Bennett S, Maton K, Kervin L. The ‘digital natives’ debate: a critical review of the evidence. *Br J Educ Technol.* 2008;39(5):775–86. <https://doi.org/10.1111/j.1467-8535.2007.00793.x>.
13. Pander T, Pinilla S, Dimitriadis K, Fischer MR. The use of Facebook in medical education—a literature review. *GMS Z Med Ausbildung.* 2014;31(3):Doc33. <https://doi.org/10.3205/zma000925>.
14. Kind T, Patel PD, Lie D, Chretien KC. Twelve tips for using social media as a medical educator. *Med Teach.* 2014;36(4):284–90. <https://doi.org/10.3109/0142159X.2013.852167>.
15. Jaffar AA. Exploring the use of a Facebook page in anatomy education. *Anat Sci Educ.* 2014;7(3):199–208. <https://doi.org/10.1002/ase.1404>.
16. Ekarattanawong S, Thuppia A, Chamod P, Pattharanitima P, Suealek N, Rojpiibulstit P. Perception of social networking benefits in the support of a PBL module according to students’ performance levels. *J Med Assoc Thai.* 2015;98(Suppl 2):S77–83.
17. Amgad M, AlFaar AS. Integrating web 2.0 in clinical research education in a developing country. *J Cancer Educ.* 2014;29(3):536–40. <https://doi.org/10.1007/s13187-013-0595-5>.
18. Hennessy CM, Kirkpatrick E, Smith CF, Border S. Social media and anatomy education: using twitter to enhance the student learning experience in anatomy. *Anat Sci Educ.* 2016;9(6):505–15. <https://doi.org/10.1002/ase.1610>.

19. Sturiale A, Dowais R, Porzio FC, Bruscianno L, Gallo G, Morganti R, Naldini G. Youtube as a source of patients' and specialists' information on hemorrhoids and hemorrhoid surgery. *Rev Recent Clin Trials*. 2020;15(3):219–26. <https://doi.org/10.2174/1574887115666200525001619>.
20. <https://www.youtube.com/c/ColorectalDiseaseJournalVideoChannel>.
21. <https://www.youtube.com/c/DiseasesoftheColonandRectumJournal>.
22. Barry DS, Marzouk F, Chulak-Oglu K, Bennett D, Tierney P, O'Keeffe GW. Anatomy education for the YouTube generation. *Anat Sci Educ*. 2016;9(1):90–6. <https://doi.org/10.1002/ase.1550>.
23. Wall J, Krummel T. The digital surgeon: how big data, automation, and artificial intelligence will change surgical practice. *J Pediatr Surg*. 2020;55S:47–50. <https://doi.org/10.1016/j.jpedsurg.2019.09.008>.
24. Nisar S, Alshanberi AM, Mousa AH, El Said M, Hassan F, Rehman A, Ansari SA. Trend of social media use by undergraduate medical students; a comparison between medical students and educators. *Ann Med Surg (Lond)*. 2022;81:104420. <https://doi.org/10.1016/j.amsu.2022.104420>.
25. Han JL, Pappas TN. A review of empathy, its importance, and its teaching in surgical training. *J Surg Educ*. 2018;75(1):88–94. <https://doi.org/10.1016/j.jsurg.2017.06.035>.
26. Rueda Esteban RJ, López-McCormick JS, Rodríguez-Bermeo AS, Andrade M, Hernández Restrepo JD, Targarona Soler EM. Face, content, and construct validity evaluation of simulation models in general surgery laparoscopic training and education: a systematic review. *Surg Innov*. 2022;1:15533506221123704. <https://doi.org/10.1177/15533506221123704>.
27. Gumbs AA, Frigerio I, Spolverato G, Croner R, Illanes A, Chouillard E, Elyan E. Artificial intelligence surgery: how do we get to autonomous actions in surgery? *Sensors (Basel)*. 2021;21(16):5526. <https://doi.org/10.3390/s21165526>.
28. Humm G, Harries RL, Stoyanov D, Lovat LB. Supporting laparoscopic general surgery training with digital technology: the United Kingdom and Ireland paradigm. *BMC Surg*. 2021;21(1):123. <https://doi.org/10.1186/s12893-021-01123-4>; PMID: 33685437; PMCID: PMC7941971.
29. Mathias B, Lipori G, Moldawer LL, Efron PA. Integrating “big data” into surgical practice. *Surgery*. 2016;159(2):371–4. <https://doi.org/10.1016/j.surg.2015.08.043>.
30. The world's most valuable resource is no longer oil, but data. *Economist*. <https://www.economist.com/leaders/2017/05/06/the-worlds-most-valuable-resource-is-no-longer-oil-but-data>. Accessed 15 Aug 2019.
31. <https://www.escp.eu.com>.
32. Rimmer L, Howard C, Picca L, Bashir M. The automaton as a surgeon: the future of artificial intelligence in emergency and general surgery. *Eur J Trauma Emerg Surg*. 2021;47(3):757–62. <https://doi.org/10.1007/s00068-020-01444-8>; Epub 2020 Jul 26. PMID: 32715331.
33. Gallo G, Trompetto M. The effects of COVID-19 on academic activities and surgical education in Italy. *J Investig Surg*. 2020;33(7):687–9. <https://doi.org/10.1080/08941939.2020.1748147>.
34. COVID Surg Collaborative. Outcomes from elective colorectal cancer surgery during the SARS-CoV-2 pandemic. *Colorectal Dis*. 2020;23(3):732–49. <https://doi.org/10.1111/codi.15431>.
35. COVID Surg Collaborative. Preoperative nasopharyngeal swab testing and postoperative pulmonary complications in patients undergoing elective surgery during the SARS-CoV-2 pandemic. *Br J Surg*. 2021;108(1):88–96. <https://doi.org/10.1093/bjs/znaa051>.
36. COVID Surg Collaborative. Head and neck cancer surgery during the COVID-19 pandemic: an international, multicenter, observational cohort study. *Cancer*. 2021;127(14):2476–88. <https://doi.org/10.1002/cncr.33320>.
37. COVID Surg Collaborative, Global Surg Collaborative. SARS-CoV-2 infection and venous thromboembolism after surgery: an international prospective cohort study. *Anaesthesia*. 2022;77(1):28–39. <https://doi.org/10.1111/anae.15563>.

38. Doulias T, Gallo G, Rubio-Perez I, Breukink SO, Hahnloser D. Doing more with less: surgical training in the COVID-19 era. *J Investig Surg.* 2022;35(1):171–9. <https://doi.org/10.1080/08941939.2020.1824250>; Epub 2020 Sep 22. PMID: 32959688.
39. Pertile D, Gallo G, Barra F, Pasculli A, Batistotti P, Sparavigna M, Vizzielli G, Soriero D, Graziano G, Di Saverio S, Meniconi RL, Guaitoli E, Mazzarri A, SPIGC Working Group. The impact of COVID-19 pandemic on surgical residency programmes in Italy: a nationwide analysis on behalf of the Italian polyspecialistic young surgeons society (SPIGC). *Updat Surg.* 2020;72(2):269–80. <https://doi.org/10.1007/s13304-020-00811-9>.
40. Bianco F, Incollingo P, Grossi U, Gallo G. Preventing transmission among operating room staff during COVID-19 pandemic: the role of the aerosol box and other personal protective equipment. *Updat Surg.* 2020;72(3):907–10. <https://doi.org/10.1007/s13304-020-00818-2>.
41. Hollander JE, Carr BG. Virtually perfect? Telemedicine for Covid-19. *N Engl J Med.* 2020;382(18):1679–81. <https://doi.org/10.1056/NEJMp2003539>; Epub 2020 Mar 11. PMID: 32160451.
42. Gallo G, Grossi U, Sturiale A, Di Tanna GL, Picciariello A, Pillon S, Mascagni D, Altomare DF, Naldini G, Perinotti R, Telemedicine in Proctology Italian Working Group. E-consensus on telemedicine in proctology: a RAND/UCLA-modified study. *Surgery.* 2021;170(2):405–11. <https://doi.org/10.1016/j.surg.2021.01.049>; Epub 2021 Mar 22. PMID: 33766426.
43. Gallo G, Picciariello A, Di Tanna GL, Santoro GA, Perinotti R. Telemedicine in colorectal surgery Italian working group, Grossi U. E-consensus on telemedicine in colorectal surgery: a RAND/UCLA-modified study. *Updat Surg.* 2022;74(1):163–70. <https://doi.org/10.1007/s13304-021-01139-8>; Epub 2021 Jul 26.

Chapter 5

Online Surveys and Collaborative Groups: Big Numbers, Low Evidence?



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Collaborative Research

How Did It Start?

Collaborative research is a model where different researchers have a different role in the studies delivered and where teamwork is in the centre of the research. This model is characterised by a steering committee and a wide network of collaborators, who work together to deliver a multicentre study, whether it is observational or a trial.

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This model was formally described and adopted by the surgical community in 2007 with the foundation of the first surgical research collaborative, the **West Midlands Research Collaborative (WMRC)**. The idea emerged from trainees who were research enthusiasts and realised that the single centre studies that they have conducted so far would have low impact in clinical practice [1]. Considering that research was part of their curriculum, and that they were rotating through several hospitals, working in collaboration would be an advantage to run multicentre studies, with trainees as the ideal figure to deliver this model. In addition, the experience acquired would create the basis for long lasting surgical networks with benefits for patients and surgical care.

In 2013, the WMRC published the results of the first randomised trial **ROSSINI** (Reduction Of Surgical Site Infection using a Novel Intervention). The study recruited 760 patients from 21 centres to demonstrate the impact of a wound-edge protection device in lowering surgical site infections (SSI) in comparison with the standard practice [2], showing the ability of SRC in delivering high-quality trials, with good coordination among centres and minimal loss to follow-up.

In surgery, there is relative paucity of high-quality trials and structured research programs, so that any effort in this direction may add stronger evidence to help the clinical decision-making and to add baseline data to inform research questions and randomised clinical trials.

The model was successfully translated internationally and taken on by medical students, with the foundation of student- and trainee-led collaboratives such as **STARsurg** (2013) in the UK and **EuroSurg** in Europe (now involving also overseas countries, such as New Zealand and Australia) founded during the Annual Meeting of the European Society of Coloproctology (ESCP) in Dublin in 2015 [3, 4].

To date, there are more than 249 collaboratives developing surgical clinical research worldwide [5].

What Has Happened Since WMRC?

After the foundation of WMRC in 2007, some years passed by without new initiatives following this milestone.

In 2013, **GlobalSurg**, a surgical research collaborative, was founded in the UK with the aim of collecting data on surgery variation globally. Traditionally, surgery was the “neglected stepchild of global health”: although it accounted for 30% of global burden disease and the number of 30-day postoperative deaths per year was superior to the deaths for malaria, tuberculosis, and AIDS combined [6]. However, robust data from low- and middle-income countries (LMICs) was lacking and which was a major obstacle in plan improvement and mitigation strategies.

In 2014, GlobalSurg launched its first Global cohort study (GlobalSurg-1) about mortality and postoperative outcomes after emergency abdominal surgery [7], followed by the GlobalSurg-2 study about Surgical Site Infection rate after gastrointestinal surgery in 2016 [8], and by the GlobalSurg-3 study focused on quality and outcomes following surgery for breast, gastric, and colon cancers in 2018 [9]. These



Fig. 5.1 Timeline resuming creation of relevant surgical research collaboratives since the foundation of WMRC in 2007

studies recruited more than >40,000 patients from more than 80 countries. They provided baseline data to inform future studies and supported the creation of new national research networks inclusive of researchers who were previous in local isolation [10].

In 2015, the **Irish Surgical Research Collaborative (ISRC)**, aiming to involve all Irish surgical trainees, was founded with the support of the Royal College of Surgeons of Ireland (RCSI), followed by the **Italian Surgical Research Group (ItSURG)** in 2016 [11].

The COVID-19 pandemic also represented an unexpected challenge for surgical patients considering the absence of any robust data on postoperative outcomes in patients with perioperative coronavirus infection. From the core network of GlobalSurg, the **CovidSurg collaborative** was set up in 2020, launching 4 international snapshots achieving a massive recruitment (more than 150 thousand patients) from every part of the world. They found an answer to many unanswered questions related to surgical activity during the pandemic. The first study provided invaluable data about postoperative outcomes of operated patients infected with SARS-CoV-2, which informed mitigation strategies and guidelines [12]. Figure 5.1 resumes the timeline of the foundation of some pivotal surgical research collaboratives.

As it can be seen in Table 5.1, the original purpose set by the WMRC group—to increase clinical impact of research by getting access to higher numbers of patients in each study—was achieved by most of the groups that came afterwards. Some studies also managed to reach more than 25 thousand patients, as the case of GlobalSurg or STARSurg studies, extending the boundaries and significance of the study’s results.

How Is It Organised?

Collaborative research groups are formed by a central committee, usually named **steering committee**, and a network of **collaborators**. The first is responsible for the definition, design, and dissemination of the study. The second group is responsible for data collection and dissemination of the study. Additionally, to facilitate communication between the central team and collaborators, a **national lead** and/or a **local lead** for each participating centre may be appointed [13].

The steering committee is usually formed by a group of motivated clinicians and/or medical students that have an interest in clinical research. There are many collaboratives that are trainee-led that were developed to address the challenges of

Table 5.1 Information about some surgical research collaboratives around the world

Name of the SRC	Country	Starting year	Number of projects	Number of patients recruited	Main topic
WMRC	UK	2007	> 7	> 30.000	Trainee-led collaborative research on different topics related to surgery
STARSurg	UK/ Ireland	2013	7	> 30.000	Student-led collaborative research aimed to generate scientific evidence and improve clinical practice
GlobalSurg	UK	2014	3	> 40.000	Collaborative research aimed to improve outcomes of surgery across the world
EuroSurg	Europe	2015	4	> 10.000	Student-led collaborative research directed to develop research networks across Europe and improve patient care and management
ItSURG	Italy	2016	4	> 15,000	Trainee-led, surgical intern-led collaborative aiming to perform national and international studies in surgery
SIGMA	Germany	2017	2		Student-led collaborative research created to perform clinical studies in Germany
PTSurg	Portugal	2018	1	> 800	Surgical intern-led collaborative research creates to promote multicentre studies, training in research methodology and to contribute to advancement of scientific knowledge
CovidSurg	UK	2019	3	> 140.000	Surgeon and anaesthesia-led studies to determine the impact of COVID-19 in surgical patients and services
TASMAN	New Zealand/ Australia	2019	1	Results not yet published	Student-led audit and research network that empowers and equips students to be engaged in high-quality collaborative surgical research
LatamCCR	Latin America	2020	5	> 5.000	Surgeon-led initiative to improve outcomes in colorectal surgery by generating reliable data which will then lead to improvement strategies

delivering high-quality and high impact studies by each individual. Considering that research is usually required in the curriculum of any trainee from any specialty, it can be particularly challenging for trainees who are not keen on research to lead high impact studies by themselves. Participating in collaborative studies allows a different commitment from each trainee which addresses the identified problem. Additionally, considering that trainees rotate during their programme, it is easier to establish a network with peers that might have interest in clinical research too. The steering committee is usually advised by an advisory group formed by expert consultants, that have previous experience in collaborative research and in the topic, that help in the prioritisation of research questions, with the design of the study, as well as with managing some challenges that the collaborative face.

Collaborators are responsible for data collection and site approval according to local and national rules. Data collection usually occurs within groups of 3–5 researchers who work together, highlighting even more the teamwork concept behind collaborative research. To facilitate the connection between collaborators and the central team, there are leads that vary according to the complexity of the network involved in the study, such as national leads, regional leads, and hospital leads. In international studies, national leads coordinate local collaborators to get local approval, which vary across countries. Data quality is ascertained by hospital leads or by data validators. The aim is to evaluate if the registered data is consistent with patient records and if all eligible patients were included in the study.

This model is reflected in the **corporate authorship** of all resulting publications [7–9]. The name of the collaborative group is the named author of all papers, while the full list of everyone involved and the correspondent role is recognised separately. In this section, the writing group and data analysis group is usually recognised as such, besides steering committee, existing leads, advisory group, data validators, and collaborators. In the last few years, it has become more frequent to also work with patient and public involvement (PPI) groups, who should also be recognised in the supplement. Following this authorship strategy, everyone involved in the study is a PubMed citable co-author which not only enriches the curriculum, but also increases the research experience for each individual. Verification of the effort and work by each individual in the authorship has an increased complexity as the number of collaborators increases too. The responsibility for this is transferred to national leads and hospital leads in international studies and it is impossible for the steering committee to identify if there is someone listed who did not have a role in the research developed. However, this is expected to be a small number and the collaborative model prioritises the recognition of everyone who was involved [14].

This authorship model might not be recognised or accepted by all journals. This problem has been decreasing overtime, particularly with the publication of collaborative studies in high-level impact journals (i.e., *GlobalSurg 2* published in *The Lancet*) [8]. However, it is still relevant to check this detail ahead of the submission of a collaborative paper.

Currently, collaborative research is adopted outside the UK, with groups emerging from different income countries, such as **LatAm Colorectal Surgery Consortium** (Latin America), **ItsURG** (Italy), and **PTSurg** (Portugal). There is already a collaborative (**GlobalSurg-CovidSurg Collaborative**) that was recognised by the Guinness

World Record by having the highest number of authors in the GlobalSurg-Covid Surg Week study (15,027). As we mentioned before, this network in particular provided the best evidence about surgical care during the COVID-19 pandemic, being adopted as a reference to international and World Health Organization (WHO) guidelines. It was already proven that research collaboratives can deliver more than observational studies. Successful examples like ROSSINI [2], FALCON [15], and CHEETAH [16], showed that high-quality, multicentric, randomised controlled trials can be organised and developed too. Additionally, studies focused on global health have a clear benefit in adopting this model as a strategy to collect real-world data while ascertaining their high quality [17].

Collaborative research also fills a previously identified gap in global health research, which is the low involvement of LMICs [10]. The Lancet Commission on Global Surgery identified that LMICs are underrepresented in surgical research and that their empowerment is crucial for the future. There are specific clinical areas which have a particular relevance to these countries that need to be explored to improve their health care and patient outcomes. Having in mind that collaborative research is not limited to the production of high impact research but also involves knowledge and skill sharing, this is the ideal environment for researchers from LMICs to be included. Their acquired skills in collaborative studies will empower them to lead and deliver high-quality research in the future [13, 17].

Advantages of Collaborative Research

- Collaborative research allows the **production of a large dataset** collected by clinicians that is reliable considering the associated data validation process. It also reflects the real practice by engaging district and rural hospitals, instead of limiting the data collection to high-volume centres.
- **Data analysis and writing can occur at a fast pace** which leads to a short time between the beginning of the study and the publication of the results.
- **Everyone involved represents a wide network that are keen on the dissemination of the results** which increases the chances of a significant impact in clinical practice.
- The **knowledge and skill sharing** that occurs throughout the whole process is fundamental to enrich each individual research experience and to empower some of them to lead future projects.

Controversies and Limitations Related to Collaborative Research

Authorship of Manuscripts: Defying the Traditional Methodology

When submitting a manuscript for publication in peer-reviewed journals, in particular if it has a high impact factor, historically there has been specific criteria that needs to be met to qualify as “author”. Some entities, like the International

Committee of Medical Journal Editors (ICMJE) propose such definitions based on participation of the researcher in all or most of the steps of the study procedure (confection, analysis of results, manuscript draft, etc.) [18].

As the reader can imagine, this criterion is easily applicable when only one or few centres are participating, but when it comes to collaborative studies, this classification of authorship turns into a matter of controversy for many reasons.

Firstly, the collaborative studies are usually multicentric, sometimes reaching different countries or even continents, as the case of GlobalSurg [7–9]. Furthermore, the number of patients recruited is also higher than most studies. All this carries a lot of work behind the scenes and large groups of people working to undertake this work. Then, who gets to be an author? As we said before, this is unconventional.

Conversely, we need to consider the role of the participant centres, without which there would be no study. These centres do not participate in the idea conception, or the protocol design, nor do they write the paper. Yet, they undertake a lot of work recruiting patients, in some cases hundreds of them, without perceiving any remuneration for this, other than being able to be participants of the effort. Should they not be recognised for this work, even though they do not strictly meet the Vancouver standards for authorship?

Last (but not least), we have the example of medical students, who in many cases (like TASMAN or SIGMA collaboratives) are the soul and creators of the initiatives. Yet, since they are students, they need to count on more experienced professionals for advice, design of the research questions, etc. The old trend relied on giving the credit to the more experienced participant, making the work developed by less experienced researchers not recognised. However, this tradition might not fit the new generation who are exposed to a more significant burden than in the past, since now students are not only doing data collection, but actually they are proposing and taking care of all the process from the beginning to the end. Should they not be considered important in the process?

The answer to all these questions has been debated for many years now, and a partial solution has been proposed, which is the Collaborative Model for participation proposed by The National Research Collaborative and Association of Surgeons in Training Collaborative Consensus Group [14].

In summary, this model proposes a corporate author (which is the name of the group working behind the initiative) and then establishes a number of definitions to acknowledge the efforts of the different persons involved. We recommend reading this manuscript when looking into standardisation of authorship for collaborative research.

However, some specific adjustments of the rules in terms of using these publications for career progression might be needed [13, 19].

Controversies Behind Multicentre Studies

When there is a high number of centres involved, there is a **heterogeneity of practices** that is translated into heterogeneous data and an impact of the results. This is relevant in observational studies where a deep understanding of these differences is

desirable besides being recognised as a limitation of the study. Additionally, trainees rota can be a problem regarding data collection specially during follow-up of patients. Each centre should identify the best strategy to manage reliability of data collection in case the collaborators involved cannot be there for the whole period of data collection. Looking at the involvement of LMICs centre, inclusion of rural hospitals is always challenging but having their data is extremely helpful to represent the reality of the country. All efforts should be made to include these centres when LMICs are involved, which emphasise the role of national leads and local leads.

Currently, the biggest challenge that collaborative research is facing is the same as any type of research: the **implementation of the findings into practice**. Dissemination of the results, reaching medical societies, and developing PPI work is not enough to ensure that it will change clinical practice. Behaviour change and adoption of new strategies is hard and challenging for everyone. Monitoring the results months after the study can be a strategy to measure the impact in clinical practice that might be worth exploring further.

Is Collaborative Research the Future of Research?

Looking further, there is a high probability that collaborative research will be adopted widely. The increase in collaborative research has been significant since its beginning and it is expected that it keeps increasing. It will be particularly relevant for future global health studies. All the established networks are important to be maintained to ascertain connections between different countries to continue developing international studies in areas of interest for everyone involved. It will make future studies smoother and easier to coordinate.

However, to increase collaboratives, the support and recognition from surgical societies need to be improved as well as funding opportunities [20]. Collaborative research is the best strategy to deliver relevant studies with the correct sample size to have the potential to be adopted in clinical practice. This strategy will avoid having multiple single centre studies, with small sample size and consequently lower translation to clinical practice. In summary, collaborative research is a joint effort to deliver high-quality studies with high level of evidence able to promote change in clinical practice [17].

One of the challenges that will be faced is translating the findings into practice, particularly when change in practice and behaviour change is needed. Implementation science has its own barriers and this will be the next logical step that collaborative efforts could put their efforts into. Measuring the change in practice and understanding the barriers and solutions associated with it will be essential to actually modify clinical practice.

Survey-Based Research

Definition and Type of Surveys

A survey is a research method orientated to collect data from a number of respondents (which need to be defined before designing the questionnaire), and it is used to gain knowledge and/or insights about various topics [21].

Artino et al. established a precise definition of Survey as “*any tool directed at a select group of people that is used to gather opinions*”.

Specifically applied to surgical specialties, it is a widely used resource to acquire knowledge about different points of view on a particular topic or technique. For example, it can be helpful to determine the rates of adherence to minimally invasive surgery in a determined region or country, but also to determine quality of life or functional results after certain surgical procedures.

We can stratify surveys into different categories, according to how they are delivered and what is expected of them:

- **Paper surveys:** Not very common in surgical research, since it involves time from the person in charge of the survey to deliver a questionnaire to each involved respondent, as well as from the respondent to fill it in and give it back.
- **Telephone surveys:** These involve a person in charge of making questions through the phone to each respondent, as well as the previous methodology, they are not very popular among surgeons for timing issues.
- **In-person or face-to-face interviews:** Even though this methodology is commonly used for commercial purposes (i.e., to test a client’s opinion regarding a determined product), it is seldomly used in surgical surveys because, as well as the previous options, it demands time that surgeons usually do not have.
- **Panel surveys:** This type of survey involves engaging a group of people supposedly representative of a whole population. It is also used commonly for commercial purposes to evaluate the impact of a particular strategy/product among a specific population.
- **Online surveys:** These are the most commonly used type of surveys within the medical community, since it comprises an easy and fast way to approach health-care professionals, and they can be completed at any time. These types of questionnaires can be delivered by email or using an internet platform (see ahead). This includes also Social Media polls (i.e., drawing a question on Twitter with some possible answers, and see that people think).

Irrespective of how the investigator conducts the research, it represents an excellent tool to gather information, provided it is designed correctly and chosen for the adequate reason [22].

Since there has been a considerable raise in the number of surveys delivered in the last years (especially during and after COVID-19 pandemic), this chapter will address the most important key-points to design an adequate questionnaire.

Which Surveys Can Be Used for Surgical Research

Surveys for medical research in general and in surgical research in particular can have a substantial number of purposes [23, 24].

Basically, it involves collecting a number of opinions or responses covering particular aspects of physicians' everyday practices, and they are useful to get a representative measure of that phenomenon in a determined population. Then, for example, if you want to know how many surgeons are using robotic technology to operate on rectal cancer patients in Spain, you could prepare a basic questionnaire and direct it to surgeons practising within the country.

We will enumerate some of the surveys' possible purposes:

1. **To explore the adherence to a determined new technology/technique within a region.**
2. **To evaluate trends of how a disease is handled in different hospitals.** For example, studying the management of rectal cancer in different settings, exploring questions about the use of neoadjuvant treatment, the access to colorectal specialist, and the availability to high resolution magnetic resonance or MDT.
3. **To investigate different approaches to the same disease.** For example, management of grade IV hemorrhoidal disease (conventional surgery, stappled, laser, etc.).
4. **To establish differences in medical education and training,** including information about working hours of residents in different centres, number of on-call days per month, and also identify areas for improvement.
5. **To attract physicians for an ulterior more complex study.** For example, run a survey on a particular subject, like current management of breast cancer, and include a couple of questions at the end to inquire whether the respondent would like to be reached for participation in further studies in this area. This can be translated by participation in future cohort studies or qualitative studies, where purpose sampling would be relevant to explore one topic in-depth.
6. **To act as a registry of procedures and techniques,** more basic than a cohort study but easier to distribute among collaborators. That is, Livermetsurvey on colorectal metastases.

What Surveys Should Not Be Used for

Surveys are a useful tool for some objectives (like those mentioned before), and one could be tempted to use them for everything, since they can be easily launched, and using social media platforms, a vast audience could be reached in a very short time, getting the feeling that definitive answers can be drawn based on these results.

Yet, we should clarify that high-quality scientific evidence can hardly be generated by this approach, and it is considered low quality evidence (type VI–VII). This is mostly due to the fact that surveys express opinions, but those opinions must not necessarily be based on actual facts, because they implicate a person’s perspective of a determinate phenomenon which might or might not be accurate.

For example, a surgeon can have an opinion that elder patients get worse postoperative results in his experience, and when asked about it in a survey context, he will express that, to his consideration, age is definitely associated with poor outcomes when compared to younger patients. However, this can be biased by personal bad experiences with elder patients, and it would require an actual comparative study including patients to prove the assumption.

Therefore, this type of questionnaires should not be used for:

1. **Writing guidelines for management of a disease**—they can be used as aid, but harder evidence is needed for this purpose.
2. **Evaluating the efficacy of a determined treatment.**
3. **Making assumptions about specific rates of morbidity of a procedure.**
4. **Defining an actual policy of a surgical department regarding a determined technique**—again, they can be used to assess the opinion of the members of the department to the extent of that technique but cannot assess the actual results of the procedure and therefore, another type of research should accompany the opinions.

How to Plan and Execute a Survey

Before Starting the Actual Survey

Brasel et al. [21] state that, for a survey to be correctly designed, the investigator must first formulate the question to be answered, and after that, follow a process of

- **Item generation** → A vast number of questions directed to the responders involving all aspects surrounding the survey’s objective. There are many ways to do this, and the investigator might use some help to undertake this particular step from reading previous published studies, consulting to experts, using Delphi-consensus methodology, etc.
- **Item reduction** → Choose from all the aforementioned questions, those that are more suitable to represent the objective of the survey. Burns et al. suggest that most research questions can be answered with 5 domains and 25 or fewer items (which is particularly important to address the fact that surgeons usually have limited time to answer any type of survey, therefore underestimating the importance of reducing items might lead to a high number of incomplete responses).
- **Formatting and composition** → State the items in a clear and concise way, in order to avoid misinterpretations and therefore, incorrectly answered questions.

- **Pilot testing** → Before extending the survey to a broader audience, the investigator should test it on a shorter number of people, to identify potential flaws that need to be corrected.

This first step for delivering a quality survey should not be avoided, since by doing so, the investigator might fall into methodological errors that might then invalidate the whole result of this investigation. In other words, no matter how many people respond to the survey, if the basic organisation of it was incorrect, that will lead to invalid results [25].

Furthermore, this first step must be concisely explained in potential publications, to help the reviewers understand how the survey was planned before it was launched, and therefore, correctly assess its methodology.

Define the Population to Be Addressed

During the planning of a survey, a key step to be considered is to define the population of interest, and more important, if the planned number of answers will be representative of that population [23, 24].

Considering the above, a “denominator” needs to be defined. By denominator, we refer to the number of people that will be intended to answer the questions, and this will also affect the validity of the survey’s results, since a low response rate might carry along implicit bias. An analysis should also be made in advance regarding the reasons why someone could/would not respond to a survey, and all this must be addressed in the methods section of a subsequent publication [26].

As an example, if the author wants to assess quality of life of patients after being operated for colon cancer in one hospital by delivering prospective surveys to all patients in this condition, the denominator will be estimated based on the number of patients operated in the same time period, in the previous years. After defining that expected number, the investigator should consider how many responses are expected, which will be considered the “numerator”.

Particular aspects from each patient might affect the ability/willingness to answer a survey, for example, advanced disease, lack of understanding of the language, lack of access to the way the survey is delivered (for example, if it is delivered electronically and patient does not have an email address), or plain and simple unwillingness to participate.

Some of these limitations can and must be addressed before launching the survey. Strategies to overcome them, for example, delivering the survey in more than one language, or choosing more than one way of delivering (email, printed, etc.) should be identified [27].

Nevertheless, the calculation of both numerator and denominator must be done in advance, and clearly informed when discussing the results of the survey, defining a “response rate”, which is the result of what the investigator expected to get, and what it was obtained. Several numbers have been considered as acceptable to face validity when speaking about response rate, and we should consider who we are

addressing for this (i.e., health physicians usually have lower response rates) [28, 29].

Making a sample calculation can be difficult if the investigator is expecting to address a wider population. For example, while trying to assess the adherence to laparoscopy in Latin America. However, there are online tools to help the investigator to make a correct calculation.

All the information about denominator, final numerator, and a possible explanation for differences between them (number of surveys delivered and actual number of responses, and information about why some people did not respond) can be presented in a flowchart. This will be useful to identify possible bias in the results, for example, underrepresentation of a determinate population, etc [30].

How to Improve Response Rates

A systematic review by Meyer et al. [31]. identified over 1746 health care professionals' surveys, and overall response rate of 53.3%, with a specific response rate to web-based surveys of 45.8%. Even though this might be taken as a baseline reference, there are strategies to improve these numbers.

Before we refer to potential tools to get higher response rates, we need to identify non-responses and divide these results in two categories “Unit non-responses” represent everyone not answering a survey at all because are not participating, whereas “item non-responses” represent the questions that were left unanswered during the participation in the survey [32].

(a) Improving “Unit non-responses”.

- *Choosing different ways to deliver the survey will directly impact the number of people responding.* For example, an investigator should not assume that everyone can handle online surveys. Therefore, choose an alternative way to deliver the survey, for example, to mail-boxes.
- *Ascertain that everyone eligible to answer the survey (part of the population of interest) receives the survey.* In other words, after defining the targeted population, the investigator must make sure that such population has access to the survey. For example, while addressing adherence to laparoscopy in a particular region, a number of resources can be used to guarantee a higher number of people that are reached—social media, local societies, local leaders that grant extension of the survey to their colleagues, etc.
- *Incentives to respond.* A person can receive a survey and not be inclined to spend time on it. Therefore, a way to overcome this limitation is to offer incentives to answer. Among different things that can be included, two particular ways of maximising responses are (1) keeping the questionnaire short and give the estimated time (“Please answer this 2 minutes survey”) and (2) including the respondents in a subsequent publication of results (“While answering to this survey, you will be included in the resulting manuscript as collaborator”).

- *Personalise the invitation to potential respondents*, meaning that, instead of delivering a generic invitation to everyone, identify potential different populations and address them individually. For example, “We would like to include you in this opinion survey since your hospital and your country are key factors among the region”.

(b) **Improving survey dissemination:**

- *Distribute survey along a collaborative network*, that will increase the impact of participants receiving the survey in a focussed field of interest. That is, after a more complex study, there may exist a network of collaborators that are focussed on a field of research and could be a good target for a survey acting as a supplement for previous research.

(c) **Adapt the questionnaire to the population of interest and facilitate response:**

- *Use a mobile-friendly platform for your survey*, that way responders could respond from any place at any moment. There exist many platforms like Google Forms, SurveyMonkey, REDCap ... that allow to develop surveys in a fancy look.
- *Make sure it is not too long for responders*. If so, consider which queries are more relevant to be included. Also, rewrite questions to make them simple and clear.
- *Avoid long replies, better register answers that can be assessed later in a quantitative way* (i.e., Yes/No, more than 50%/less than 50%, always/sometimes/never, etc.).

Online Tools to Plan and Deliver Surveys

A list of online platforms that can be useful while conducting a survey is reported below.

1. **SurveyMonkey** (<https://www.surveymonkey.com/>): This online platform will help the investigator to perform a survey from the beginning to the end, including tools to make a correct sample-size calculation, with adequate questions regarding your topic of interest, and finally helping to analyse the results of the survey. It has different plans for individuals or groups and also offers some basic educational tools on how to improve the way the survey is done.
2. **Forsta** (<https://www.forsta.com/>): This is a very similar platform to SurveyMonkey, designed to help the investigator to conduct a high-quality survey. Yet, it has the additional benefit of counting on a well-developed e-learning platform, with short courses designed to increase the knowledge of the audience.
3. **Mopinion** (<https://mopinion.com/>): Even though this is not a particular platform designed for scientific surveys (and actually, is more oriented to commercial

purposes), it has a significant advantage on the way results are presented, with in-depth analysis and advanced data visualisation, including text—analytics.

4. Other platforms:

- (a) **HubSpot** (www.hubspot.com).
- (b) **Feedier** (www.feedier.com).
- (c) **Google Forms** (www.google.com).
- (d) **REDCap** (<https://www.project-redcap.org>).

References

1. Ong ZZ, Henein C, Swampillai AJ, et al. Trainee research network (TRN): a potential global model for promoting research training and outputs among trainees. *Eye*. 2022;36:2358–60. <https://doi.org/10.1038/s41433-022-02060-z>.
2. Pinkney TD, Calvert M, Bartlett DC, Gheorghe A, Redman V, Dowswell G, Hawkins W, Mak T, Youssef H, Richardson C, Hornby S, Magill L, Haslop R, Wilson S, Morton D, West Midlands Research Collaborative, ROSSINI Trial Investigators. Impact of wound edge protection devices on surgical site infection after laparotomy: multicentre randomised controlled trial (ROSSINI trial). *BMJ*. 2013;347:f4305. <https://doi.org/10.1136/bmj.f4305>.
3. STAR Surg Collaborative. Students' participation in collaborative research should be recognised. *Int J Surg*. 2017;39:234–7. <https://doi.org/10.1016/j.ijso.2017.01.114>.
4. Sgrò A, Simioni A, Farina V, et al. Increasing the participation of medical students in surgical research: the Italian case and the role of research collaboratives. *Int J Surg*. 2018;60:111–2. <https://doi.org/10.1016/j.ijso.2018.11.002>.
5. Croghan SM, Mohan HM, Bolger JC, et al. Collaboration is the new competition: developing sustainable international collaborative research delivered by a National Surgical Trainee Collaborative Group. *ANZ J Surg*. 2022;92(5):957–63. <https://doi.org/10.1111/ans.17559>.
6. Nepogodiev D, Martin J, Biccard B, Makupe A, Bhangu A, National Institute for Health Research Global Health Research Unit on Global Surgery. Global burden of postoperative death. *Lancet*. 2019;393:401. [https://doi.org/10.1016/S0140-6736\(18\)33139-8](https://doi.org/10.1016/S0140-6736(18)33139-8).
7. GlobalSurg Collaborative. Mortality of emergency abdominal surgery in high-, middle- and low-income countries. *Br J Surg*. 2016;103:971–88. <https://doi.org/10.1002/bjs.10151>.
8. GlobalSurg Collaborative. Surgical site infection after gastrointestinal surgery in high-income, middle-income, and low-income countries: a prospective, international, multicentre cohort study. *Lancet Infect Dis*. 2018;18:516–25. [https://doi.org/10.1016/S1473-3099\(18\)30101-4](https://doi.org/10.1016/S1473-3099(18)30101-4).
9. GlobalSurg Collaborative National Institute for Health Research Global Health Research Unit on Global Surgery. Global variation in postoperative mortality and complications after cancer surgery: a multicentre, prospective cohort study in 82 countries. *Lancet*. 2021;397:387–97. [https://doi.org/10.1016/S0140-6736\(21\)00001-5](https://doi.org/10.1016/S0140-6736(21)00001-5).
10. Bath M, Bashford T, Fitzgerald JE. What is 'global surgery'? Defining the multidisciplinary interface between surgery, anaesthesia and public health. *BMJ Global Health*. 2019;4:e001808.
11. Pata F, Pellino G, Italian Surgical Research Group (ItSURG). ItSURG: a challenge for surgical research in Italy. *Updat Surg*. 2017;69(4):551–2. <https://doi.org/10.1007/s13304-017-0434-z>; Epub 2017 Apr 12.
12. COVIDSurg Collaborative. Mortality and pulmonary complications in patients undergoing surgery with perioperative SARS-CoV-2 infection: an international cohort study. *Lancet*. 2020;396(10243):27–38. [https://doi.org/10.1016/S0140-6736\(20\)31182-X](https://doi.org/10.1016/S0140-6736(20)31182-X).
13. Gladman MA. International trials: surgical research networks. In: Pawlik T, Sosa J, editors. *Clinical trials. Success in academic surgery*. Cham: Springer; 2020. https://doi.org/10.1007/978-3-030-35488-6_18.

14. The National Research Collaborative & Association of Surgeons in Training Collaborative Consensus Group. Recognising contributions to work in research collaboratives: guidelines for standardising reporting of authorship in collaborative research. *Int J Surg*. 52:355–60. ISSN 1743-9191. <https://doi.org/10.1016/j.ijssu.2017.12.019>.
15. NIHR Global Research Health Unit on Global Surgery. Reducing surgical site infections in low-income and middle-income countries (FALCON): a pragmatic, multicentre, stratified, randomised controlled trial. *Lancet*. 2021;398(10312):1687–99. [https://doi.org/10.1016/S0140-6736\(21\)01548-8](https://doi.org/10.1016/S0140-6736(21)01548-8).
16. NIHR Global Health Research Unit on Global Surgery. Routine sterile glove and instrument change at the time of abdominal wound closure to prevent surgical site infection (ChEETAH): a pragmatic, cluster-randomised trial in seven low-income and middle-income countries. *Lancet*. 2022;400(10365):1767–76. [https://doi.org/10.1016/S0140-6736\(22\)01884-0](https://doi.org/10.1016/S0140-6736(22)01884-0).
17. Li E, Bhangu A. Collaborative research in surgery: a rising tide lifts all boats. *Br J Surg*. 2022;109(7):576–7. <https://doi.org/10.1093/bjs/znac099>.
18. International Committee of Medical Journal Editors (ICMJE) Recommendations. Defining the role of authors and contributors.
19. Picciariello A, Altomare DF. Big data papers and COVID-19: a “false friend” for academic surgeons. *Tech Coloproctol*. 2021;25(4):485. <https://doi.org/10.1007/s10151-020-02382-8>.
20. Bansal S, Mahendiratta S, Kumar S, Sarma P, Prakash A, Medhi B. Collaborative research in modern era: need and challenges. *Indian J Pharmacol*. 2019;51(3):137–9. https://doi.org/10.4103/ijp.IJP_394_19. PMID: 31391680; PMCID: PMC6644188.
21. Brasel K, Haider A, Haukoos J. Practical guide to survey research. *JAMA Surg*. 2020;155(4):351–2. <https://doi.org/10.1001/jamasurg.2019.4401>.
22. Burns KEA, Kho ME. How to assess a survey report: a guide for readers and peer reviewers. *CMAJ*. 2015;187(6):E198–205. <https://doi.org/10.1503/cmaj.140545>; Epub 2015 Feb 17. PMID: 25691790; PMCID: PMC4387061.
23. Asch DA, Jedrzwieski MK, Christakis NA. Response rates to mailed physician questionnaires. *J Clin Epidemiol*. 1997;50:1129–36.
24. Cummings SM, Savitz LA, Konrad TR. Reported response rates to mailed physician questionnaires. *Health Serv Res*. 2001;35:1347–55.
25. Guidolin K, Wexner SD, Jung F, et al. Strengths and weaknesses in the methodology of survey-based research in surgery: a call for standardisation. *Surgery*. 2021;170:493–8.
26. Banning LBD, Meyer VM, Keupers J, et al. Surveys in surgical education: a systematic review and reporting guideline. *Eur Surg Res*. 2021;62:61–7.
27. Krosnick JA. Survey research. *Ann Rev Psychol*. 1999;50:537–67.
28. Phillips AW, Reddy S, Durning SJ. Improving response rates and evaluating nonresponse bias in surveys: AMEE guide no. 102. *Med Teach*. 2016;38(3):217–28. <https://doi.org/10.3109/0142159X.2015.1105945>; Epub 2015 Dec 9.
29. Eysenbach G. Improving the quality of web surveys: the checklist of reporting results of internet E-surveys (CHERRIES). *J Med Internet Res*. 2004;6:e34.
30. Bennet C, Khangura S, Brehaut JC, et al. Reporting guidelines for survey research: an analysis of published guidance and reporting practices. *PLoS Med*. 2010;8(8):e1001069. <https://doi.org/10.1371/journal.pmed.1001069>.
31. Meyer VM, Benjamins S, El Moumni M, et al. Global overview of response rates in patient and health care professional surveys in surgery. A systematic review. *Ann Surg*. 2022;275:1.
32. Jones TL, Baxter MAJ, Khanduja V. A quick guide to survey research. *Ann R Coll Surg Engl*. 2013;95:5–7.

Part III
Technical Skills

Chapter 6

When Surgery Meets the Metaverse



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Nowadays, the main field of development of surgery is no longer technical, but technological. Modern surgery is enhanced by technologies which aim to improve safety, effectiveness, training, outcomes. These technologies are increasingly dependent on digital interfaces with the aim of empowering human action. Simulation training, robotic assisted surgery, patient-specific 3D surgical planning and reconstruction, remote assistance, up to 3D printing of individualized models or tissues and augmented reality operative scene with holograms are just some of the “extended reality” (XR) (or mixed or hybrid reality) possibilities that may influence our surgical activity [1].

The concept of XR starts from virtual reality and evolves to augmented reality and augmented virtuality up to the Metaverse.

Actually, XR support is primarily for training or perioperative planning, but its impact can be even more decisive, not only in the treatment of individual cases, but in particular in the global dissemination of surgical knowledge and in the shared decision making.

Training

Minimally invasive surgery has been accepted worldwide as the gold standard for many surgical procedures. However, its spread has made the development of specific skills even more necessary, which can only be gained through extensive

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Table 6.1 Comparison of different training approaches

	Physical reality	Virtual reality	Augmented reality
Realistic haptic feedback	X		X
Realistic instruments	X		X
Objective performance assessment		X	X
Interactivity		X	X
Easily sustainable costs	X		

training. Even if surgical training has traditionally been achieved by observation and apprenticeship in operating theaters, like any other craft activity, concern about patient safety, the need for learning not only technical elements but also familiarize with surgical tools, spatial 2D/3D relationship and instruments manipulation and the need of frequent repetition of single gestures, have made surgical training an area requiring innovation [2].

Moreover, developing these skills before entering an operating room, or strengthening the operating room activity by combining it with additional simulation, helps to enable a more focused and efficient performance. From the earliest homemade box trainer [3] up to the latest virtual/augmented reality simulators many systems have been proposed, making the literature about training the richest in the field of XR.

Compared to virtual reality, augmented reality has some potential advantages. In fact it adds virtual information to a real simulation field, combining them in a single system. It allows the trainees to use the same instruments currently used in the OR, providing a realistic haptic feedback and an objective performance assessment (Table 6.1).

Several augmented reality simulators have been developed over the recent years, rapidly improving and becoming progressively less expensive. However, virtual reality simulators are still the most studied, efficient, and cost-effective training method, waiting for the validation and effectiveness evaluation of the new augmented reality systems.




Even if the benefits of a virtual surgical training could impact our surgical approach (in particular in minimally invasive surgery), this has been usually suggested in low quality studies and the dissemination of this technology among clinically active surgeons still remains low [4].

Finally, simulation systems can also be used as a “warm-up” before surgery. If the activity is performed immediately before surgery a significant increase in subjective and objective performance was reported, especially for more complex procedures [5].

Visualization: From Glasses to Holograms

Another very promising field of application for XR is the support of perioperative evaluation, allowing surgeons to visualize patient data, 3D imaging scans, literature updates and enabling remote consultation and collaboration between surgeons [6, 7].

Table 6.2 Commercially available optical see-through head-mounted displays reported in clinical study [adapted from [8]]

			
	Google lens	Microsoft HoloLens	Magic leap
Optics	Beam splitter	Waveguide	Waveguide
Resolution	640 × 480 px	2048 × 1080 px	1280 × 960 px
Field of view	30° diagonal	43 × 29°	40x30°
Focal planes	Single fixed	Single fixed	Two fixed
Computing	On board	On board	External pad
Eye tracking	No	Yes	Yes
Weight	46 g	566 g	345 g
Design	Glasses-like	Hat-like	Glasses-like
Interaction	Touchpad	Head, eye, voice	Controller

For operative application of augmented reality during surgical performance a large number of devices and display modalities have been reported. These can be divided into three main groups: head-mounted displays, hand-held displays, and spatial displays.

Head-mounted displays (glasses-like or hat-like) (some examples in Table 6.2) can combine the information provided by augmented reality with the real world in two different ways: a video see-through, in which a video display merges virtual content with a video of real world, or an optical see-through, in which a transparent optical device can project into the field of view additional virtual contents [8]. The video see-through display does not allow the operator's visual field to have direct contact with the real world, giving a more immersive experience, while the optical see-through display does, allowing a better control of the environment.

Hand-held displays like mobile devices (smartphones or tablets) are now globally widespread. However, their use in surgery is limited by small screen size and requirement for hand-held interaction.

Spatial display systems are the most common in operating rooms, although often not implemented with XR functions, and usually include a 2D/3D screen-based video monitor. Their main limitations can be considered the static nature of the display and the requirement of a remote control of the content displayed. The evolution of these systems leads to the use of projection devices, which find their greatest expression in the creation of holograms.

As modern medicine is moving toward personalized precision treatment, patient-specific holographic MRI/CT 3D reconstruction, projected on the anatomical working area or on head-mounted displays could further enhance individually customized surgical plans and improve surgical performance. However, holograms should still not be considered for navigation, but only for simulation. Their use has already been reported in liver surgery [9], rectal cancer surgery [10], but also neurosurgery, orthopedics, maxillofacial, cardiac, and vascular surgery.

When discussing XR application to these devices, human factors such as perception, mental mapping, spatial awareness, attention shift, and ergonomics are usually considered, beside technical factors such as resolution, occlusion, tracking accuracy, delayed transmission, or other technical drawbacks.

On this subject, much is yet to be written. To date, most studies on the topic of user interface improvement have been experimental or feasibility tests. So far, there is still no evidence of added value for patient care.

Navigation: Intraoperative Guidance

The idea of a system that allows us to optimize incisions, see through structures, and make our gestures increasingly precise has always been on the minds of surgeons. However, a major issue is the accuracy and reliability of the XR system, mainly in integrating patient data and matching virtual and real views. In particular, the main limitation to the use of navigation systems is tissue movement. Respiratory motion, patient positioning, CO₂ insufflation, surgical tissue manipulation, or other deformation can make any traditional landmark-based registration algorithm useless [11].

Liver surgery is the area where intraoperative navigation systems have been most widely applied, aiming to avoid unnecessary liver resection that may subsequently impact on liver function and postoperative outcome [12]. By rendering transparent or holographic superimposed virtual images of the organ and the lesions, ER application can minimize the lack of tactile sensation, usually experienced during video-assisted procedures.

Even if ultrasonography or computed tomography imaging is commonly used for intraoperative evaluation, the inability to provide real-time continuous imaging data does not allow an adequate construction of a three-dimensional mental image of the intrahepatic structures.

Display methods used for augmented reality intraoperative navigation include a see-through display, a video-based display, and a projection-based display, which are used to present the virtual reconstructed images overlaid on the surgical field in a 3D visual environment [13]. Main characteristics are summarized in Table 6.3.

Even if promising results on shorter operative times, less blood loss and reduced radiation required have been reported [14–16], especially for orthopedic surgery, suggesting a more precise surgical approach, most of the ER guided navigation studies are experimental development approaches rather than clinical studies, still leaving open questions about their effective impact in clinical and surgical practice.

However, information that can be integrated within XR systems is not limited to radiological images (CT, MRI, ultrasound, etc.), but they can also take advantage of tracer-based molecular imaging strategies (fluorescence, radio-markers, etc.), providing a more comprehensive view of the potential role of XR in the future of precision surgery [17].

Table 6.3 Display methods used for augmented reality intraoperative navigation

	See-through display	Video-based display	Projection-based display
Features	<ul style="list-style-type: none"> • Semitransparent display • Autostereoscopic 3D technology 	<ul style="list-style-type: none"> • Images shown on a screen • External or head-mounted video display 	<ul style="list-style-type: none"> • Images projected on the surgical field • Optimal for superficial structures
Advantages	<ul style="list-style-type: none"> • Larger field of view • No tactile feedback limitation 	<ul style="list-style-type: none"> • Visual perspective shared by the OR team • Easy control of resolution and brightness 	<ul style="list-style-type: none"> • Minimize operation time • Avoid repetitive imaging
Disadvantages	<ul style="list-style-type: none"> • Discomfort after long session • Continuous vergence-accommodation conflict 	<ul style="list-style-type: none"> • Resolution of the camera • Inverse proportion between precision of registration and area of the surgical field or distance from the landmarks 	<ul style="list-style-type: none"> • Frequent tracking and calibration required • 2D projected images may affect perception

Simulation: From 3D Reconstruction to Printing

The possibility of three-dimensional virtual reconstruction from radiological images is now commonplace and integrated into many radiological image processing software. The next step is to make this reconstruction available for analysis and study by the surgeon, in order to analyze and optimize the surgical strategy, using virtual reality or XR systems. Moreover, the same technology could be used to take a further step, creating realistic, patient-specific 3D models, which would potentially be superior to 2D or 3D images on a computer monitor or projection screen.

Three-dimensional printing may help advance surgical practice in terms of preoperative planning, education and training, construction of specific surgical instruments and, in particular, creation of 3d printed personalized implants and prostheses [18].

A wide range of 3D printed devices have been developed and studied, mainly anatomical models for preoperative planning or intraoperative guiding, especially in the field of maxillofacial or orthopedic surgery [19].

General surgery has been quite slow in the adoption of 3D reconstruction models, even if some applications have been reported in particular in liver surgery [20], but also in colorectal [21] or gastroesophageal surgery [22]. This may reflect both limited resource availability as well as image related organ specific complexities. In fact, visceral organs are more difficult to reconstruct compared to bone or vessels.

Moreover, the relatively high costs (100–215\$ per patient [23]) and the time needed to develop and print a 3D model (up to 160 h [24]), besides to errors of measurements or materials, make such application still difficult to sustain on a large population.

Nevertheless, as 3D printing continues to evolve and develop, most of these limitations may be resolved in the future and new applications of this method will undoubtedly emerge.

According to the World Health Organization, only 5–15% of people in lower-income countries have access to prostheses, largely due to low availability of materials and high costs of prostheses. In addition to this, the availability of surgical or daily clinical practice materials is also often limited. The easiest accessibility of 3D printing techniques can offer the creation of customized objects (basic medical supplies, laboratory equipment, operating room equipment, etc.) and patient-specific components, reducing or bypassing the current manufacturing and post-processing steps [25, 26].

Moreover, in the field of 3D printing, inkjet techniques have been implemented to construct functional body parts and organs with high degree of accuracy and various applications of implants have already been approved by the Food and Drug Administration, such as the mandible bone, dental prostheses or hip, femoral and knee functional parts, taking advantages of one of the most important benefit of this technology: no latency between design and final production.

This means that in the future it may be possible to reproduce entire functional organs, or possibly hybrid systems where the printed anatomical component acquires function through implementation with technological devices.

However, attempts to predict the clinical application of 3D printing are currently highly speculative. Literature analysis shows that a wide range of 3D-printed devices have been clinically reported, but few papers have rigorously assessed their efficacy or effectiveness. Because 3D-printed devices can have different safety and efficacy issues than the equivalent devices, further testing and studies may be required to confirm the available results.

Patient

Potential benefits of XR application are not limited to improved precision surgery but they extend to various other moments in the patient's surgical journey.

One of these benefits can be related to anxiety and pain reduction. Various studies suggest a potential role of immersive virtual reality systems in reducing anxiety before medical procedures, anxiety and pain during medical procedures and post-surgical pain and use of analgesics [27].

It is well known that the patient's psychological state of mind can influence the dosage of sedatives needed to achieve the target sedation level.

When patients were exposed to sessions of meditative virtual reality applications focused on calmness and relaxation, performed once daily for up to 7 days, they improved their intensive care unit experience with reduced levels of anxiety and depression [28]. The same result was reported for virtual reality interventions for

colonoscopy-induced anxiety and pain that revealed a similar effect as conventional sedation and a statistically significant reduction in non-sedated patients [29].

Moreover, virtual reality therapy demonstrated potential improvements in both the patient-clinical outcomes and patient-reported experiences of those undergoing surgical procedures [30, 31].

Another very promising application of the XR is in the physician–patient relationship and patient information. 3D virtual reality can help surgeons and patients in building a better relationship before surgery and immersive 3D-supported informed consent improves patients’ comprehension of their condition without increasing anxiety [32].

Moreover, another potential application of technology is the use of patient-specific 3D printed models to improve education for patients. For example, the use of personalized 3D models was reported for stoma care education, allowing the patients to practice with their own 3D printed ostomies, cutting the plate and attaching it to the stoma bag [33]. This means fewer skin problems associated with daily stoma care, but most importantly an improved awareness and self-reliability.

Patient information, problem sharing, and shared decision making are increasingly relevant topics that will shape the surgery of the future. Being able to access increasingly precise and personalized surgery without the patient being able to understand its significance, its value and its advantages will risk slowing down the spread of the surgery of the future and the technological advances that will make it possible.

Conclusion

Although XR is predicted to revolutionize surgery, several challenges that involve surgeons, administrations, and patients still need to be addressed to ensure a widespread adoption. Despite many papers having been published in recent years from a variety of surgical disciplines on this topic, heterogeneous methodologies, lack of comparison, and few results with clinical impact have not yet allowed us to really understand the clinical impact of this technology.

However, future studies will surely demonstrate that we can change the fantasy into reality.

References

1. Zhang J, Lu V, Khanduja V. The impact of extended reality on surgery: a scoping review. *Int Orthop*. 2023;47(3):611–21. <https://doi.org/10.1007/s00264-022-05663-z>.
2. Botden SM, Jakimowicz JJ. What is going on in augmented reality simulation in laparoscopic surgery? *Surg Endosc*. 2009;23(8):1693–700. <https://doi.org/10.1007/s00464-008-0144-1>.
3. Martellucci J, Fontani A, Papi F, Tanzini G. Training in laparoscopic surgery using home-made simulators. *Surg Laparosc Endosc Percutan Tech*. 2010;20(5):357–9. <https://doi.org/10.1097/SLE.0b013e3181f3249d>.

4. Balla A, Sartori A, Botteri E, Podda M, Ortenzi M, Silecchia G, Guerrieri M, Agresta F; ARMIS (augmented reality in minimally invasive surgery) collaborative group. Augmented reality (AR) in minimally invasive surgery (MIS) training: where are we now in Italy? The Italian Society of Endoscopic Surgery (SICE) ARMIS survey. *Updat Surg*. 2023;75(1):85–93. <https://doi.org/10.1007/s13304-022-01383-6>.
5. Lendvay TS, Brand TC, White L, Kowalewski T, Jonnadula S, Mercer LD, Khorsand D, Andros J, Hannaford B, Satava RM. Virtual reality robotic surgery warm-up improves task performance in a dry laboratory environment: a prospective randomized controlled study. *J Am Coll Surg*. 2013;216(6):1181–92. <https://doi.org/10.1016/j.jamcollsurg.2013.02.012>.
6. Moro C, Štromberga Z, Raikos A, Stirling A. The effectiveness of virtual and augmented reality in health sciences and medical anatomy. *Anat Sci Educ*. 2017;10(6):549–59. <https://doi.org/10.1002/ase.1696>.
7. Dinh A, Yin AL, Estrin D, Greenwald P, Fortenko A. Augmented reality in real-time telemedicine and telementoring: scoping review. *JMIR Mhealth Uhealth*. 2023;11:e45464. <https://doi.org/10.2196/45464>.
8. Doughty M, Ghugre NR, Wright GA. Augmenting performance: a systematic review of optical see-through head-mounted displays in surgery. *J Imaging*. 2022;8(7):203. <https://doi.org/10.3390/jimaging8070203>.
9. Saito Y, Sugimoto M, Imura S, Morine Y, Ikemoto T, Iwahashi S, Yamada S, Shimada M. Intraoperative 3D hologram support with mixed reality techniques in liver surgery. *Ann Surg*. 2020;271(1):e4–7. <https://doi.org/10.1097/SLA.0000000000003552>.
10. Tokunaga T, Sugimoto M, Saito Y, Kashihara H, Yoshikawa K, Nakao T, Nishi M, Takasu C, Wada Y, Yoshimoto T, Yamashita S, Iwakawa Y, Yokota N, Shimada M. Intraoperative holographic image-guided surgery in a transanal approach for rectal cancer. *Langenbeck's Arch Surg*. 2022;407(6):2579–84. <https://doi.org/10.1007/s00423-022-02607-4>.
11. Meershoek P, van den Berg NS, Lutjeboer J, Burgmans MC, van der Meer RW, van Rijswijk CSP, van Oosterom MN, van Erkel AR, van Leeuwen FWB. Assessing the value of volume navigation during ultrasound-guided radiofrequency- and microwave-ablations of liver lesions. *Eur J Radiol Open*. 2021;8:100367. <https://doi.org/10.1016/j.ejro.2021.100367>.
12. Hallet J, Gayet B, Tsung A, Wakabayashi G, Pessaux P. Second international consensus conference on laparoscopic liver resection group. Systematic review of the use of pre-operative simulation and navigation for hepatectomy: current status and future perspectives. *J Hepatobiliary Pancreat Sci*. 2015;22(5):353–62. <https://doi.org/10.1002/jhbp.220>.
13. Tang R, Ma LF, Rong ZX, Li MD, Zeng JP, Wang XD, Liao HE, Dong JH. Augmented reality technology for preoperative planning and intraoperative navigation during hepatobiliary surgery: a review of current methods. *Hepatobiliary Pancreat Dis Int*. 2018;17(2):101–12. <https://doi.org/10.1016/j.hbpd.2018.02.002>.
14. Assink N, Reininga IHF, Ten Duis K, Doornberg JN, Hoekstra H, Kraeima J, Witjes MJH, de Vries JPM, FFA I. Does 3D-assisted surgery of tibial plateau fractures improve surgical and patient outcome? A systematic review of 1074 patients. *Eur J Trauma Emerg Surg*. 2022;48(3):1737–49. <https://doi.org/10.1007/s00068-021-01773-2>.
15. Guo Q, Li X, Tang Y, Huang Y, Luo L. Augmented reality and three-dimensional plate library-assisted posterior minimally invasive surgery for scapula fracture. *Int Orthop*. 2022;46(4):875–82. <https://doi.org/10.1007/s00264-022-05303-6>.
16. Hu MH, Chiang CC, Wang ML, Wu NY, Lee PY. Clinical feasibility of the augmented reality computer-assisted spine surgery system for percutaneous vertebroplasty. *Eur Spine J*. 2020;29(7):1590–6. <https://doi.org/10.1007/s00586-020-06417-4>.
17. Wendler T, van Leeuwen FWB, Navab N, van Oosterom MN. How molecular imaging will enable robotic precision surgery: the role of artificial intelligence, augmented reality, and navigation. *Eur J Nucl Med Mol Imaging*. 2021;48(13):4201–24. <https://doi.org/10.1007/s00259-021-05445-6>.
18. Cornejo J, Cornejo-Aguilar JA, Vargas M, Helguero CG, Milanezi de Andrade R, Torres-Montoya S, Asensio-Salazar J, Rivero Calle A, Martínez Santos J, Damon A, Quiñones-Hinojosa A, Quintero-Consuegra MD, Umaña JP, Gallo-Bernal S, Briceño M, Tripodi P, Sebastian R, Perales-Villarreal P, De la Cruz-Ku G, Mckenzie T, Arruana VS, Ji J, Zuluaga

- L, Haehn DA, Paoli A, Villa JC, Martinez R, Gonzalez C, Grossmann RJ, Escalona G, Cinelli I, Russomano T. Anatomical engineering and 3D printing for surgery and medical devices: international review and future exponential innovations. *Biomed Res Int.* 2022;2022:6797745. <https://doi.org/10.1155/2022/6797745>.
19. Diment LE, Thompson MS, Bergmann JHM. Clinical efficacy and effectiveness of 3D printing: a systematic review. *BMJ Open.* 2017;7(12):e016891. <https://doi.org/10.1136/bmjopen-2017-016891>.
 20. Witowski JS, Coles-Black J, Zuzak TZ, Pędziwiatr M, Chuen J, Major P, Budzyński A. 3D printing in liver surgery: a systematic review. *Telemed J E Health.* 2017;23(12):943–7. <https://doi.org/10.1089/tmj.2017.0049>.
 21. Emile SH, Wexner SD. Systematic review of the applications of three-dimensional printing in colorectal surgery. *Color Dis.* 2019;21(3):261–9. <https://doi.org/10.1111/codi.14480>.
 22. Robb H, Scrimgeour G, Boshier P, Przedlacka A, Balyasnikova S, Brown G, Bello F, Kontovounisios C. The current and possible future role of 3D modelling within oesophago-gastric surgery: a scoping review. *Surg Endosc.* 2022;36(8):5907–20. <https://doi.org/10.1007/s00464-022-09176-z>.
 23. Luzon JA, Andersen BT, Stimec BV, Fasel JHD, Bakka AO, Kazaryan AM, Ignjatovic D. Implementation of 3D printed superior mesenteric vascular models for surgical planning and/or navigation in right colectomy with extended D3 mesenterectomy: comparison of virtual and physical models to the anatomy found at surgery. *Surg Endosc.* 2019;33(2):567–75. <https://doi.org/10.1007/s00464-018-6332-8>.
 24. Hamabe A, Ito M. A three-dimensional pelvic model made with a three-dimensional printer: applications for laparoscopic surgery to treat rectal cancer. *Tech Coloproctol.* 2017;21(5):383–7. <https://doi.org/10.1007/s10151-017-1622-z>.
 25. Ibrahim AM, Jose RR, Rabie AN, Gerstle TL, Lee BT, Lin SJ. Three-dimensional printing in developing countries. *Plast Reconstr Surg Glob Open.* 2015;3(7):e443. <https://doi.org/10.1097/GOX.0000000000000298>.
 26. Abbady HEMA, Klinkenberg ETM, de Moel L, Nicolai N, van der Stelt M, Verhulst AC, Maal TJJ, Brouwers L. 3D-printed prostheses in developing countries: a systematic review. *Prosthetics Orthot Int.* 2022;46(1):19–30. <https://doi.org/10.1097/PXR.0000000000000057>.
 27. Hitching R, Hoffman HG, Garcia-Palacios A, Adamson MM, Madrigal E, Alhalabi W, Alhudali A, Sampaio M, Peterson B, Fontenot MR, Mason KP. The emerging role of virtual reality as an adjunct to procedural sedation and anesthesia: a narrative review. *J Clin Med.* 2023;12(3):843. <https://doi.org/10.3390/jcm12030843>.
 28. Ong TL, Ruppert MM, Akbar M, Rashidi P, Ozrazgat-Baslanti T, Bihorac A, Suvajdzic M. Improving the intensive care patient experience with virtual reality—a feasibility study. *Crit Care Explor.* 2020;2(6):e0122. <https://doi.org/10.1097/CCE.0000000000000122>.
 29. Găină MA, Szalontay AS, Ștefănescu G, Bălan GG, Ghiciuc CM, Boloș A, Găină AM, Ștefănescu C. State-of-the-art review on immersive virtual reality interventions for colonoscopy-induced anxiety and pain. *J Clin Med.* 2022;11(6):1670. <https://doi.org/10.3390/jcm11061670>.
 30. Wang S, Lim SH, Aloweni FBAB. Virtual reality interventions and the outcome measures of adult patients in acute care settings undergoing surgical procedures: an integrative review. *J Adv Nurs.* 2022;78(3):645–65. <https://doi.org/10.1111/jan.15065>.
 31. Haisley KR, Straw OJ, Müller DT, Antiporda MA, Zihni AM, Reavis KM, Bradley DD, Dunst CM. Feasibility of implementing a virtual reality program as an adjuvant tool for peri-operative pain control; results of a randomized controlled trial in minimally invasive foregut surgery. *Complement Ther Med.* 2020;49:102356. <https://doi.org/10.1016/j.ctim.2020.102356>.
 32. Perin A, Galbiati TF, Ayadi R, Gambatesa E, Orena EF, Riker NI, Silberberg H, Sgubin D, Meling TR, DiMeco F. Informed consent through 3D virtual reality: a randomized clinical trial. *Acta Neurochir.* 2021;163(2):301–8. <https://doi.org/10.1007/s00701-020-04303-y>.
 33. Tominaga T, Takagi K, Takeshita H, Miyamoto T, Shimoda K, Matsuo A, Matsumoto K, Hidaka S, Yamasaki N, Sawai T, Nagayasu T. Usefulness of three-dimensional printing models for patients with stoma construction. *Case Rep Gastroenterol.* 2016;10(1):57–62. <https://doi.org/10.1159/000442663>.

Chapter 7

Towards the Future of Endoscopic Ultrasound



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Introduction

Despite created in the 1980s [1], endoscopic ultrasound (EUS) has not experienced weighty advances as the other domains in medicine or technology. While certain milestones such as the development of the EUS-fine needle aspiration (EUS-FNA) constituted a breakthrough on the impact generated by this technique [2], there have been no further major developments regarding aspects such as scope design and ergonomics. Similarly, although numerous accessories for therapeutic EUS have been created over the last few decades and continue to develop, many of the tools and devices used in interventional EUS are old and require the presence of an additional person interacting with the endoscopist during the key steps of the intervention, leading to possible errors arising from this interaction.

In spite its broad diagnostic and therapeutic possibilities, the adoption of EUS worldwide is relatively low [3]. Pancreatic cancer, for example, is one of the

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diagnostic fields where EUS plays a decisive role, as it is the tool with the highest sensitivity to detect small lesions that are potentially curable with surgery [4]. However, there is great inter-operator variability on the quality of the examinations among the operators who perform it. Although it is well-known that EUS outcomes depend to a large extent on an adequate previous dedicated EUS training period, learning opportunities remain scarce and with very heterogeneous content [5]. In addition, the unavailability of EUS material in some centres, and a relatively smaller number of patients for whom this study is indicated when compared to other endoscopic approaches may contribute to the lack of the expansion of the technique despite its real utility, as well as its unequal performance.

When attempting to explain the low practice rate of EUS among general endoscopists, not only arises the insufficient formal learning opportunities [6], but also the fact that the technique is particularly complex to perform and requires a wide range of skills to conduct a quality study [7, 8]. On the one hand, the interpretation of EUS images is complex, and this is especially true on the area of pancreatobiliary anatomy and pathology [9]. Ideally, trans-abdominal ultrasound and cross-sectional images interpretation should be learnt before embarking into EUS training [10]. However, having this background knowledge does not equate to an exhaustive interpretation of the EUS images obtained, and this task must be fully covered along the EUS training period. On the other hand, navigating the scope according to anatomical landmarks as well as the obtaining proper ultrasound images follows a slightly different logic when compared to the standard upper and lower endoscopy. Also, the manipulation of the insertion tube together with the control knobs and valves and the maintenance of a stable position through a therapeutic gest require a minimum of strength and depend in part on the size of the operator's hands. Although this applies to the whole sphere of flexible endoscopy, the largest size of the EUS scope and the longest duration of these exams may emphasize these drawbacks.

Since its creation more than four decades ago, the EUS scopes have not evolved significantly in proportion to other technological developments such as aviation, computers, or automotive industry. Although EUS was initially conceived as diagnostic tool, today its main interest lies in the possibility of performing minimally invasive treatments, and its applications in interventionism are constantly expanding [7]. However, both the design of the equipment and the way in which it is handled have not changed since its creation. Most of the progresses observed along the last years are related to improvement in the endoscopic image quality, changes in the composing materials that entail more resistance to impacts and heat, simplicity of the connecting components, etc.

As for the devices used in therapeutic EUS, although some of them have evolved to allow the use by a single operator, most of these accessories still need the presence of at least two operators. Therefore, a trained nurse/assistant presence and a fluid coordination between the operating members will influence the ultimate success of the procedure. Taking the aforementioned aspects into account, the development of new scopes whose use does not depend on the physical characteristics of the operator is imperative. Even the future of flexible endoscopy is likely to be robotic

and less dependent on operator skills, autonomous scopes will not be developed for at least a decade.

History of EUS: Rapid Evolution in “Add-Ons”, Slow in Design

Three discoveries have shaped EUS as we know it today: the first description of ultrasound-guided navigation in bats by an Italian scientist in 1744, the discovery of the piezoelectric effect in 1880, and the development of a flexible gastrointestinal (GI) endoscope by Hirschovitz in 1956 [11–13].

It was not until the late 1970s that ultrasound was combined with a flexible endoscope to investigate the GI tract and mediastinum in animals and later in humans [14–17]. By 1982, EUS had been introduced into gastroenterological practice primarily as a diagnostic tool, with advances in image quality and processing continuing until the present day. With the first linear echoendoscope developed in the 1990, important innovations in the field of EUS were made and its applications were extended from diagnosis and staging to a therapeutic tool [18–20].

With the advent of EUS-FNA, the working channel of the echoendoscope became its main port of innovation allowing the passage of biopsy needles, wires, pigtailed, and lumen-apposing metal stents (LAMS) to be passed through the scope. This allowed the performance of EUS-guided tumour biopsies, tissue and fluid acquisition, chemotherapy application, radiofrequency and chemoablation, drainage of walled off necrosis as well as pancreatic and biliary drainage [21]. In recent years vascular interventions such as EUS-guided portal vein pressure measurements as well as coiling of gastric varices allow for minimally invasive EUS-guided vascular diagnostic and therapeutic interventions [2, 18, 22–29]. The timeline of technical and interventional novelties in EUS is summarized in Fig. 7.1.

Despite the development of therapeutic “add-ons” has revolutionized the field of EUS, its evolution in terms of design, usability, and ergonomics has been limited. All flexible endoscopes have crucial components and design in common. In essence, this design has not changed for the last 60 years. To visualize the target tissue, a fibre-optic bundle transmits light to the tip or side of the endoscope and the image is transmitted to a video processor in the endoscopy tower and displayed on a screen. In addition to light and video transmission, all endoscopes possess a working, irrigation, and insufflation channel, with working and suction channel often combined. To control the tip of the endoscope, an angulation knob allows the tip to be moved up and down, as well as left and right, by means of metal wires running through the endoscope. Early in its development, ultrasound processors were large and provided low-quality images, though anatomic knowledge was essential to figure out the structures being imaged. Throughout its evolution, smaller, multifunctional processors with higher images resolution were created. The connection section has also evolved to a simpler, smaller device whose functions have improved

Fig. 7.1 Timeline of technical and interventional novelties in EUS

1740 / 1800	Description of ultrasound phenomenon in bats
1880	Description of pizeoelectric effect
1956	Flexible Endoscopy
1956	Abdominal Ultrasound
1976-1980	First animal and human application of GI EUS
1982	First description of diagnostic EUS in humans
1990	First linear flexible echoendoscope
1992	First EUS FNA
1992/1996	EUS guided Cystgastrostomy / cyst drainage
1999	EUS guided celiac plexus neurolysis
2006	EUS with Elastography
2007	EUS guided chemotherapy injection
2011	EUS guided confocal endomicroscopy
2012	EUS guided Lumen Apposing Metal Stent
2012	Radiofrequency ablation of pancreatic tumors
2017	EUS guided portal pressure vein measurement
2020	EUS guided coil therapy for gastric varices

in terms of image qualities, enabling the use of filters and magnification [30]. Although improvements in material for endoscope casing and wires have increased manoeuvrability, flexibility, strength, and hygiene, the overall configuration of GI endoscopes has not fundamentally changed since the inception of flexible endoscopy [31].

While radial endoscopes offer front view, most linear EUS scopes have a side-viewing optics in addition to the tip-mounted ultrasound probe. Although linear endoscopes with frontal view have been introduced to the market, their acceptance has been limited and clinical trials have shown no difference in safety and efficacy between linear and side-view EUS endoscopes [32]. Echoendoscopes differ from

Table 7.1 Summary of innovations related to the design and mechanical engineering of current endoscopes

Component	Innovation	Action
Endoscope design	–	
Ergonomics	+	Eye piece attached to scope - > monitor display of endoscopic images
Mechanical engineering	++	
Flexibility	++	Change to coat material and wire material
Weight	+	Use of lighter materials
Imaging quality	+++	Better visualization with higher definition imaging

standard diagnostic gastroscopes and colonoscopes in length, tip flexibility, and diameter [33]. The design of echoendoscopes with side-view optic and stiffer, longer tips entails a different spectrum of possible complications such as a hypopharyngeal and duodenal perforations and requires advanced endoscopic skills to reach the target area within the GI tract [34, 35].

Endoscope design has focused on improving patient outcomes but not on usability. Current flexible endoscopes follow a “one-size-fits-all” design approach that has focused almost predominantly on male endoscopists. This becomes evident in terms of hand strength and size, which starkly differ between men and women [36]. In a survey done to endoscopy trainees, those with a surgical glove size smaller than 6.5” would prefer an endoscope with smaller controls [37]. Table 7.1 summarizes the main areas of innovation in endoscopy related to the design and mechanical engineering of today’s endoscopes. It is evident that the main achievements have focused on image improvement and flexibility, but not on human-centred design and ergonomics.

The development of non-human (endoscopist) centred scopes is also reflected in the high number of musculoskeletal injuries in endoscopists. The high prevalence of musculoskeletal disorders in medical staff is well known, and endoscopists are far from being an exception, having a prevalence ranging from 37% to 89% [38]. This not only has serious economic consequences but also affects the professional’s quality of life. The most common injuries in endoscopists are to the neck, back, shoulder, and elbow [39]. The main risk factors identified are the high volume of procedures, the long duration of endoscopic procedures, doing repetitive movements, static and awkward postures, most of them being particularly important in the field of therapeutic EUS. Both diagnostic and interventional EUS are related to high strain on the neck as well the right hand and thumb [40–42]. This is compounded by the need to perform simultaneous actions, such as having to activate multiple controls and hold the endoscope body and interventional tools steady at the same time. In addition, interventional tools, such as deployment systems for LAMS, suffer from the same lack of human-centred design and are conceived for larger and stronger hands [43]. Inappropriate patient and monitor positions are also related to injuries and pain, so adjusting the height of the bed and screens is essential. The picture is even worse in inexperienced hands, notably during the first year of

endoscopy fellowship, reason to believe that at least some notions of ergonomics should be incorporated into endoscopy fellowship curricula [38]. In addition, depending on the brand of scope used, the design of the equipment is somehow challenging to get used to. The location of some EUS towers may require the operator to look to the right to view the endoscopic image and to the left to view the EUS one. This is probably particularly detrimental in cases where a fixed position of the equipment is required to be maintained for a relatively long time, as what happens with many interventional EUS procedures, adding to the list of risk factors that make EUS a physically uncomfortable procedure to perform.

Future echoendoscopes should take the aforementioned issues into account. However, development of new, more ergonomic scope's design with better usability has not been taken up widely [43]. This could also be because today's experienced endoscopists have been trained on current systems and have gained high proficiency in scope handling and hand-eye control, which may cause reluctance to train on a new and revised system with which they are unfamiliar. Trainees might be more willing to train with the new systems, not only to obtain better diagnostic qualities, but also to avoid professional injuries related to EUS and endoscopy in general.

Ongoing Developments in EUS and Possibilities for the Future

On the way towards a more user-friendly scope whose images can be understood more effectively, some complementary tools have already been put in place to democratize its practice. The use of colour Doppler initially, followed by the application of enhanced EUS imaging methods such as elastography and contrast enhanced EUS (CE-EUS) are the classical examples of these complementary modalities [44]. In this scenario, artificial intelligence (AI) advance is unstoppable, and its application in every field of medicine is expanding exponentially [45, 46].

Application of AI Systems: Computer-Aided Diagnosis for the Assessment of Pancreatic Disorders

AI was first defined in 1956, when John McCarthy described it as “the science and engineering of making intelligent machines” [47]. Since then, it has dramatically evolved over the last 50 years and nowadays it includes subfields such as machine learning (ML), deep learning (DL), and computer vision (CV) [48]. ML is the use of specific features to identify patterns that will be further applied to analyse a specific situation. The computers are considered to learn from patterns and then, apply the information when exposed to similar scenarios. Differently that following a fixed algorithm, this prediction tool has the advantage of considering the specific case's particularities to individualize the prediction. Later, ML has progressed to

what is now commonly referred to as DL, which consists of algorithms disposed in a multi-layer neural networks which enable machines to learn and make decisions on its own. Among them, convolutional neural networks (CNNs) are particularly attractive because they are capable of extracting discriminative features from images (at a pixel processing level) while preserving the spatial structure, thus being useful for region recognition and classification of medical images [49]. Finally, CV refers to the process by which a computer gains information and understanding from a series of pictures or videos; when it is used for diagnostic objectives it is known as computer-aided diagnosis (CAD) [50].

In the area of flexible endoscopy, AI-based polyp detection and differentiation have been widely explored and already available for its use in clinical practice [51, 52]. Other applications include the classification of Barrett's oesophagus through the differentiation of neoplastic or nondysplastic lesions [53], the detection of abnormalities during small-bowel capsule endoscopy [54], and the detection of gastric cancer in endoscopic images [55].

In pancreato-biliary EUS, AI is gradually being applied in almost every areas, such as in training [56], pancreatic cancer screening in population with incremented risk [57], differential diagnosis of focal pancreatic masses [49, 58, 59], determination of the presence/absence of pancreatic cancer [60, 61], therapy monitoring and targeted chemotherapy strategies [62], and real-time analysis of the EUS-fine needle biopsy EUS-FNB specimen [63]. The AI assistance during EUS procedures is one of the major points of interest, and related studies have mainly focused on the differentiation (classification) of focal pancreatic lesions through ancillary techniques such as elastography [64] or contrast enhanced EUS [65]. One study also explored the combination of these imaging techniques by analysing multiparametric EUS (grey-scale ultrasound images, colour Doppler, contrast-enhancement, and elastography) for focal masses classification between ductal adenocarcinoma, chronic pseudo tumoral pancreatitis, and neuroendocrine tumours [49]. This was achieved using a hybrid prediction method (one CNN model with a long short-term memory model) which considered not only the visual features of the analysed masses but also their behaviour over the time, with a reported overall accuracy of 98.26%.

The combination of DL models seems to be crucial for considering both spatial and temporal components of EUS to efficiently detect not only lesions and parenchyma but also the specific anatomical pancreatic part scanned in an EUS video [66, 67]. This is of vital interest for a breakthrough in AI-guided EUS image interpretation since the recognition of many anatomical structures is almost impossible to be achieved from still images and needs to consider successive images (or videos) to interpret certain structures. Moreover, in the cases of ill pancreases where the lack of precise boundaries and the inhomogeneous parenchyma texture complex the task, automatic AI-based detection becomes a tool of growing interest.

Another current talking point is optical biopsies, whose development is in full swing. However, they are still many years away from replacing EUS-FNB. The term optical biopsy refers to the group of methods that allows to make in situ non-invasive tissue assessment through the use of light properties [68]. Some of these enhanced

microscopic diagnostic technologies are confocal laser endomicroscopy, endocytoscopy, and optical coherence tomography [69]. However, the “tissue is the issue” remains an important principle in the current clinical practice, not only for pathological diagnosis as a wide concept, but also in personalized medicine, where sufficient tissue for biomarker assessments is mandatory in many diagnostic scenarios [70]. In the sphere of tissue acquisition, AI has the potential to mark the area of the target that is likely to provide the highest diagnostic yield according to the suspected pathology.

Despite the tremendous progress made in recent years, so far there are no studies aiming at differentiating normal from diffusely altered parenchyma, nor to detect lesions within abnormal pancreatic parenchyma such as pancreatic steatosis or chronic pancreatitis, where the inflammatory state often makes early diagnosis of lesions difficult, even for experts [71]. Also, to the best of our knowledge, the detection of early-stage solid lesions for potential curative surgery has not been widely addressed, with the exception of one study that considered within the context of CE-EUS use [65]. Therefore, there is still a long way to go before an established employment of real-time AI-assisted EUS, especially in the most difficult cases.

The AI to analyse tons of information in a short time and in an objective manner makes its use of great interest to improve patient outcomes. However, the use of CAD does not necessarily imply a possible decline in the interpretative capacity of the operators. Differently from detection, the use of an AI-based system for lesions differentiation and characterization (classification) would imply a more challenging task as it may require confirming or rectifying the prediction given by the model [72]. While this may initially be seen as widening the gap between experts and non-experts, it reminds us that the final decision is for the physician to judge whether the prediction is adequate or not. It is therefore essential that the use of these systems in daily practice is accompanied, at least in part for beginners, by an expert who can convey the reasoning behind the diagnostic suspicion.

Navigation Tools Combining EUS with Other Diagnostic Modalities: Potential Arising from the Integration of Imaging Techniques for a Better Use of Technology

Regardless many groups are nowadays focusing their studies on the development of AI-based systems for helping at the detection and differentiation of pancreatic lesions, the AI-based scope navigation is not being addressed in as much depth as image recognition tools.

Fusion imaging (FI) systems combine electromagnetic (EM) tracking and co-registration of an imaging method such as computer tomography (CT), magnetic resonance imaging (MRI), or positron emission tomography (PET) [73]. In the case of EUS, navigation can be improved by displaying, in real-time, the location of the scope tip within a three-dimensional (3D) reconstruction displayed to the operator.

A CT-based FI system for EUS navigation assistance was developed and tested in a phantom by operators with different degrees of expertise, achieving a good accuracy and precision even for the inexperienced one [74]. In this case, the navigation catheter was designed to pass through the working channel, so the system was feasible for providing orientation until reaching the target but needed to be retrieved for FNA/FNB [74].

Another EM tracking guidance system developed to assist less-experienced EUS endoscopists was tested in a phantom and in an animal model preclinical study [75]. This computer-assisted guidance consisted of a 3D model made from a previous CT scan together with a real-time visualization of the EUS probe for navigation, achieving an accuracy of 10.4 ± 4.0 mm. As the navigation system does not go through the working channel, it also allows real-time guidance along therapeutic gestures. Clinical trials testing this system are currently being conducted prior to translation into clinical practice [76].

The use of these FI systems has the potential to improve navigation as well as the tissue acquisition through the lesions tagging, especially those in challenging areas such as the uncinate process. Moreover, the use of these tools during EUS training may be beneficial for enhancing landmarks recognition and anatomical understanding, as the correlation between EUS images and other images reconstruction may lead to a deep understanding that might otherwise take years to acquire. While it is expected that the use of these systems in clinical practice ensures a minimum level of performance and minimizes the error rate regardless of the level of the operator, the real consequences are unknown and will not be seen for at least a decade. Despite the potential of AI-based systems in real-time diagnosis, further clinical trials are needed before translation to daily clinical care.

Application of AI-Based Systems in Training and Education

EUS is not easy to be taught. In many cases, an adequate or even expertise performance of the technique does not guarantee a good ability to transmit knowledge to trainees. Many of the gestures done while performing EUS become automatic after many years of practice, and the mechanism by which certain movements are achieved is unconscious and unknown to the operator itself. In many cases, this implies that the trainer needs to take the scope and reproduce the desired movement to consciously detect what was done and then be able to exactly explain them. When this occurs, trainees may need trial and error before they can successfully achieve a specific action, such as know the mechanical force needed to introduce a EUS needle in a given tissue [77] or some movements of the control knobs in combination with the insertion tube to achieve a certain image. Moreover, the lack of qualified experts for training together with their limited time to cover the trainees demand makes it attractive to create an AI-based tool that could lead to a decrease in the workload of trainers.

A DL-based model conceived for helping in EUS training and quality control achieved good results on both pancreas segmentation and station recognition, comparable with that of experts [56]. As for the pancreas segmentation, this model was interestingly designed for detecting whether the pancreas was lost from view during the scanning, what is essential to prevent lesions misdiagnosis.

Robotics in EUS

Although its use has become more focused in the area as an alternative to laparoscopic surgery, robotic surgery is gradually increasing annually, thus its use around EUS is possibly imminent. Some of the benefits of using these technologies include the improvement in the angle of vision, the reduction in hand tremor, and the access to narrower areas, thanks to the greater flexibility and the smaller size of the instruments used [77]. Moreover, its use reduces the number of operators required and allows them to work remotely in real-time via an internet connection [78]. Considering all the previously mentioned EUS particularities, all the benefits of robotic surgery are extremely attractive for its use in EUS, especially for interventional purposes. With the expansion of EUS-guided procedures, precise and more sophisticated manoeuvres are frequently needed, and robotics offers a unique opportunity to help in this regard [79].

However, the potential for the use of robots is not limited to the area of therapeutics and has infinite applications in diagnostics, as it allows to increase objectivity and precision. In abdominal ultrasound, that is also a highly operator-dependent imaging modality, a telerobotic ultrasound system has demonstrated to be feasible for its clinical application [78].

Regarding the application of robots in endoscopy, they have been developed mainly in the field of endoscopic submucosal dissection (ESD) and colonoscopy. Like other domains, robotic endoscopy platforms are master–slave systems composed by an operator console and a flexible endoscope with variable number of multi-articular arms [79]. The Endoluminal Assistant for Surgical Endoscopy, for example, master–slave robotic system conceived for ESD [80, 81]. As particularities that may be of interest for their application in an EUS robot, the presence of several working channels and the design that allows a single-operator manipulation are highlighted.

In the area of diagnostic EUS, delicate movements are needed to scan most of the structures of interest, but the performance of these precise, sensitive manoeuvres is sometimes difficult to achieve for beginners. The use of robotic tools can therefore have a great impact on the quality of the exams performed by less-experienced operators, as well as on general EUS learning. In addition, robotics could be applied to select and control the puncture strength needed to biopsy the different tissues, which is one of the main challenges for trainees during diagnostic EUS learning and also the first step of most therapeutic procedures [77]. Moreover, as the robotic platforms are designed to reduce the range of motion carried out by the operator, its

use could be directly applied in interventional EUS. With this tool, most of the problems encountered during therapeutic EUS (loss of the guidewire, loss of position) could be solved, reducing not only patients' overall outcomes but also the physical overload generally experienced by endosonographers.

The potential opportunities brought by the redesign of endoscopes would include not only the reinsurance of some of the basic EUS principles such as the maintenance of a stable position or the achievement of a millimetric precision but also an improved navigation, lesser rate of adverse events while alleviating the physical load [82]. If combined with availability of patient-related data and AI-based supporting decision tools with, objective patient assessment may be achieved together with the reduction of cognitive burden and potential complications. Ultimately, all these tools should be used to support evidence-based practice while considering the specific case's factors to improve patient care.

Development of Endosound: A Tool for Democratizing EUS

Echo-EGD (echographic upper endoscopy) and echo-colonoscopy (echographic lower endoscopy) from EndoSound's represent a quantum advancement in conventional endoscopy and ultrasound technology. By adding a fully functional ultrasound diagnostic and therapeutic tip to standard forward viewing video endoscopes, EndoSound's Echo-series completely changes the landscape. It adds ultrasound capability to standard forward viewing endoscopes and therefore can be offered at a price that promises to encourage worldwide adoption.

The transducer orientation can be adjusted so that it operates from linear to forward viewing and all positions in between, as the clinical situation demands. Its disposable design and absence of an elevator eliminate the infection risk of legacy endosonographic systems. For these reasons, EndoSound's Echo-EGD device was granted Breakthrough Device designation by the US FDA in 2021. Initial human evaluations have demonstrated excellent image quality and functionality. Targets are easily acquired, and FNA/FNB's are reliably performed. Successful drainage of collections with lumen-apposing metal stents has been accomplished in a swine model.

This new and revolutionary upper endoscopy solution offers the promise of "democratizing" internal sonography while performing EGD, making Echo-EGD widely available to all the patients with upper digestive symptoms. One could imagine a time when internal sonography will maximize the diagnostic yield of every upper endoscopy, providing visualization of luminal features and at the same time, adjacent, extra-luminal structures.

Conclusions

Over the last decades, procedures traditionally approached by open surgery have been evolving towards minimally invasive techniques. In this sense, natural orifice approaches are gaining strength by offering lower rates of adverse effects, shorter hospitalisations as well as quicker recovery times. In therapeutic endoscopy, the availability of tools adapted to the working channel has greatly expanded the treatment possibilities. However, the more complex procedures remain difficult to access for most professionals and therefore difficult to apply uniformly in the population. In the new era of medicine that we are living through, technological advances provided by AI and robotics are gradually coupling to a wide range of fields, such as risk assessment strategies, personalized diagnostic capabilities, and more precise therapeutics. Moreover, potential applications go beyond patient care could be targeted to reduce professional's welfare and improve overall workflow efficiency.

Despite the boom in interventional EUS, there are still many areas for improvement. Early diagnosis of pancreatic cancer remains a crucial objective to improve prognosis. However, the factors that work against a homogeneous and standardized practice have not been overcome, and mortality rates for this disease are augmenting annually. It is therefore urgent to push for research and investment in improving EUS quality and democratizing its practice, and both AI and robotics are key factors for this since they are expected to have a profound impact on patient's outcomes. Nevertheless, the study and validation of AI-based strategies in the clinical practice are still in their earliest stages, and few tools are available for their commercialization. Similarly, robotic endoscopic multitasking platforms are emerging technologies with promising results in other areas of flexible endoscopy such as colonoscopy or bronchoscopy, but their implementation in EUS has not been addressed so far. Also, cost-effectiveness analysis should be carried out before application to public health systems. Finally, the translation of these concepts into education programmes may have an impact on the EUS training periods, and it would allow access to expert's knowledge all over the world through telementoring. Hopefully, this will not only change the way of performing EUS-guided procedures but also boost the expansion of innovative techniques.

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References

1. Friedberg SR, Lachter J. Endoscopic ultrasound: current roles and future directions. *World J Gastrointest Endosc.* 2017;9(10):499–505.
2. Cazacu I, Luzuriaga Chavez A, Saftoiu A, Vilmann P, Bhutani M. A quarter century of EUS-FNA: progress, milestones, and future directions. *Endosc Ultrasound.* 2018;7(3):141.

3. Wani S, Han S, Simon V, Hall M, Early D, Aagaard E, et al. Setting minimum standards for training in EUS and ERCP: results from a prospective multicenter study evaluating learning curves and competence among advanced endoscopy trainees. *Gastrointest Endosc.* 2019;89(6):1160–1168.e9.
4. Kitano M, Yoshida T, Itonaga M, Tamura T, Hatamaru K, Yamashita Y. Impact of endoscopic ultrasonography on diagnosis of pancreatic cancer. *J Gastroenterol.* 2019;54(1):19–32.
5. Wang MH, Dy F, Vu VK, Lim LG, Tayyab GUN, Ratanachu-ek T, et al. Structured endoscopic ultrasonography (EUS) training program improved knowledge and skills of trainees: results from the Asian EUS group: structured EUS training program. *Dig Endosc.* 2015;27(6):687–91.
6. Das A, Mourad W, Lightdale CJ, Sivak MV, Chak A. An international survey of the clinical practice of EUS. *Gastrointest Endosc.* 2004;60(5):765–70.
7. Saumoy M, Kahaleh M. Progress in endoscopic ultrasonography. *Gastrointest Endosc Clin N Am.* 2017;27(4):749–58.
8. Wani S, Wallace MB, Cohen J, Pike IM, Adler DG, Kochman ML, et al. Quality indicators for EUS. *Gastrointest Endosc.* 2015;81(1):67–80.
9. Eisen GM, Dornitz JA, Faigel DO, Goldstein JA, Petersen BT, Raddawi HM, et al. Guidelines for credentialing and granting privileges for endoscopic ultrasound. *Gastrointest Endosc.* 2001;54(6):811–4.
10. Johnson G, Webster G, Boškoski I, Campos S, Gölder SK, Schlag C, et al. Curriculum for ERCP and endoscopic ultrasound training in Europe: European Society of Gastrointestinal Endoscopy (ESGE) position statement. *Endoscopy.* 2021;53(10):1071–87.
11. Roelandt J. Seeing the invisible: a short history of cardiac ultrasound. *Eur J Echocardiogr.* 2000;1(1):8–11.
12. Curie J, Curie P. Sur l'électricité polaire dans les cristaux hémihédres à faces inclinées. *CR Acad Sci Gen.* 1880;91:383–6.
13. Ponsky JL, Strong AT. A history of flexible gastrointestinal endoscopy. *Surg Clin North Am.* 2020;100(6):971–92.
14. Hisanaga K. A new trans-esophageal real-time two-dimensional echocardiographic system using a flexible tube and its clinical application. In: *Proceedings of the 32th scientific Meeting of the Japan Society of Ultrasonics in Medicine; 1977.* p. 43–4.
15. Hisanaga K, Hisanaga A. A new real-time sector scanning system of ultra-wide angle and real-time recording of entire adult cardiac images: transesophagus and trans-chest-wall methods. *Ultrasound Med.* 1978;4:391–402.
16. Hisanaga K, Hisanaga A, Ichie Y. A new transesophageal real-time linear scanner and initial clinical results. *Reflections.* 1978;4:203–6.
17. Lutz H, Rösch W. Transgastroscopic ultrasonography. *Endoscopy.* 1976;8(04):203–5.
18. DiMagno EP, DiMagno MJ. Endoscopic ultrasonography: from the origins to routine EUS. *Dig Dis Sci.* 2016;61(2):342–53.
19. Dimagno E, Regan P, Wilson D, Buxton J, Hattery R, Suarez J, et al. Ultrasonic endoscope. *Lancet.* 1980;315(8169):629–31.
20. Dimagno EP, Regan PT, Clain JE, James EM, Buxton JL. Human endoscopic ultrasonography. *Gastroenterology.* 1982;83(4):824–9.
21. Kroh M, Reavis KM, editors. *The SAGES manual operating through the endoscope* [internet]. Cham: Springer; 2016. <https://doi.org/10.1007/978-3-319-24145-6>.
22. Konda VJ, Aslanian HR, Wallace MB, Siddiqui UD, Hart J, Waxman I. First assessment of needle-based confocal laser endomicroscopy during EUS-FNA procedures of the pancreas (with videos). *Gastrointest Endosc.* 2011;74(5):1049–60.
23. Chan AT, Heller SJ, Van Dam J, Carr-Locke DL, Banks PA. Endoscopic cystogastrostomy: role of endoscopic ultrasonography. *Am J Gastroenterol Springer Nat.* 1996;91(8):1622.
24. Itoi T, Binmoeller KF, Shah J, Sofuni A, Itokawa F, Kurihara T, et al. Clinical evaluation of a novel lumen-apposing metal stent for endosonography-guided pancreatic pseudocyst and gallbladder drainage (with videos). *Gastrointest Endosc.* 2012;75(4):870–6.

25. Giovannini M, Hookey LC, Bories E, Pesenti C, Monges G, Delpero JR. Endoscopic ultrasound elastography: the first step towards virtual biopsy? Preliminary results in 49 patients. *Endoscopy*. 2006;38(04):344–8.
26. Arcidiacono PG, Carrara S, Reni M, Petrone MC, Cappio S, Balzano G, et al. Feasibility and safety of EUS-guided cryothermal ablation in patients with locally advanced pancreatic cancer. *Gastrointest Endosc*. 2012;76(6):1142–51.
27. Gress F, Schmitt C, Sherman S, Ikenberry S, Lehman G. A prospective randomized comparison of endoscopic ultrasound-and computed tomography-guided celiac plexus block for managing chronic pancreatitis pain. *Am J Gastroenterol*. 1999;94(4):900–5.
28. Huang JY, Samarasena JB, Tsujino T, Lee J, Hu KQ, McLaren CE, et al. EUS-guided portal pressure gradient measurement with a simple novel device: a human pilot study. *Gastrointest Endosc*. 2017;85(5):996–1001.
29. Irisawa A, Shibukawa G, Hoshi K, Yamabe A, Sato A, Maki T, et al. Endoscopic ultrasound-guided coil deployment with sclerotherapy for isolated gastric varices: case series of feasibility, safety, and long-term follow-up. *Dig Endosc*. 2020;32(7):1100–4.
30. Sharma M, Hollerbach S, Fusaroli P, Löwe A, Koch J, Ignee A, et al. General principles of image optimization in EUS. *Endosc Ultrasound*. 2021;10(3):168.
31. Baillie J. The endoscope. *Gastrointest Endosc*. 2007;65(6):886–93.
32. Voermans RP, Ponchon T, Schumacher B, Fumex F, Bergman JJGHM, Larghi A, et al. Forward-viewing versus oblique-viewing echoendoscopes in transluminal drainage of pancreatic fluid collections: a multicenter, randomized, controlled trial. *Gastrointest Endosc*. 2011;74(6):1285–93.
33. Marks JM, Dunkin BJ. Principles of flexible endoscopy for surgeons. Cham: Springer; 2013.
34. Early DS, Acosta RD, Chandrasekhara V, Chathadi KV, Decker GA, Evans JA, et al. Adverse events associated with EUS and EUS with FNA. *Gastrointest Endosc*. 2013;77(6):839–43.
35. Jenssen C, Alvarez-Sánchez MV, Napoléon B, Faiss S. Diagnostic endoscopic ultrasonography: assessment of safety and prevention of complications. *World J Gastroenterol*. 2012;18(34):4659–76.
36. Shergill AK, Adamson CH. Failure of an engineered system: the gastrointestinal endoscope. *Tech Gastrointest Endosc*. 2019;21(3):116–23.
37. Cohen DL, Naik JR, Tamariz LJ, Madanick RD. The perception of gastroenterology fellows towards the relationship between hand size and endoscopic training. *Dig Dis Sci*. 2008;53:1902–9.
38. Villa E, Attar B, Trick W, Kotwal V. Endoscopy-related musculoskeletal injuries in gastroenterology fellows. *Endosc Int Open*. 2019;07(6):E808–12.
39. Shah SZ, Rehman ST, Khan A, Hussain MM, Ali M, Sarwar S, et al. Ergonomics of gastrointestinal endoscopies: musculoskeletal injury among endoscopy physicians, nurses, and technicians. *World J Gastrointest Endosc*. 2022;14(3):142–52.
40. Hansel SL, Crowell MD, Pardi DS, Bouras EP, DiBaise JK. Prevalence and impact of musculoskeletal injury among endoscopists: a controlled pilot study. *J Clin Gastroenterol*. 2009;43(5):399–404.
41. Buschbacher R. Overuse syndromes among endoscopists. *Endoscopy*. 1994;26(6):539–44.
42. Yung DE, Banfi T, Ciuti G, Arezzo A, Dario P, Koulaouzidis A. Musculoskeletal injuries in gastrointestinal endoscopists: a systematic review. *Expert Rev Gastroenterol Hepatol*. 2017;11(10):939–47.
43. Khanicheh A, Shergill AK. Endoscope design for the future. *Tech Gastrointest Endosc*. 2019;21(3):167–73.
44. Krishnan K, Bhutani MS, Aslanian HR, Melson J, Navaneethan U, Pannala R, et al. Enhanced EUS imaging (with videos). *Gastrointest Endosc*. 2021;93(2):323–33.
45. The Precise4Q Consortium, Amann J, Blasimme A, Vayena E, Frey D, Madai VI. Explainability for artificial intelligence in healthcare: a multidisciplinary perspective. *BMC Med Inform Decis Mak*. 2020;20(1):310.

46. Ramesh A, Kambhampati C, Monson J, Drew P. Artificial intelligence in medicine. *Ann R Coll Surg Engl.* 2004;86(5):334–8.
47. Amisha MP, Pathania M, Rathaur V. Overview of artificial intelligence in medicine. *J Fam Med Prim Care.* 2019;8(7):2328.
48. Kaul V, Enslin S, Gross SA. History of artificial intelligence in medicine. *Gastrointest Endosc.* 2020;92(4):807–12.
49. Udriștoiu AL, Cazacu IM, Gruionu LG, Gruionu G, Iacob AV, Burtea DE, et al. Real-time computer-aided diagnosis of focal pancreatic masses from endoscopic ultrasound imaging based on a hybrid convolutional and long short-term memory neural network model. *PLOS One.* 2021;16(6):e0251701.
50. Tonozuka R, Mukai S, Itoi T. The role of artificial intelligence in endoscopic ultrasound for pancreatic disorders. *Diagnostics.* 2020;11(1):18.
51. Livovsky DM, Veikherman D, Golany T, Aides A, Dashinsky V, Rabani N, et al. Detection of elusive polyps using a large-scale artificial intelligence system (with videos). *Gastrointest Endosc.* 2021;94(6):1099–1109.e10.
52. Yao L, Zhang L, Liu J, Zhou W, He C, Zhang J, et al. Effect of an artificial intelligence-based quality improvement system on efficacy of a computer-aided detection system in colonoscopy: a four-group parallel study. *Endoscopy.* 2022;54(8):757–68.
53. de Groof AJ, Struyvenberg MR, Fockens KN, van der Putten J, van der Sommen F, Boers TG, et al. Deep learning algorithm detection of Barrett’s neoplasia with high accuracy during live endoscopic procedures: a pilot study (with video). *Gastrointest Endosc.* 2020;91(6):1242–50.
54. Wu RM, Fisher LR. Early detection of GI bleeding: “starting the clock for the capsule drop”. *Gastrointest Endosc.* 2019;89(1):44–6.
55. Hirasawa T, Aoyama K, Tanimoto T, Ishihara S, Shichijo S, Ozawa T, et al. Application of artificial intelligence using a convolutional neural network for detecting gastric cancer in endoscopic images. *Gastric Cancer.* 2018;21(4):653–60.
56. Zhang J, Zhu L, Yao L, Ding X, Chen D, Wu H, et al. Deep learning–based pancreas segmentation and station recognition system in EUS: development and validation of a useful training tool (with video). *Gastrointest Endosc.* 2020;92(4):874–885.e3.
57. Gallo M, Adinolfi V, Morviducci L, Acquati S, Tuveri E, Ferrari P, et al. Early prediction of pancreatic cancer from new-onset diabetes: an Associazione Italiana Oncologia Medica (AIOM)/Associazione Medici Diabetologi (AMD)/Società Italiana Endocrinologia (SIE)/Società Italiana Farmacologia (SIF) multidisciplinary consensus position paper. *ESMO Open.* 2021;6(3):100155.
58. Săftoiu et al. Efficacy of an Artificial Neural Network–Based App.pdf. 2012.
59. Norton ID, Zheng Y, Wiersema MS, Greenleaf J, Clain JE, DiMagno EP. Neural network analysis of EUS images to differentiate between pancreatic malignancy and pancreatitis. *Gastrointest Endosc.* 2001;54(5):625–9.
60. Das A, Nguyen CC, Li F, Li B. Digital image analysis of EUS images accurately differentiates pancreatic cancer from chronic pancreatitis and normal tissue. *Gastrointest Endosc.* 2008;67(6):861–7.
61. Zhang MM, Yang H, Jin ZD, Yu JG, Cai ZY, Li ZS. Differential diagnosis of pancreatic cancer from normal tissue with digital imaging processing and pattern recognition based on a support vector machine of EUS images. *Gastrointest Endosc.* 2010;72(5):978–85.
62. Iqbal MJ, Javed Z, Sadia H, Qureshi IA, Irshad A, Ahmed R, et al. Clinical applications of artificial intelligence and machine learning in cancer diagnosis: looking into the future. *Cancer Cell Int.* 2021;21(1):270.
63. Naito Y, Tsuneki M, Fukushima N, Koga Y, Higashi M, Notohara K, et al. A deep learning model to detect pancreatic ductal adenocarcinoma on endoscopic ultrasound-guided fine-needle biopsy. *Sci Rep.* 2021;11(1):8454.
64. Săftoiu A, Vilmann P, Gorunescu F, Janssen J, Hocke M, Larsen M, et al. Efficacy of an artificial neural network–based approach to endoscopic ultrasound elastography in diagnosis of focal pancreatic masses. *Clin Gastroenterol Hepatol.* 2012;10(1):84–90.e1.

65. Săftoiu A, Vilmann P, Dietrich CF, Iglesias-Garcia J, Hocke M, Seicean A, et al. Quantitative contrast-enhanced harmonic EUS in differential diagnosis of focal pancreatic masses (with videos). *Gastrointest Endosc.* 2015;82(1):59–69.
66. Fleurentin A, Mazellier JP, Meyer A, Montanelli J, Swanstrom L, Gallix B, et al. Automatic pancreas anatomical part detection in endoscopic ultrasound videos. *Comput Methods Biomech Biomed Eng Imaging Vis.* 2023;11(4):1136–42.
67. Meyer A, Fleurentin A, Montanelli J, Mazellier JP, Swanstrom L, Gallix B, et al. Spatio-temporal model for EUS video detection of pancreatic anatomy structures. In: Aylward S, Noble JA, Hu Y, Lee SL, Baum Z, Min Z, editors. *Simplifying medical ultrasound*. Cham: Springer; 2022. p. 13–22. (Lecture Notes in Computer Science; vol. 13565). https://doi.org/10.1007/978-3-031-16902-1_2.
68. Wang TD, Van Dam J. Optical biopsy: A new frontier in endoscopic detection and diagnosis. *Clin Gastroenterol Hepatol.* 2004;2(9):744–53.
69. Nie Z, Yeh SCA, LePalud M, Badr F, Tse F, Armstrong D, et al. Optical biopsy of the upper GI tract using fluorescence lifetime and spectra. *Front Physiol.* 2020;11:339.
70. Hirsch FR, Wynes MW, Gandara DR, Bunn PA. The tissue is the issue: personalized medicine for non-small cell lung cancer. *Clin Cancer Res.* 2010;16(20):4909–11.
71. Zhu M, Xu C, Yu J, Wu Y, Li C, Zhang M, et al. Differentiation of pancreatic cancer and chronic pancreatitis using computer-aided diagnosis of endoscopic ultrasound (EUS) images: a diagnostic test. *PLoS One.* 2013;8(5):e63820.
72. Hassan C, Antonelli G, Repici A. Artificial intelligence for polyp characterization: Don't save on your competence! *Gastrointest Endosc.* 2020;92(4):912–3.
73. Singh BS, Cazacu IM, Deza CA, Rigaud BS, Saftoiu A, Gruionu G, et al. Image fusion involving real-time transabdominal or endoscopic ultrasound for gastrointestinal malignancies: review of current and future applications. *Diagnostics.* 2022;12(12):3218.
74. Gruionu L, Saftoiu A, Gruionu G. A novel fusion imaging system for endoscopic ultrasound. *Endosc Ultrasound.* 2016;5(1):35.
75. Mazellier JP, Rolland C, Wernert E, Montanelli J, Hostettler A, Swanstrom L, et al. Electromagnetic tracking of endoscopic ultrasound probe for pancreas examination: accuracy assessment under realistic medical conditions. *Comput Methods Biomech Biomed Eng Imaging Vis.* 2023;11:1–8.
76. First-in-human Navigation Endoscopic Ultrasound (EUS) System Clinical Study (APEUS-Nav1). IHU Strasbourg. [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/NCT05515705). Identifier NCT05515705. Updated February 28, 2023. <https://classic.clinicaltrials.gov/ct2/show/NCT05515705>.
77. Guo J, Li H, Chen Y, Chen P, Li X, Sun S. Robotic ultrasound and ultrasonic robot. *Endosc Ultrasound.* 2019;8(1):1.
78. Adams SJ, Burbridge BE, Badea A, Langford L, Vergara V, Bryce R, et al. Initial experience using a telerobotic ultrasound system for adult abdominal sonography. *Can Assoc Radiol J.* 2017;68(3):308–14.
79. Kim SH, Choi HS, Keum B, Chun HJ. Robotics in gastrointestinal endoscopy. *Appl Sci.* 2021;11(23):11351.
80. Zorn L, Nageotte F, Zanne P, Legner A, Dallemagne B, Marescaux J, et al. A novel Telemanipulated robotic assistant for surgical endoscopy: preclinical application to ESD. *IEEE Trans Biomed Eng.* 2018;65(4):797–808.
81. Mascagni P, Lim SG, Fiorillo C, Zanne P, Nageotte F, Zorn L, et al. Democratizing endoscopic submucosal dissection: single-operator fully robotic colorectal endoscopic submucosal dissection in a pig model. *Gastroenterology.* 2019;156(6):1569–1571.e2.
82. Seeliger B, Swanström LL. Robotics in flexible endoscopy: current status and future prospects. *Curr Opin Gastroenterol.* 2020;36(5):370–8.

Chapter 8

New Frontiers in Post-Surgical Rehabilitation



Helena Biancuzzi, Francesca Dal Mas , Rym Bednarova, Giulia Bongiorno, and Luca Miceli

Introduction

Pain is a subjective and individual experience, and it has different characteristics in each person. For this reason, the International Association for the Study of Pain (IASP) and the World Health Organization define pain as “an unpleasant sensory and emotional experience, whether or not associated with actual or potential tissue damage, or described in terms of such damage” [1].

In order to be able to classify pain, it is necessary to carry out assessments using pain scales. Through them, different aspects of pain are scored, in order to rank it in a position that ranges from mild to unbearable.

Although pain is an extremely subjective perception, there are diseases that cause more pain than others. The National Health Service has compiled a list of diseases that cause more pain than others from an objective point of view, and in the first place puts cancer [2], today considered one of the most important public health problems.

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According to data from the European Commission, cancer is the second leading cause of mortality in EU countries after cardiovascular disease. This disease is diagnosed in 2.6 million people each year and kills 1.2 million people. Given that Europe accounts for nearly a quarter of total cancer cases and less than 10% of the world population, it is clear that cancer poses a huge threat to our society. The overall economic impact of cancer in Europe amounts to € 100 billion per year [3].

The data from the Italian Association of Medical Oncology-Italian Association of Cancer Registries (AIOM-AIRTUM) volume “Cancer numbers in Italy 2021” presented to the Higher Institute of Health underline that in Italy, in 2021, tumors were the cause of death for 100,200 men and 81,100 women [4]. Of all cancer patients undergoing treatment, it is estimated that nearly 40% suffer from cancer pain [5]. Surgery stands as one of the most effective long-time cures for several types of cancers [6], and post-surgical rehabilitation may be challenging and should require a tailored approach [7].

Cancer pain occurs in cancer patients and is an intense and disabling pain that can arise due to the pressure of the tumor, the ongoing treatment, changes in the immune system, post-surgical rehabilitation, etc. Unfortunately, in the final stages of cancer, cancer pain appears in almost 80% of patients. It is a highly complex and challenging situation to deal with. Each patient responds differently and to different treatments, most of which use potent drugs [8, 9]. Treatment for cancer pain must be tailored to the patient’s needs, as it depends on the type of cancer suffered, what causes it, and the individual’s perception of pain.

However, there are general guidelines for the treatment of cancer pain according to its intensity. This is the analgesic scale, set on three steps and designed by the World Health Organization (WHO) [10]. Starting from a minor to a greater intensity of pain, the following groups of drugs are used:

- Simple analgesics, given to patients suffering from mild pain (for example, paracetamol, non-steroidal anti-inflammatory drugs, such as ibuprofen or naproxen);
- weak opioids, for patients suffering from moderate pain (codeine, tramadol, dihydrocodeine);
- strong opioids, in case the perceived pain is intense (for example, morphine, methadone, fentanyl).
- It is important to be aware that, unfortunately, step 3 drugs are required for more than half of patients [5].

Opioids are a class of substances that inhibit the transmission of painful stimuli [11]. They are characterized by a strong analgesic effect by acting on brain receptors called opioid receptors. The latter are distributed throughout the central and peripheral nervous system. These drugs attach to these receptors and restrain nerve stimuli. By slowing down the stimulus, pain transmission does not occur.

However, it must be considered that opioids have numerous side effects. First, they are addictive. Other effects that may occur especially at the beginning of therapy are nausea, vomiting, drowsiness, dizziness, mental confusion, and constipation [12, 13]. The possible problems also extend beyond the field of mere side effects. Abuses and addictions often occur, which in turn can lead to numerous social,

health, and legal implications, such as, among others, the increase in health costs for the treatment of overdoses, the increase in the number of deaths, and an increase in the number of infants with neonatal abstinence syndrome [14].

Suffice it to say that in the USA, from 1999 to 2019, opioid overdose, due to both regularly prescribed and illegally purchased drugs, was the cause of death for almost 500,000 people [15]. The deaths, however, did not follow a homogeneous annual trend but gradually increased over time. In fact, opioid overdoses from 1999 to 2018 quadrupled [14, 16].

However, understanding the developments, consequences, and containment strategies of this phenomenon is relevant for all those countries which, today, are still in a phase of under-prescription [17].

In light of these premises, it is essential to think and act, in the post-operative oncology field, about paths that accompany patients in 360-degree rehabilitation, which includes the prescription of painkillers but also incentives for personalized rehabilitation activities.

It should be clarified here that the surgical process is not limited to surgery in the operating room but includes, for example, in the field of breasts, activities prior to the surgery itself. For example, if a particularly demolitive intervention is foreseen, therapeutic preparatory exercises are recommended prior to entering the operating room to have the muscle tissues as toned as possible. After surgical stress, with variable times depending on the type of operation, the surgical procedure also includes the rehabilitation procedure, with the aim of preventing asymmetries, muscle and nerve deficits, and above all, the onset of lymphedema, all conditions that can reduce the effectiveness of the intervention.

The National Cancer Institute Case Study

The National Cancer Institute of Aviano, Italy, one of the leading hospitals in Europe for breast cancer surgery [18], has recently launched an innovative approach to cancer rehabilitation, mainly dedicated to the post-surgical pathway of breast-operated patients. The purpose of the course is to combine proper rehabilitation, analgesic therapy, and a physical activity program [7, 19]. In breast pathology, in fact, the part of physical activity is essential both in restoring the function of the shoulder ipsilateral to the intervention and in reducing the side effects associated with anti-abnormal therapy (mostly migratory arthromyalgia) that most patients must take for 5 years after surgery. In all this, it must also be considered that almost half of the institute's users come from outside the region [20] and that pain in the operated limb is one of the major limitations to the rehabilitation itself [21].

The rehabilitation process includes a post-surgical physiatric visit in the immediate post-operative period for patients undergoing lymphadenectomy or radical mastectomy, during which the medical doctor, if (s)he recognizes it, sends the patients to the dedicated physiotherapist. The physiotherapist can then, at her discretion, carry out a kinematic and muscular evaluation of the patient if she deems it useful for resetting her own therapeutic path: first, the muscle mass is assessed through an

impedance balance, then the strength of the forearm muscles is measured. Through a dynamometer called “hand grip,” since sarcopenia, that is, the loss of muscle mass and strength connected to the disease or to oncological treatments is itself a negative prognostic factor on the patient’s outcome. From these two data, a muscle quality index is calculated (dividing strength by muscle mass), to get a global idea of the patient’s set-up. A sarcopenia index is then calculated using ultrasound, derived from the study of the inclination of the muscle fibers of the vastus lateral muscle of the thigh. The sum of this information helps to create a part of the patient’s “personalized rehabilitation file,” that is the part that will be used by the graduate in motor science, in the gym where the patient will go after discharge, to build a dedicated program of physical activity [7, 19].

It should be noted that the World Health Organization (WHO) recommends, even for cancer patients, 150 minutes a week of moderate aerobic activity, along with two weekly sessions of anaerobic activity [22]. To monitor the aerobic activity, patients are advised to download the “Oncology in Motion” APP [20, 21, 23–25], created by the institute itself thanks to European funding, which allows the patient and qualified health worker to view daily progress both on the aerobic side (steps taken) and anaerobic (cardio points), by connecting to the free “Google fit” APP and detecting them from it. The APP also allows you to remotely program goals for patients and send notifications to the user. This is first remote use (telerehabilitation) of an important coaching phase for patients, especially those who reside far from the institution where they have been operated, keeping in continuous contact and stimulating them to achieve the objectives set in accordance with the WHO guidelines, also resumed by the Italian Ministry of Health. Since often the ipsilateral shoulder pain with the surgery is a limit to physical activity, patients who complain of this disorder are referred to the pain therapist who offers them the most appropriate treatments, preferring neuromodulation techniques (pulsed radiofrequency, nerve blocks peripheral) to the use of opiate drugs, which can have annoying side effects (nausea, dizziness, loss of attention, constipation). In case of doubts about the real aerobic potential of the patients, it is possible to calculate, using a cycle ergometer and metabolimeter, the aerobic threshold of the patients, in order to be able to suggest the optimal heart rate during the aerobic training phase. Arriving at physiotherapy proper, the construction of the personalized path, where necessary, involves an advanced kinematic assessment of the shoulder joint performed by the physiotherapist responsible for the path: using a non-invasive inertial sensor, the amplitude (expressed in degrees) of the movement of the upper limb, the speed of execution of the movement, the Jerk index (i.e. the fluidity index of the movement itself). Subsequently, non-invasive surface electromyographs are applied to the main muscles involved in the movement of the upper limb, capable of measuring the percentage contribution of each muscle to each specific movement: it is not uncommon, in fact, that patients are able to obtain angles of almost correct movement but by activating certain muscles in an abnormal way to the detriment of others, and this in the long run leads to an asymmetry of movement and an incorrect rehabilitation process. The patients are periodically re-evaluated with the same instruments during the periodic checks in the institute, and they always have the possibility of a televisit

in case of problems or need for clarification on the current path [26, 27]. Finally, there is the possibility of a visit with the institute's dietician to better plan nutrition in this delicate period. This virtuous path has a series of advantages over the traditional path:

- The patient feels that the physical activity part is an important stage of oncological treatment and not an accessory part: to obtain this result, the oncologist or surgeon or pain therapist prescribes the physiotherapy evaluation for the study on a normal prescription before discharging body composition and, if necessary, the measurement of the aerobic threshold together with the kinematic and joint muscle assessment. This is not a medicalization of physical activity but health supervision (doctor and physiotherapist) with the task of identifying patients who may not benefit from this path and motivating those who can instead take part;
- The fact that at the periodic oncological checks, the patient will be re-evaluated with these methods puts the emphasis on taking care of her body from an athletic and not just a health point of view (the patient will not focus only on the hoped-for value of the tumor makers but also on one's own body composition and muscular and cardiovascular performance).
- The "Oncology in Motion" APP becomes a link with the institute at any time since if the operator detects that the patient is not performing the suggested activity, he or she can send her a notification or can call her directly and proactively intercept a potential problem;
- Pain therapist and nutritionist are always available, and the patient can request a televised e-mail at any time;
- The kinematic assessments remain, always within the "personalized rehabilitation file," available to the physiotherapist and these are also repeated, if necessary, during periodic checks in the institute.
- In this process, the part of exercises in the gym or at home is not standardized, except for the instructions contained in the brochures that the institute, like any other cancer hospital, gives to patients. Each patient has their own gym of reference, probably close to their home, and the instructor may have doubts about which exercises to propose to patients who are certainly more fragile than others, for which a specific manual has been prepared not for patients but for the instructors themselves, with suggestions, recommendations, and instructions to better build the gymnastic path of the patients themselves. In addition to this, a course format is at an advanced stage, both in presence mode and online training, precisely to make this approach homogeneous throughout the national territory. In this course, doctors, physiotherapists, and graduate teachers of motor science will give the basic notions to allay some fears of gym instructors and, at the same time, suggest some types of exercise that are more effective than others in the cancer patient.
- At the same time, a network of gyms, as well as hospitals, will also be created, with a link between healthcare and non-healthcare able to offer users the best of these two worlds [19].

Conclusions

In the opinion of the authors, this path represents a new frontier in the field of oncological surgery, since it includes the kinesiological part of preparation for surgery (which can be supported by adequate instrumental biometric measurements if necessary), the post-surgical rehabilitation part properly said however built in a personalized way, based on accurate joint kinematic measurements and non-invasive surface electromyography, and adequate pain treatment both with classic drugs of consolidated use (opiates) and with innovative neuromodulation methods if indicated.

References

1. Raja SN, Carr DB, Cohen M, Finnerup NB, Flor H, Gibson S, et al. The revised International Association for the Study of Pain definition of pain: concepts, challenges, and compromises. *Pain Press*. 2020;10:161.
2. Lisa Girello. Le 10 malattie che provocano più dolore: quali sono. 2022.
3. European Commission. *Cancer*. 2022.
4. Ministero della Salute. Tumori, i dati Aiom-Airtum “I numeri del cancro in Italia 2021.” 2021.
5. Leonardo Biolatto. Dolore oncologico e trattamento con oppioidi. 2022.
6. Barcellini A, Peloso A, Pugliese L, Vitolo V, Cobianchi L. Locally advanced pancreatic ductal adenocarcinoma: challenges and Progress. *Onco Targets Ther*. 2020;13:12705–20.
7. Biancuzzi H, Dal Mas F, Bongiorno G, Bednarova R, Miceli L. Physical activity in oncology: to do, not to do, and how to do it? An announcement of an educational program. *J Cancer Educ*. 2022;38:1019.
8. Strassels SA. Economic burden of prescription opioid misuse and abuse. *J Manag Care Pharm*. 2009;15(7):556–62.
9. El Moheb M, Herrera-Escobar JP, Breen K, Orlas C, Haynes AN, Levy-Carrick NC, et al. Long-term outcomes of psychoactive drug use in trauma patients: a multicenter patient-reported outcomes study. *J Trauma Acute Care Surg*. 2021;90(2):319. https://journals.lww.com/jtrauma/Fulltext/2021/02000/Long_term_outcomes_of_psychoactive_drug_use_in.15.aspx.
10. Bandieri E, Romero M, Ripamonti CI, Artioli F, Sichetti D, Fanizza C, et al. Randomized trial of low-dose morphine versus weak opioids in moderate cancer pain. *J Clin Oncol*. 2016;34(5):436–42.
11. Tucci P. Oppioidi. *Diz di Med - Treccani*. 2010.
12. Hooman Khademi MD, Farin Kamangar MD, Paul Brennan MD, Reza Malekzadeh MD. Opioid therapy and its side effects: a review. *Arch Iran Med*. 2016;19(12):870.
13. Baldini A, Von Korff M, Lin EHB. A review of potential adverse effects of long-term opioid therapy: a practitioner’s guide. *Prim Care Companion CNS Disord*. 2012;14(3):27252.
14. Biancuzzi H, Dal Mas F, Brescia V, Campostrini S, Cascella M, Cuomo A, et al. Opioid misuse: a review of the Main issues, challenges, and strategies. *Int J Environ Res Public Health*. 2022;19(18):11754.
15. Centers for Disease Control and Preventions. National Center, Control IP and. *Understanding the Epidemic*. 2020.
16. CDC. Drug Overdose Deaths [Internet]. Maps & Graphs on U.S. Drug Overdose Death Rates. 2021 [cited 2022 Mar 25]. <https://www.cdc.gov/drugoverdose/deaths/index.html>.

17. Biancuzzi H, Dal Mas F, Bednarova R, Bert F, Campostrini S, Cobianchi L, Massaro M, Rizzardo A, Miceli L. Trend e conseguenze dell'epidemia di abuso di oppioidi: problematiche e sfide. Una revisione strutturata della letteratura. *Polit Sanit.* 2022;23(2):1–13.
18. Biancuzzi H, Dal Mas F, Miceli L, Bednarova R. Post breast cancer coaching path: a co-production experience for women. In: Paoloni P, Lombardi R, editors. *Gender studies, entrepreneurship and human capital IPAZIA 2019 Springer proceedings in business and economics.* Cham: Springer; 2020. p. 11–23.
19. Bongiorno G, Biancuzzi H, Dal Mas F, Bednarova R, Miceli L. The rehabilitation tailor: applying personalized medicine to cancer recovery. *Front Glob Women's Heal.* 2022;3:914302.
20. Miceli L, Bednarova R, Biancuzzi H, Garlatti A. Nascita di un percorso riabilitativo in un Ircs oncologico del Friuli-Venezia Giulia: "oncology in motion". *Polit Sanit.* 2019;20(2):89–95.
21. Bednarova R, Biancuzzi H, Rizzardo A, Dal Mas F, Massaro M, Cobianchi L, et al. Cancer rehabilitation and physical activity: the "oncology in motion" project. *J Cancer Educ.* 2022;37:1066–8.
22. Schmitz KH, Courneya KS, Matthews C, Demark-Wahnefried W, Galvão DA, Pinto BM, et al. American college of sports medicine roundtable on exercise guidelines for cancer survivors. *Med Sci Sports Exerc.* 2010;42:1409.
23. Dal Mas F, Biancuzzi H, Massaro M, Miceli L. Adopting a knowledge translation approach in healthcare co-production. A case study. *Manag Decis.* 2020;58(9):1841–62.
24. Biancuzzi H, Dal Mas F, Peloso A, Miceli L. Coinvolgimento del paziente nel percorso riabilitativo dopo l'intervento per cancro al seno: impatto sui costi. Stato dell'arte e nuove prospettive. *Recenti Prog Med.* 2020;111(12):733–9.
25. Biancuzzi H, Miceli L, Bednarova R, Garlatti A. Post-breast cancer coaching: the synergy between health and fitness through co-production. *Ig Sanita Pubbl.* 2019;75(3):181–7.
26. Miceli L, Dal Mas F, Biancuzzi H, Bednarova R, Rizzardo A, Cobianchi L, et al. Doctor@ home: through a telemedicine co-production and co-learning journey. *J Cancer Educ.* 2022;37:1236–8.
27. Dal Mas F, Biancuzzi H, Marseglia GR, Bednarova R, Cobianchi L, Miceli L. Doctor @ home: new perspectives on telemedicine for women during the COVID pandemic. In: Ordonez de Pablos P, Tai Chui K, Lytras M, editors. *Digital innovation for healthcare in Covid-19 pandemic: strategies and solutions.* Amsterdam: Elsevier; 2022.

Part IV
Non-technical Skills

Chapter 9

New Surgical Leaders Built on Non-technical Skills: Communication, Team Dynamics, and Leadership



Maximilian Scheiterle, Jacopo Martellucci , and Francesca Dal Mas 

The Discovery of Non-technical Skills in Surgery

Globally an estimated 234 million major surgical operations occur annually. This volume of procedures is thought to result in seven million complications and one million deaths [1].

More comprehensive analysis of worldwide literature suggests that as many as 10–15% of patients admitted to hospital experience an adverse event not directly related to their underlying condition, around 50% of which are classified as avoidable. Concern arises if we consider that approximately half of all adverse events occur in the operating room (OR).

There is no doubt that technical skills are important. Much has been written about the importance of developing good hand–eye coordination, manual dexterity, and focused psychomotor skills in a “craft” specialty like surgery [2]. The focus on technical skills development has led to the creation of standard assessments for technical skills, such as the objective structured assessment of technical skills (OSATS) [3]. We also know that technical skills tend to improve with experience and this is evidenced by the volume–outcome relationship in much of surgery, especially complex operations [4, 5].

However, technical ability may not be enough. Reports from the US stated that between 44,000 and 98,000 people die in US hospitals each year from medical

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errors that could have been prevented [6]. A similar problem was recorded in the UK with an estimated cost for the NHS of £2bn a year in additional hospital stays alone and £400 m a year settling clinical negligence claims. The majority were surgical patients [7].

Publications sparked a worldwide interest in patient safety research and interventions. The World Health Organization validated and promulgated a surgical checklist. The effectiveness is due not only because it provides specific reminders on the specific case but also because it addresses some of the human factors related to the patient safety. The systematic adoption and implementation of the procedure showed a significant reduction in mortality and morbidity in large studies but adverse events still occurred.

These findings all support the argument that although technical skills are necessary for safe surgery, taken in isolation they are not sufficient to maintain high levels of performance over time.

In surgery, there is increasing evidence that such harm is not due to deficient technical skills alone, reports show that technical errors during the surgery itself constituted just 4.3% of the operative areas of concern identified, with far more errors originating from poor decision-making [8]. Further, numerous studies have shown that deficiencies in teamwork in the OR are significant contributors to adverse events and patient harm reaching surgical patients [9–12].

This suggests that generally in healthcare but especially in surgery adverse events strongly relate to behavioral failures.

In the operating room, surgical team members are expected to work together to prevent adverse patient outcomes. Effective communication and teamwork are essential, and flaws in these processes are associated with a higher risk of error and harm [13–15].

An analysis of incident reports of the National Patient Safety Agency had shown that about half of the incidents were due to failures in non-technical skills (NTS) [16]. A recent analysis of fatal adverse events in Japan came to the same conclusion that about half of them were primarily due to failures in NTS [17].

When combined, the evidence is strong that NTS failures seem to be a major factor in causing medical errors in surgery, hence developing communication and teamwork skills among OR personnel are essential for ensuring patient safety.

This was confirmed by the analysis of adverse events and accidents in modern high-risk industries, such as civil aviation, offshore oil exploration, and nuclear power generation, showing that accidents happened more often not because of technical failure or human error but because of communication errors. Especially the aviation industry devoted resources training pilots in what was known as cockpit resource management. CRM was developed as a response to new insights into the causes of aircraft accidents which followed the introduction of flight data recorders (FDRs) and cockpit voice recorders (CVRs) into modern jet aircraft. Information gathered from these devices has suggested that many accidents do not result from a technical malfunction of the aircraft or its systems, nor from a failure of aircraft handling skills or a lack of technical knowledge on the part of the crew; it appears instead that they are caused by the inability of crews to respond appropriately to the situation in which they find themselves. For example, inadequate communications between crew members and other parties could lead to a loss of

situational awareness, a breakdown in teamwork in the aircraft, and, ultimately, to a wrong decision or series of decisions which result in a serious incident or a fatal accident.

Inside Non-technical Skills

NTS, also known as “soft skills” refer to behavioral, cognitive, and relational skills present in every activity and working sector. They include a set of soft skills such as the ability to communicate effectively, leadership, teamwork, situational awareness, decision-making, and stress management.

NTS were defined by Flin as “the cognitive, social and personal resource skills that complement technical skills, and contribute to safe and efficient task performance” [18]. Subsequently, NTS have been made explicit and operational for surgery by Yule et al. in their behavioral marker system containing four categories: situation awareness, decision-making, communication and teamwork, and leadership [19] (Table 9.1).

Emotional intelligence (EI), also known as emotional quotient, is the ability to successfully identify and manage our emotions and those of the people around us. Although a number of definitions have been proposed since Salovey and Mayer first described EI both as a trait and as ability. Distinct from general cognitive ability (IQ), the concept is now understood as the awareness, control, and expression of one’s emotions and the ability to handle interpersonal relationships judiciously and empathetically [20]. It is a mechanism to successfully relieve stress, communicate effectively, empathize with others, overcome challenges, and defuse conflict and it is therefore likely to improve the outcome of our actions [21].

Moreover, EI is the basis for an effective interpretation of one’s role in the team, and the basis of leadership principles.

Occupying a central role on the healthcare team, surgeons have the potential to improve patient outcomes, reduce medical errors, and improve patient satisfaction

Table 9.1 Role of non-technical skills in surgical practice (modified from [19])

Dimension	Category	Element
Cognitive	Situation awareness	Gathering information Understanding information Projecting and anticipating future state
	Decision-making	Considering options Selecting and communicating option Implementing and reviewing decisions
Interpersonal	Leadership	Setting and maintaining standards Supporting others Coping with pressure and stress
	Communication and teamwork	Exchanging information Establishing a shared understanding Coordinating team

through their leadership of the multidisciplinary team. However surgical teams require leaders who understand the needs of patients and can inspire and manage the team to deliver those needs.

Historically, surgeons took sole responsibility for the patient and behaved in the operating room with absolute authority, using a command-and-control style of leadership. Modern surgical practice has now evolved from single provider-based care toward a team-based approach, which requires collaborative leadership skills.

Leadership in surgery entails many other NTS, including professionalism, technical competence, motivation, innovation, teamwork, communication skills, decision-making, business acumen, emotional competence, resilience, and effective teaching.

Communication is the foundation of teamwork [22]. Its goal is to allow all the members of a team, regardless of their role, to have the same perception of a situation and its potential risks and continuously and effectively exchange information about the different steps of the intervention. Common limitations to communication may be internal (differences in culture, experience, motivation, hierarchy, mood) or external (noise, absence of visual signs, low voices, hearing problems, etc.). For sure, improving communication is not an individual task, but a team goal.

Situational awareness is being aware of one's surroundings and any potential hazards, risks, potential incidents, complications, or operational activities. Good situational awareness is fundamental to being able to make good decisions. The three common stages of situational awareness are: information gathering, understanding information, and anticipation. In accordance with the three stages of situational awareness, each member of the surgical team should know the typical sources of information available, be able to interpret the information they have gathered, together with their knowledge and past experience, into a coherent picture to understand the situation and then be able to anticipate how an incident will develop and change based on their understanding. In particular, they should be able to predict the impact of their actions on incident development and outcomes.

Among the factors that may adversely affect the situation awareness stress, fatigue, poor communication, or distractions should be considered.

Fatigue and stress are two elements that can affect NTS, independently of any technical mastery issues. Sleep deprivation, even minimal, can affect cognitive capacities similar to moderate alcohol consumption [23], even if the impact of fatigue remains underestimated according to one inquiry revealing that 70% of surgeons considered that fatigue did not affect the technical gesture. Moreover, surgeons were continuously exposed to chronic stress, usually related to anxiety of a possible complications or other burnout predisposing factors [24].

Decision-making happens every day in surgical practices, and it looks particularly challenging in some settings like trauma and emergency surgery [25].

In surgical practice, individual decisions are usually reached by a combination of intuition and analysis, experience and improvisation, according to the complexity of the situation and the expertise of the surgeon. The interesting DECIDE model is the acronym of 6 particular activities needed in the decision-making process: (1) D = define the problem, (2) E = establish the criteria, (3) C = consider all the

alternatives, (4) I = identify the best alternative, (5) D = develop and implement a plan of action, and (6) E = evaluate and monitor the solution and feedback when necessary [26].

Training for Non-technical Skills

The main problem about training that the literature still fails to answer is how much personal traits and habits can influence possessing specific soft skills, and thus how much soft skills can be learned as technical skills are?

Since NTS failures seem to be a major factor in the cause of medical errors and given that the rates of medical errors in surgery appear to be not insignificant, one would expect NTS training to reduce errors and improve patient outcomes. When considering surgical training “hard skills,” such as operative log books and publications are still often used to assess junior staff for promotion to training positions. Despite the recognized role of NTS in surgery, these are usually not considered during surgical education programs. The young surgeons are supposed to acquire their knowledge of these factors observing the behavior of senior surgeons, without specific training. But the “Halsted-apprenticeship” traditional method of surgical training with its long hours, steep hierarchies, subjective feedback of performance, and ambiguous definitions of competence does not longer seem appropriate or possible. Surgeons work in interprofessional teams and are required to not only perform procedures, but effectively communicate, lead, and manage teams. Modern surgical training should involve competency-based training, multi-modal educational approaches, such as simulation with appropriate and structured feedback. To obtain proficiency in these skills, residents often take years to gain the confidence and expertise to master the needed non-technical and technical skills.

Teaching NTS can be done using either a didactic lecture model, implemented by interactive instruction support or by a simulation-based model, finalized by structured discussions and event analysis. Specific courses were designed both for permanent surgical teams, based on task analysis of team roles and teamwork, as for individuals not working in permanent teams. In this latter case individual NTS for a particular role are formally identified and systematically trained [27].

Evaluation scores have been designed to evaluate a teamwork performance, namely the NOTECHS (Non-TECHnocal Skills) or OTAS (Observational Teamwork Assessment for Surgery), or on individual performance within a team, referring to NOTSS (NOn Technical Skills for Surgeons), OSANTS (Objective Structured Assessment of Non-technical Skills), or ANTS (focused on anesthesiologists). Their application may help to improve the objectivity of training programs. Overall simulation training appears to be a powerful tool that highlights EI flaws while ensuring patients come to no harm [21, 28].

Surgical teams with low mortality rates communicate more effectively and frequently, and team training is associated with reduced mortality rates [29, 30].

The results from a recent systematic review showed that NTS training may have a true benefit on mortality reduction but, maybe due to insufficient available data, no significant reduction on complication rate could be detected, even if a nominal reduction was reported in complication rate after NTS training [31].

The Surgeon of the Future

A skillful operation is 75% decision-making and 25% dexterity [32]. After almost 50 years we begin to understand this statement, and after more than 100 years also Harvey Cushing might meet the surgeon of his prediction, when he wrote to Dr. Henry Christian in 1911: *I would like to see the day when somebody would be appointed surgeon somewhere who had no hands, for the operative part is the least part of the work.*

In recent years, especially with the COVID pandemic and the new and unexpected health challenges it has proposed, the need for NTS has been dramatically evident as never before. Facing this unknown clinical situation, where the value of experience was marginal, it was skills such as resilience, teamwork, leadership, decision-making (even through trial-and-error modalities), but also ethics, passion, and willingness to interface with new organizational models that allowed us to be called heroes.

Thus, such skills represent key assets, besides pure technical knowledge, for the next surgical leaders [33].

Beside the importance of training for the acquisition of surgical technical skills, other factors such as improving communication in the surgical team, developing leadership skills, and exercising improvisational skills through simulation and clinical practice seem to be essential for a complete management of adverse or unexpected events that can occur during surgery. According to this, the surgical team has been compared to a jazz band, since despite evidence-based rules, the best treatment of every single patient still needs the valuable intervention of improvisation to be effective [34].

References

1. Weiser TG, Regenbogen SE, Thompson KD, Haynes AB, Lipsitz SR, Berry WR, Gawande AA. An estimation of the global volume of surgery: a modelling strategy based on available data. *Lancet*. 2008;372(9633):139–44. [https://doi.org/10.1016/S0140-6736\(08\)60878-8](https://doi.org/10.1016/S0140-6736(08)60878-8).
2. Moorthy K, Munz Y, Sarker SK, Darzi A. Objective assessment of technical skills in surgery. *BMJ*. 2003;327(7422):1032–7. <https://doi.org/10.1136/bmj.327.7422.1032>.
3. van Hove PD, Tuijthof GJ, Verdaasdonk EG, Stassen LP, Dankelman J. Objective assessment of technical surgical skills. *Br J Surg*. 2010;97(7):972–87. <https://doi.org/10.1002/bjs.7115>.
4. Holt PJ, Karthikesalingam A, Hofman D, Poloniecki JD, Hinchliffe RJ, Loftus IM, Thompson MM. Provider volume and long-term outcome after elective abdominal aortic aneurysm repair. *Br J Surg*. 2012;99(5):666–72. <https://doi.org/10.1002/bjs.8696>.

5. Archampong D, Borowski D, Wille-Jørgensen P, Iversen LH. Workload and surgeon's specialty for outcome after colorectal cancer surgery. *Cochrane Database Syst Rev.* 2012;(3):CD005391. <https://doi.org/10.1002/14651858.CD005391.pub3>.
6. Institute of Medicine (US). In: Kohn LT, Corrigan JM, Donaldson MS, editors. Committee on quality of health Care in America. To err is human: building a safer health system. Washington, DC: National Academies Press (US); 2000.
7. Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *BMJ.* 2001;322(7285):517–9. <https://doi.org/10.1136/bmj.322.7285.517>. Erratum in: *BMJ* 2001 Jun 9;322(7299):1395.
8. Scottish Audit of Surgical Mortality. Annual Report, 2010 [online]. <http://www.sasm.org.uk/Publications/Main.htm>
9. Gawande AA, Zinner MJ, Studdert DM, Brennan TA. Analysis of errors reported by surgeons at three teaching hospitals. *Surgery.* 2003;133(6):614–21. <https://doi.org/10.1067/msy.2003.169>.
10. Rogers SO Jr, Gawande AA, Kwaan M, Puopolo AL, Yoon C, Brennan TA, Studdert DM. Analysis of surgical errors in closed malpractice claims at 4 liability insurers. *Surgery.* 2006;140(1):25–33. <https://doi.org/10.1016/j.surg.2006.01.008>.
11. Greenberg CC, Regenbogen SE, Studdert DM, Lipsitz SR, Rogers SO, Zinner MJ, Gawande AA. Patterns of communication breakdowns resulting in injury to surgical patients. *J Am Coll Surg.* 2007;204(4):533–40. <https://doi.org/10.1016/j.jamcollsurg.2007.01.010>.
12. Lingard L, Espin S, Whyte S, Regehr G, Baker GR, Reznick R, Bohnen J, Orser B, Doran D, Grober E. Communication failures in the operating room: an observational classification of recurrent types and effects. *Qual Saf Health Care.* 2004;13(5):330–4. <https://doi.org/10.1136/qhc.13.5.330>.
13. Catchpole K, Mishra A, Handa A, McCulloch P. Teamwork and error in the operating room: analysis of skills and roles. *Ann Surg.* 2008;247(4):699–706. <https://doi.org/10.1097/SLA.0b013e3181642ec8>.
14. Leonard M, Graham S, Bonacum D. The human factor: the critical importance of effective teamwork and communication in providing safe care. *Qual Saf Health Care.* 2004;13 Suppl 1(Suppl 1):i85–90. https://doi.org/10.1136/qhc.13.suppl_1.i85.
15. Christian CK, Gustafson ML, Roth EM, Sheridan TB, Gandhi TK, Dwyer K, Zinner MJ, Dierks MM. A prospective study of patient safety in the operating room. *Surgery.* 2006;139(2):159–73. <https://doi.org/10.1016/j.surg.2005.07.037>.
16. Panesar SS, Carson-Stevens A, Mann BS, Bhandari M, Madhok R. Mortality as an indicator of patient safety in orthopaedics: lessons from qualitative analysis of a database of medical errors. *BMC Musculoskelet Disord.* 2012;13:93. <https://doi.org/10.1186/1471-2474-13-93>.
17. Uramatsu M, Fujisawa Y, Mizuno S, Souma T, Komatsubara A, Miki T. Do failures in non-technical skills contribute to fatal medical accidents in Japan? A review of the 2010-2013 national accident reports. *BMJ Open.* 2017;7(2):e013678. <https://doi.org/10.1136/bmjopen-2016-013678>.
18. Flin RH, O'Connor P, Crichton M. Safety at the sharp end: a guide to non-technical skills. London: CRC Press; 2008. <https://doi.org/10.1201/9781315607467>.
19. Yule S, Paterson-Brown S. Surgeons' non-technical skills. *Surg Clin North Am.* 2012;92(1):37–50. <https://doi.org/10.1016/j.suc.2011.11.004>.
20. Mayer JD, Salovey P, Caruso DR, Sitarenios G. Emotional intelligence as a standard intelligence. *Emotion.* 2001;1(3):232–42.
21. McKinley SK, Phitayakorn R. Emotional intelligence and simulation. *Surg Clin North Am.* 2015;95(4):855–67. <https://doi.org/10.1016/j.suc.2015.03.003>.
22. Nurok M, Sundt TM 3rd, Frankel A. Teamwork and communication in the operating room: relationship to discrete outcomes and research challenges. *Anesthesiol Clin.* 2011;29(1):1–11. <https://doi.org/10.1016/j.anclin.2010.11.012>.
23. Williamson AM, Feyer AM. Moderate sleep deprivation produces impairments in cognitive and motor performance equivalent to legally prescribed levels of alcohol intoxication. *Occup Environ Med.* 2000;57:649–55. <https://doi.org/10.1136/oem.57.10.649>.

24. Orri M, Revah-Lévy A, Farges O. Surgeons' emotional experience of their everyday practice—a qualitative study. *PLoS One*. 2015;10(11):e0143763. <https://doi.org/10.1371/journal.pone.0143763>.
25. Stahel PF, Cobianchi L, Dal Mas F, Paterson-Brown S, Sakakushev BE, Nguyen C, Fraga GP, Yule S, Damaskos D, Healey AJ, Biffi W, Ansaloni L, Catena F. The role of teamwork and non-technical skills for improving emergency surgical outcomes: an international perspective. *Patient Saf Surg*. 2022;16(1):8. <https://doi.org/10.1186/s13037-022-00317-w>.
26. Guo KL. DECIDE: a decision-making model for more effective decision making by health care managers. *Health Care Manag (Frederick)*. 2020;39(3):133–41. <https://doi.org/10.1097/HCM.0000000000000299>.
27. Flin R, Yule S, Paterson-Brown S, Maran N, Rowley D, Youngson G. Teaching surgeons about non-technical skills. *Surgeon*. 2007;5(2):86–9. [https://doi.org/10.1016/s1479-666x\(07\)80059-x](https://doi.org/10.1016/s1479-666x(07)80059-x).
28. Moorthy K, Munz Y, Adams S, Pandey V, Darzi A. A human factors analysis of technical and team skills among surgical trainees during procedural simulations in a simulated operating theatre. *Ann Surg*. 2005;242(5):631–9. <https://doi.org/10.1097/01.sla.0000186298.79308.a8>.
29. Neily J, Mills PD, Young-Xu Y, Carney BT, West P, Berger DH, Mazzia LM, Paull DE, Bagian JP. Association between implementation of a medical team training program and surgical mortality. *JAMA*. 2010;304(15):1693–700. <https://doi.org/10.1001/jama.2010.1506>.
30. Young GJ, Charns MP, Daley J, Forbes MG, Henderson W, Khuri SF. Best practices for managing surgical services: the role of coordination. *Health Care Manag Rev*. 1997;22(4):72–81. <https://doi.org/10.1097/00004010-199710000-00010>.
31. Leuschner S, Leuschner M, Kropf S, Niederbichler AD. Non-technical skills training in the operating theatre: a meta-analysis of patient outcomes. *Surgeon*. 2019;17(4):233–43. <https://doi.org/10.1016/j.surge.2018.07.001>.
32. Spencer FC. Teaching and measuring surgical techniques: the technical evaluation of competence. *Bull Am Coll Surg*. 1978;63:9–12.
33. Cobianchi L, Dal Mas F, Verde JM, et al. Why non-technical skills matter in surgery. New paradigms for surgical leaders. *Discov Health Systems*. 2022;1:2. <https://doi.org/10.1007/s44250-022-00002-w>.
34. Martellucci J. Surgery and jazz: the art of improvisation in the evidence-based medicine era. *Ann Surg*. 2015;261(3):440–2. <https://doi.org/10.1097/SLA.0000000000000782>.

Chapter 10

High Reliability: The Next Frontier for Patient Safety in Surgery



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Introduction

The high standard of regulatory compliance-mandated patient safety protocols in the USA originates from decades of work by lawyers, legislators, and patient advocacy groups, rather than from a physician-driven approach to owning patient safety as a surgical responsibility [1]. Notably, most surgical complications and adverse patient outcomes do not originate from intraoperative technical errors but rather from deficiencies in non-technical skills, such as communication breakdown [1, 2]. The success of high reliability organizations (HROs) is based on high-performing teams, standardized communication, and redundant fail-safe backup options which

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prevent an error from causing harm [3]. In healthcare, the concept of high reliability does not imply that errors will not happen, but high reliability will ensure that errors do not lead to patient harm.

High Reliability in Surgery

Surgeons are under an increasing amount of pressure and expectation to perform at the highest level. They must deliver absolute diagnostic accuracy and infallible surgical quality under the conflicting paradigm of patient safety and maximal cost efficiency. In addition, surgeons are expected to have the highest standards of ethical values and professionalism, to be respected role models and mentors, dedicated teachers, academic researchers, and effective administrators [4]. These expectations are analogous to the task of squaring the circle. As the historic paradigm has shifted in the past two decades from a “*culture of blame and shame*” to a “*culture of systems safety*,” we have now reached a tipping point in which the expectations of “the system” are at their limit. A physician-driven approach is therefore needed to build and sustain a “*culture of individual accountability*” beyond systems safety [5]. A classic example is represented by hand hygiene—a simple core measure with an immense impact on patient safety as it relates to preventing hospital-acquired infections [6]. A “perfect system” may provide staff training programs and logistic support, including door signs and hand sanitizer dispensers in- and outside of patient rooms. However, in the absence of individual accountability and physician leadership, the expected goal of 100% hand hygiene compliance remains utopic. How is it possible that low-wage workers in the meatpacking industry are able to sustain 100% compliance with hand hygiene protocols? Intriguing insights from our own experience reveal that hand hygiene compliance rates drop from more than 90% when staff members feel observed and monitored, to less than 40% when unobserved. This phenomenon likely relates to the “Hawthorne effect” by which a subject’s behavior changes as a result of being observed and reflects poorly on the individual accountability of “doing the right thing” for our patients at all times. Therefore, senior surgeons are obligated to step up and act as role models to their junior colleagues in training by teaching non-technical virtues, including unwavering advocacy for patient safety, strict professionalism, effective communication, and individual accountability [7]. The ultimate benchmark for the success of surgeon mentors is to produce trainees who will be better surgeons and stronger patient advocates than their predecessors by embracing patient safety as a core surgical responsibility [4].

The historical approach to medical errors and surgical complications has consisted of blaming the surgeon who delivers direct patient care under the “blame and shame” paradigm. This antiquated culture of patient safety is based on the erroneous assumption that surgical errors may be prevented in the future by admonishing, blaming, suing, or firing surgeons. In contrast to “blame and shame” accountability entails that surgeons are in charge of their patient’s safety *independent of the outcome* [8]. The modern paradigm of patient safety revolves around “systems thinking” and “high reliability” in order to account for the notion that humans are prone to committing errors. The hallmark of a “high reliability

Table 10.1 Leading causes of death in the USA

1	Heart disease (696,000 deaths per year) ^a
2	Cancer (605,000 deaths per year) ^a
3	Medical errors (440,000 deaths per year) ^b
4	COVID-19 (417,000 deaths in 2021) ^a

^aXu J, et al., Mortality in the United States, 2021. *NCHS Data Brief*, No. 456, December 2022. (Retrieved from: www.cdc.gov/)

^bMakary MA, Daniel M. Medical error - the third leading cause of death in the US. *BMJ* 2016, 353: i2139

organization” (HRO) is not that it is error-free, but that errors do not disable it [3]. High reliability science represents the study of organizations in high-risk industries, such as commercial aviation and nuclear power technology, that maintain safety through redundant backup options in case of failure under hazardous conditions [3]. Unfortunately, errors in the surgical care of our patients frequently lead to unintentional harm on first occurrence in the absence of a “fail-safe” backup option, and our health care industry still shows significant gaps in achieving high reliability in a sustainable fashion. This notion is exemplified by shocking statistics which reveal that medical errors represent the third leading cause of death in the USA, after cardiovascular disease and cancer (Table 10.1) [9]. When comparing the evidence-based estimate of more than 400,000 preventable annual deaths occurring in US hospitals every year to professional aviation, this statistic is analogous to three Jumbo jets crashing each day, all year long, in perpetuity [10]. In this hypothetical scenario, the Federal Aviation Administration (FAA) would likely ground all commercial airplanes until the underlying error is recognized and irrevocably fixed [11]. In contrast, the medical profession continues to accept errors that lead to preventable patient harm as an unfortunate and inevitable “side effect” of modern health care [12].

Intriguingly, as it relates to the field of surgery, adverse events and complications are more frequently related to errors occurring *before* or *after* the procedure than by technical surgical mistakes [13]. These include: (1) a breakdown in communication; (2) a delay in diagnosis or failure to diagnose; or (3) a delay in treatment or failure to treat [14]. Surgeons are presented with challenges that reach far beyond purely technical aspects—the decision of initiating appropriate and timely surgical care, weighed against the risk of providing delayed or negligent care by choosing observation and/or non-operative treatment (“*to cut or not to cut*”). Many of the current limitations to the creation of a globally recognized and consistently practiced culture of patient safety stem from the lack of surgeon-driven leadership. Transparent leadership and credible role modeling are the prerequisites to ensure the unreserved buy-in by all members of the health care team for the adoption of safety practices, including strict adherence to patient safety checklists and core measures. From a pragmatic standpoint, surgeons can drive their own “high reliability practice” by implementing fundamental best-practice standards of patient safety derived from other HRO industries, including “team dynamics,” improved communication and non-technical skills, and the adoption of standardized safety checklists [15, 16].

The “Team Dynamics” Experience

The context of emergency and trauma surgery is complicated and characterized by high pressure, stress, and time restraints. Lack of knowledge about the trauma causes, the identity of the patients, and their existing circumstances or conditions can negatively affect surgical decision-making, leading to less effective clinical choices. Moreover, the situation may not allow the engagement with the patients or their families in order to understand their treatment preferences or wishes. While shared decision-making and co-production dynamics in a multistakeholder scenario stand today among the most relevant pillars of the patient-centric healthcare system, such processes may appear particularly challenging or even not be possible at all [17–19]. Furthermore, time constraints may not allow consulting the clinical guidelines or conferring with specialists for second opinions. In such a scenario, non-technical or soft skills look as relevant as technical abilities, as they allow multidisciplinary team members to work together smoothly [20]. Ensuring surgical patients’ safety and excellent clinical outcomes is a priority in emergency surgery. Still, while the surgical community has employed several efforts on the technical side, innovating surgical techniques and summarizing valuable clinical guidelines, a new approach should emerge. Therefore, as it happens in other industries, team performance and outcomes may also be increased by leveraging on more intangible aspects, including non-technical skills and team assembly decisions [21].

Starting from this premise, the “team dynamics” initiative carried on by the *World Society of Emergency Surgery* (WSES) stood as a multidisciplinary research project to investigate the role of non-technical skills, knowledge translation dynamics, and ethics in emergency and trauma surgery teams [22–25]. An online questionnaire following the CHERRIES checklist for online medical surveys was conducted from January to February 2021, gathering more than 400 fully filled questionnaires (response rate > 45%) from surgeons in 72 countries [26]. Results underline the perceived importance of non-technical skills, especially leadership and teamwork [21, 26]. Still, just a few surgeons declare to engage with the patients in shared decision-making processes actively [17]. While clinical guidelines and training are widely used among the participants, only half of them report using online tools and electronic medical records. Regarding ethical matters, some interesting results arise. The project investigated the role of surgical consent as a tool to engage and talk to the patient about the clinical options, the possible outcomes, and the pros and cons of the treatment, the perceived importance of the team leader as an ethical leader, and the relevance of ethical training. Interestingly enough, team members who declared to belong to a diverse group, meaning which members have different features (in terms of gender, age, education, nationality, and cultural values) paid the most significant attention to ethical-related matters. A more recent investigation enquiring the same community deepened the role of new emerging technologies, such as artificial intelligence, in supporting surgeons in making their clinical decisions. Despite the recognized potential of the latest technologies, even in limiting medical mistakes and preventing patients harm, surgeons were still skeptical about

their use, preferring more traditional decision-making support like training, guidelines, and peer consultations [27].

Starting from the “team dynamics initiative,” some takeaways emerge. Two relevant topics, namely the importance of shared decision-making and the adoption of advanced technological tools to empower surgical decision-making, should be on the agenda of the scientific societies to support the surgical community in ensuring the best possible outcomes for their patients [28]. Moreover, diversity in teams may boost the sensitivity toward patients’ engagement and shared decision-making. Therefore, team assembly decisions may represent a valuable strategy to be pursued by those institutions more engaged toward a patient-centric philosophy.

Surgical Safety Checklists

Most surgeons are intrinsically opposed to the use of checklists, as those appear to be imposed and mandated by third-party entities and appear to question the surgeons’ clinical and technical expertise for safely managing the surgical care of their patients [29]. Safety checklists do not make a surgeon any smarter, better trained, or more technically skilled. However, checklists provide a safeguard and protection from the human error of forgetting or skipping essential steps in a process, particularly when considering the high-stress and high-acuity environment, such as the trauma bay or the operating room [30]. Moreover, checklists have been named among the technical tools that facilitate knowledge translation processes, especially when multidisciplinary or temporary teams are in charge of a patient or a situation [31, 32]. In recent times, checklists have been used by medical scientific societies and professional associations to foster new practices. In such a context, we may name the recent checklists for greener (namely, environmentally sustainable) operating rooms published by the Royal Colleges of the United Kingdom [33].

Atul Gawande, the world-renowned patient safety “guru” and one of the innovative founders of the “Safe Surgery Saves Lives” campaign and WHO surgical safety checklist [34] provided a compelling argument for the use of checklists in his best-selling book “The Checklist Manifesto”:

In a complex environment, experts are up against two main difficulties. The first is the fallibility of human memory and attention, especially when it comes to mundane, routine matters that are easily overlooked under the strain of more pressing events. A further difficulty, just as insidious, is that people can lull themselves into skipping steps even when they remember them. Checklists seem to provide protection against such failures. [35]

The “Universal Protocol” by the Joint Commission represents the paradigm of a standardized, simple, and pragmatic surgical safety checklist. This is designed to avoid the “worst case scenario” complications in surgery, including operating on the wrong site or on the wrong patient [36]. The Universal Protocol was introduced in 2004 to United States hospitals participating in the Medicare/Medicaid program

(CMS) as a mandatory quality assurance checklist, consisting of the following three components:

1. A pre-procedure verification process.
2. Preoperative surgical site marking.
3. A preoperative “time-out” immediately prior to starting the procedure.

About one-third of all wrong-site and wrong-patient procedures have their genesis before patient admission to the hospital [37]. Potential scenarios include inaccurate clinic note dictations related to a wrong side, the mislabeling of radiographs or other diagnostic tests, or a mix-up of patients with similar or identical names. The rationale for conducting a pre-procedure verification process is to confirm: (1) patient identity, (2) the nature of the planned procedure, and (3) the correct surgical site [36]. Each patient is unequivocally identified by an identification bracelet which includes the patient’s name, birth date, and a medical record number. The pre-verification process further ensures the presence and adequacy of all relevant documents, including written informed consent and a current history and physical exam. The surgeon’s surgical plan and the team’s understanding of the planned procedure must be confirmed to be consistent with the patient’s expectations. A checklist is used to review and verify that all documents and pertinent information are available, accurate, and completed prior to moving the patient to the operating room.

Surgical site marking is performed as part of the pre-procedure verification process in the preoperative holding area. The following best-practice standards should be taken into consideration for a safe and accurate surgical site marking:

- Site marking must be performed by a licensed practitioner who is a member of the surgical team and will be present during the surgical “time-out” and during the procedure. Under ideal circumstances, site marking should be performed by the surgeon.
- The surgical site is marked in the preoperative holding area, before moving the patient to the operating room or to an interventional procedure room.
- The patient should be actively involved in confirming the correct surgical site marking, whenever possible.
- The site marking must be unambiguous by the use of unequivocally defined terminology, such as “YES,” “GO,” “CORRECT,” or “CORRECT SITE.” Surgical site marking with an “X” should be avoided as this may be misunderstood as “not this side.” The specific modality of marking must be defined in the respective facility’s policies and procedures.
- Additional marking of the contralateral side (e.g. “no” or “not this side”) is contraindicated, as this creates confusion and increases the risk of wrong-site surgery.
- The surgeon’s responsibility of correct site marking should be confirmed by adding the surgeon’s initials. The only exception is a surgeon with the initials “N.O.” since this may be confused with a “no” and imply that the marked site should not be operated on.

- Surgical site marking must be applied with indelible ink on skin, using permanent markers. The markers must be resistant to the surgical preparation process and remain visible at the time of skin incision. It should be noted that sterile markers are not required, since the published literature demonstrates that the use of non-sterile markers does *not* increase the risk of postoperative infections.
- The marking should be applied at or near the incision site. The side, level, and location of the procedure must be unequivocally defined by the marking, whenever possible (left vs. right; medial vs. lateral; flexor vs. extensor surface, etc.)
- Knowledge of contraindications for surgical site marking, including premature infants (risk of permanent tattoo), mucosal surfaces, teeth, and patients refusing a surgical site marking for personal reasons.
- Increased awareness in all cases where precise site marking is not possible (see below).
- Defined alternative processes should be implemented for any circumstance where surgical site marking is not feasible, to include pre- and intraoperative radiological diagnostics (e.g. spinal level marking with a needle, intraoperative arteriogram or cholangiogram, etc.)

There are specific instances in which surgical site marking may not be feasible for technical or anatomic reasons. For example, site marking is impracticable on mucosal surfaces and on the teeth. Site marking is furthermore contraindicated in premature infants due to the risk of inducing a permanent tattoo on the skin. In addition, some surgical sites are inaccessible to accurate external marking, including internal organs (general surgery), brain and spine (neurosurgery), vessels (interventional vascular procedures), and the pelvis (orthopedic surgery). Rarely, patients may refuse surgical site marking for cosmetic or other personal reasons.

An alternative process to site marking must be in place for all these circumstances. Radiological diagnostics may need to be consulted pre- and intraoperatively to determine the surgical site with accuracy. Unlike symmetric external body parts (extremities, eyes, ears), any *occult* surgical site cannot be easily confirmed and marked prior to surgery. Thus, these particular circumstances mandate the intraoperative localization and confirmation of the correct site (e.g. correct spine level by intraoperative fluoroscopy), in conjunction with a careful evaluation of preoperative imaging studies, such as CT, MR, angiography, or cholangiography.

The preoperative “time-out” represents the last part of the Universal Protocol and is performed immediately before the initiation of the planned procedure in the operating room. The time-out represents the final recapitulation and reassurance of accurate patient identity, surgical site, and planned procedure. In addition, the following items are confirmed during the time-out: correct patient positioning, known allergies, the need for perioperative antibiotics, the availability of relevant documents and diagnostic tests, instruments, and implants. The time-out is called by a designated member of the surgical team, e.g. the circulating nurse or the surgeon. A “two-stage” time-out process allows for the patient to be awake and participate in the verification process of patient identity, surgical site, and planned procedure (the so-called awake time-out) prior to induction of anesthesia. This is followed by a

second final time-out after surgical prepping and draping, and immediately before skin incision. All members of the surgical team (i.e. surgeon, anesthesiologist, certified registered nurse anesthetist (CRNA), circulating nurse, operating room technician, radiology technician, etc.) must be present in the operating room and actively participate in the time-out prior to skin incision. During the “time-out” all non-essential activities are suspended to an extent that does not compromise patient safety. The “time-out” should be repeated intraoperatively for every additional procedure performed on the same patient.

In essence, the three individual steps of the Universal Protocol checklist are intended to ensure correct patient identity, correct procedure, and correct surgical site. More importantly, this checklist empowers *any* member of the team to speak up and stop the procedure whenever there is an apparent inconsistency or risk to patient safety, independent of the hierarchy and culture in the operating room [38]. Pitfalls and limitations which may render the checklist less effective are hidden in each component of the protocol. The degradation of surgical safety checklists to a “robotic-hackneyed ritual” can be mitigated by the surgeon’s personal ownership and leadership with an unwavering and credible commitment to the checklist [39].

Non-technical Skills

Patient harm resulting from surgical complications is frequently derived from a communication breakdown within the care team rather than from a technical complication in the operating room. Published studies on closed claims by the American College of Surgeons revealed about 25% of all claims related to patients who sustained surgical harm were attributed to a breakdown in communication [13]. Of these, 85% of adverse events related to communication breakdown occurred by verbal communication [13]. While most surgeons perceive themselves as “good communicators,” in reality, less than 20% of all physicians have been formally trained on how to communicate with patients [2]. Ironically, the main predictor of patients’ perceptions of whether quality care was provided has no correlation with objective metrics of clinical care, but rather with the patients’ subjective perceptions of the *quality of communication* with their surgeon [40]. Multiple studies have shown that effective communication with patients is associated with a decreased incidence of claims and lawsuits, better clinical outcomes, improved patient compliance with recommended treatment regimens, and decreased unplanned readmission rates [2].

Surgeons are rarely trained in the competency around these “non-technical skills,” defined as the cognitive and social skills that characterize high-performing individuals and teams [41]. They broadly encompass (1) cognitive factors (situation awareness, decision-making), (2) social factors (communication, teamwork, leadership, task management), and (3) limitations of human performance (dealing with stress, fatigue, and burnout) [21]. There are several non-technical skills assessment tools available for surgeons and surgical teams. These include the “*Non-Technical Skills for Surgeons*” (NOTSS) system and the Oxford “*Non-Technical Skills*”

“Non-Technical Skills for Surgeons” (NOTSS) framework

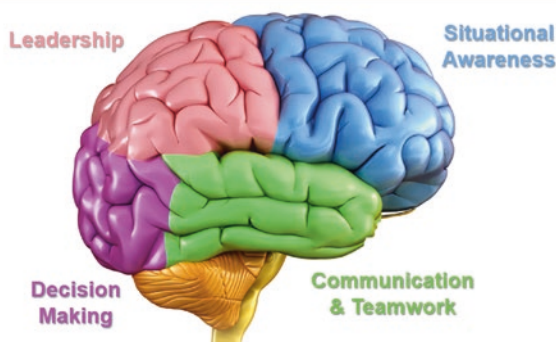


Fig. 10.1 The “Non-Technical Skills for Surgeons” (NOTSS) framework. See text for details and explanations. Adopted with permission through the Creative Commons Attribution 4.0 International License (<https://creativecommons.org/licenses/by/4.0/>), from: Stahel PF, et al., The role of teamwork and non-technical skills for improving emergency surgical outcomes: an international perspective. *Patient Saf. Surg.* 2022, 16:8. [© by the authors]

(NOTECHS) assessment tool [42]. These tools incorporate situational awareness, decision-making, communication skills, teamwork, and leadership (Fig. 10.1). The NOTSS program teaches structured observation, assessment and improvement in operative behavior, and subsequent performance [43]. Many applications in classrooms, clinical, coaching, simulation, and virtual learning forums have demonstrated the ability of surgeons to improve these skills. The specific NOTSS definitions provide a breadth of the non-technical skills concept:

- *Situational awareness*: “Developing and maintaining a dynamic awareness of the situation in the operating theater, based on assembling data from the environment (patient, team, time, displays, equipment); understanding what they mean, and thinking ahead about what may happen next.”
- *Decision-making*: “Skills for diagnosing a situation and reaching a judgment in order to choose an appropriate course of action.”
- *Team communication*: “Skills required for working in a team context to ensure that the team has an acceptable shared picture of the situation and can complete tasks effectively.”
- *Leadership*: “Leading the team and providing direction, demonstrating high standards of clinical practice and care, and being considerate about the needs of individual team members.”

The standardized use of “readbacks” for effective communication represents a fundamental pillar of commercial aviation safety [44]. In essence, a formal readback by the recipient of verbally communicated information ensures a standardized two-way communication. In the health care setting, readbacks represent a proven standard of structured language used to provide clarity and accuracy of verbal orders and critical test results, as mandated in the National Patient Safety Goals (NPSGs)

by the Joint Commission. While the current debate in the field is related to optimizing the modality of readbacks, this crucial form of communication is still virtually non-existent among surgeons. The renowned surgeon Dr. Eddie Hoover characterized the problem with the following quote: “*Getting surgeons to readback orders and instructions will age you 10 years, yet the Navies of the world have demonstrated for eons that it improves efficiency, promotes safety, and saves lives*” [45]. This notion provides the basis for a call for formal verbal “readback orders” among surgeons and other healthcare professionals in the perioperative setting with the goal of avoiding or reducing the high incidence of adverse surgical events related to a breakdown in communication [46].

Conclusion

The consistent assurance of patient safety in surgery remains challenging due to the risk stratification related to the surgical acuity and the patients’ individual underlying conditions, in conjunction with the wide variability of surgical care provided around the globe. High reliability organizations (HROs) in other high-risk industries outside of healthcare have provided the proof of concept that consistent safe performance is indeed achievable by designing streamlined processes with redundant fail-safe backup options. The key aspect of high reliability in healthcare consists of the imperative that a medical error or surgical complication will not directly lead to patient harm. Arguably, the next frontier in surgical patient safety is for surgeons to embrace the lessons learned from high reliability organizations as a “surgical responsibility.” This includes surgeon leadership and accountability toward adhering to standardized safety protocols, including surgical safety checklists, in conjunction with mastering non-technical skills, including tools of effective communication, with the goal of improving surgical patient outcomes with consistency on a global scale.

References

1. Stahel PF, Stahel VP. Principles of surgical patient safety. In: Pape HC, Borrelli J, Moore EE, Pfeifer R, Stahel PF, editors. *Textbook of polytrauma management: a multidisciplinary approach*. 3rd ed. Springer Nature; 2022. p. 631–40.
2. Stahel PF, Butler N. Effective communication: tips and tricks. In: Stahel PF, Mauffrey C, editors. *Patient safety in surgery*. New York, NY: Springer; 2014. p. 115–21.
3. Oster CA, Braaten JS. *High reliability organizations: a healthcare handbook for patient safety & quality*. 2nd ed. Indianapolis, IN: Sigma Theta Tau International; 2020.
4. Stahel PF. *Blood, Sweat & Tears: becoming a better surgeon*. Shropshire: TFM Publishing; 2016.
5. Di Saverio S, Tugnoli G, Catena F, Birindelli A, Coniglio C, Gordini G. Surgeon accountability for patient safety in the acute care surgery paradigm: a critical appraisal and need of having a focused knowledge of the patient and a specific subspecialty experience. *Patient Saf Surg*. 2015;9:38.

6. Fan CJ, Pawlik TM, Daniels T, et al. Association of safety culture with surgical site infection outcomes. *J Am Coll Surg*. 2016;222(2):122–8.
7. Wachter RM. *Understanding patient safety*. 2nd ed. New York, NY: McGraw-Hill; 2012.
8. Stahel PF, Mauffrey C. *Patient safety in surgery*. New York, NY: Springer; 2014.
9. Makary MA, Daniel M. Medical error—the third leading cause of death in the US. *BMJ*. 2016;353:i2139.
10. James JT. A new, evidence-based estimate of patient harms associated with hospital care. *J Patient Saf*. 2013;9(3):122–8.
11. Stahel PF. NASA's proven safety culture paradigm. *Safe Care*. 2015;4:54–7.
12. Stahel PF, Mauffrey C, Butler N. Current challenges and future perspectives for patient safety in surgery. *Patient Saf Surg*. 2014;8:9.
13. Greenberg CC, Regenbogen SE, Studdert DM, et al. Patterns of communication breakdowns resulting in injury to surgical patients. *J Am Coll Surg*. 2007;204(4):533–40.
14. Stahel PF. *Surgical patient safety: a case-based approach*. New York, NY: McGraw-Hill; 2018.
15. Cruz SS, Mick J. A high reliability Organization's use of the evidence-based practice process to eliminate an identified potential for wrong-site surgery. *AORN J*. 2020;112(5):520–3.
16. Ross J. Aviation tools to improve patient safety. *J Perianesth Nurs*. 2014;29(6):508–10.
17. Woltz S, Krijnen P, Pieterse AH, Schipper IB. Surgeons' perspective on shared decision making in trauma surgery. A national survey. *Patient Educ Couns*. 2018;101(10):1748–52.
18. Cobianchi L, Dal Mas F, Massaro M, et al. Hand in hand: a multistakeholder approach for co-production of surgical care. *Am J Surg*. 2022;223(1):214–5.
19. Dal Mas F, Biancuzzi H, Massaro M, Miceli L. Adopting a knowledge translation approach in healthcare co-production. A case study. *Manag Decis*. 2020;58:1841–62.
20. Briggs A, Raja AS, Joyce MF, et al. The role of nontechnical skills in simulated trauma resuscitation. *J Surg Educ*. 2015;72(4):732–9.
21. Stahel PF, Cobianchi L, Dal Mas F, et al. The role of teamwork and non-technical skills for improving emergency surgical outcomes: an international perspective. *Patient Saf Surg*. 2022;16:8.
22. Cobianchi L, Dal Mas F, Massaro M, et al. Team dynamics in emergency surgery teams: results from a first international survey. *World J Emerg Surg*. 2021;16:47.
23. Cobianchi L, Dal Mas F, Massaro M, Fugazzola P, Catena F, Ansaloni L. Knowledge management and dynamics as perceived by emergency surgery teams: a quantitative study. In: Garcia-Perez A, Simkin L, editors. *Proceedings of the 22nd European Conference on Knowledge Management (ECKM 2021)*. Coventry: Academic Conferences & Publishing International Ltd; 2021. p. 217–24.
24. Dal Mas F, Bagarotto EM, Cobianchi L. Soft skills effects on knowledge translation in healthcare. Evidence from the field. In: Lepeley MT, Beutell N, Abarca N, Majluf N, editors. *Soft skills for human centered management and global sustainability*. New York, NY: Routledge; 2021. p. 95–109.
25. Cobianchi L, Dal Mas F, Angelos P. One size does not fit all—translating knowledge to bridge the gaps to diversity and inclusion of surgical teams. *Ann Surg*. 2021;273(2):e34–6.
26. Eysenbach G. Improving the quality of web surveys: the checklist for reporting results of internet E-surveys (CHERRIES). *J Med Internet Res*. 2004;6(3):e34.
27. Cobianchi L, Piccolo D, Dal Mas F, et al. Surgeons' perspectives on artificial intelligence to support clinical decision-making in trauma and emergency contexts: results from an international survey. *World J Emerg Surg*. 2023;18(1):1.
28. Cobianchi L, Dal Mas F, Catena F, Ansaloni A. Artificial intelligence and clinical decision-making in emergency surgery. A research protocol. In: Sousa MJ, Kumar PS, Dal Mas F, Sousa S, editors. *Advancements in artificial intelligence in the service sector*. London: Routledge; 2022.
29. Biff WL, Gallagher AW, Pieracci FM, Berumen C. Suboptimal compliance with surgical safety checklists in Colorado: a prospective observational study reveals differences between surgical specialties. *Patient Saf Surg*. 2015;9:5.

30. Peceny P, Biffi WL. Surgical safety checklists - pitfalls and pearls. In: Stahel PF, editor. *Surgical patient safety: a case-based approach*. New York, NY: McGraw-Hill; 2018. p. 21–30.
31. Undre S, Healey AN, Darzi A, Vincent CA. Observational assessment of surgical teamwork: a feasibility study. *World J Surg*. 2006;30(10):1774–83.
32. Dal Mas F, Garcia-Perez A, Sousa MJ, Lopes da Costa R, Cobianchi L. Knowledge translation in the healthcare sector. A structured literature review. *Electron J Knowl Manag*. 2020;18:198–211.
33. The Royal College of Surgeons of Edinburgh; the Royal College of Surgeons of England; Royal College of Physicians and surgeons of Glasgow. *Intercollegiate green theatre checklist compendium of evidence*. Intercollegiate Green Theatre Checklist Compendium of Evidence, 2022. <https://www.rcseng.ac.uk/-/media/images/rcs/about-rcs/sustainability/greentheatre-checklist.pdf>. Accessed 27 May 2023.
34. Haynes AB, Weiser TG, Berry WR, et al. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Engl J Med*. 2009;360(5):491–9.
35. Gawande A. *The checklist manifesto: how to get things right*, vol. 1. New York, NY: Picador; 2010. p. 64.
36. Stahel PF, Mehler PS, Clarke TJ, Varnell J. The 5th anniversary of the "universal protocol": pitfalls and pearls revisited. *Patient Saf Surg*. 2009;3:14.
37. Stahel PF, Sabel AL, Victoroff MS, et al. Wrong-site and wrong-patient procedures in the universal protocol era: analysis of a prospective database of physician self-reported occurrences. *Arch Surg*. 2010;145(10):978–84.
38. Goldenberg MG, Elterman D. From box ticking to the black box: the evolution of operating room safety. *World J Urol*. 2020;38(6):1369–72.
39. Douglas N, Demedui S, Conlan K, et al. Surgical caps displaying team members' names and roles improve effective communication in the operating room: a pilot study. *Patient Saf Surg*. 2021;15:27.
40. Angelos P. Interventions to improve informed consent: perhaps surgeons should speak less and listen more. *JAMA Surg*. 2020;155(1):13–4.
41. Wood TC, Raison N, Haldar S, et al. Training tools for nontechnical skills for surgeons: a systematic review. *J Surg Educ*. 2017;74(4):548–78.
42. Pradarelli JC, Gupta A, Lipsitz S, et al. Assessment of the non-technical skills for surgeons (NOTSS) framework in the USA. *Br J Surg*. 2020;107(9):1137–44.
43. Yule S, Gupta A, Gazarian D, et al. Construct and criterion validity testing of the non-technical skills for surgeons (NOTSS) behaviour assessment tool using videos of simulated operations. *Br J Surg*. 2018;105(6):719–27.
44. Stahel PF. Learning from aviation safety: a call for formal "readbacks" in surgery. *Patient Saf Surg*. 2008;2:21.
45. Hoover EL. Patient safety and surgeons: why the resistance? *Arch Surg*. 2007;142(12):1127–8.
46. Prabhakar H, Cooper JB, Sabel A, Weckbach S, Mehler PS, Stahel PF. Introducing standardized "readbacks" to improve patient safety in surgery: a prospective survey in 92 providers at a public safety-net hospital. *BMC Surg*. 2012;12:8.

Chapter 11

Women in Surgery: A Long Way to Equity



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The History of Women in Surgery

Women in Medicine and Surgery

The history of women in surgery begins in 3500 before Christ (BC) in Mesopotamia where flint and bronze surgical instruments were uncovered from the grave of Queen Shubad of Ur [1]. Moreover, there are studies that support the presence in 1500 BC of female medical students in Heliopolis, Egypt [2], and there are also traces of an important role of women in surgery in ancient Greece. The *Tetrabiblion*, a manuscript of 150 common era (CE) authors described the surgical techniques of Aspasia, a Greco-Roman female surgeon. This served as the main surgical text into the 11th century [1].

During the Middle Ages, women were excluded from the medical and surgical practice. King Henry VIII, during the fourteenth century, said “No carpenter, smith, weaver or women shall practise surgery,” and banned women from the Company of Barber Surgeons, founded in 1540 [1]. However, during this period marked by discrimination, women continued to practice surgery in England and in North America.

With the advent of modern surgery and surgical training, we also find the names of the most famous heroines in the history of surgery. This period opens with the story of Dr. James Barry, a man who practiced medicine in the United Kingdom (UK), also called “the beardless lad” [3]. He joined the army as a surgeon during the Napoleonic wars and performed one of the first successful cesarean sections. At the

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time of his death, Dr. Barry was discovered to be a woman; the real name was Dr. Miranda Stewart.

While Dr. Miranda Stewart impersonated a man who practiced surgery in the UK, Dr. Elizabeth Blackwell was rejected by more than 20 medical schools in the USA, just because she was a woman. She was admitted to a New York medical school and in 1849 she graduated. Unfortunately, she did not obtain a residency position anywhere and ended up serving as an obstetrical nurse in France. In 1889 Dr. Blackwell was recognized as the first woman medical doctor in the USA [1, 4].

Half a century after Dr. Blackwell's graduation, women represented 6% of the national physician population [4]. However, the closure of all the women's medical colleges in 1910 caused a significant drop of the proportion, as low as 3%, of women in medical school. The percentage of women physicians would not increase again until the second half of the 20th century [5].

In 1867, the first female physician in Canada was Dr. Emily Jennings Stowe. She graduated at the New York Medical College for women, because Canadian medical schools did not admit her. Then, she took the license to practice by the College of Physicians and Surgeons of Ontario. During the same period, Dr. Mary Edwards Walker was recorded as the first female surgeon in the USA and in the US Army [6]. She was awarded the Medal of Honor and still is the one and only female recipient out of nearly 3500 medals of honor.

The era of women in surgery began during the twentieth century, when there was a rise of female representation in medical school and an initial presence of women in medical societies. The first British female surgeon was Dr. Elizabeth Garrett Anderson; she was the first female dean of a medical school, first female medical doctor in France, first woman to be elected to a school board, first female mayor in 1908, and first female magistrate in Britain [7].

Dr. Jennie Smillie Robertson was the first recorded female surgeon in Canada (1909); she was one of the founders of the Women's College Hospital and promote the Federation of Medical Women of Canada [1]. Moreover, Dr. Jessie Gray was named Canada's First Lady of Surgery in 1941 and served from 1946 as chief of surgery at the Women's College Hospital. In 1954, she was honored with the Elizabeth Blackwell Medal [7].

The first female surgeons deemed as Fellows of the American College of Surgeons (ACS) in the USA were Drs Florence W. Duckering and Alice G. Bryant. In 1934, Dr. Barbara Stimson was the first woman certified by the American Board of Surgery and the first woman member of both the New York Surgical Society and American Association for the Surgery of Trauma. Dr. Ruth Jackson, after passing her orthopedic board exam in 1937, became the first woman certified by the board and admitted to the American Academy of Orthopedic Surgeons [5].

Dr. Benjy Brooks was the first woman pediatric surgeon, and in 1958, she joined the staff at the Texas Children's Hospital and the Baylor University School of Medicine in Houston, and in 1973, she started and led the division of pediatric surgery at the new University of Texas Health Science Center at Houston. She was named to the Texas Women's Hall of Fame, and "Houston's Pioneer Women and Today's Leaders" by her adopted city.

Dr. Nina Starr Braunwald was first a beloved wife and mother of three children, and then the first surgeon to implant a prosthetic mitral valve into a human in 1960, the first woman to be certified by the American Board of Thoracic Surgery in 1963, the first woman elected to membership in the Association of Women Surgeons. Following her death in 1992, the establishment of Nina Starr Braunwald Research Awards boosted support for many of the successful women who practice cardiac surgery today [8]. Dr. Alma De Morani in 1943 was the first female member of the American Society of Plastic and Reconstructive Surgeons, which was founded in 1931.

The Foundation of Women's Surgical Societies

The last 50 years of surgical history have seen the development of women's surgical societies with the common aim to collect experiences of female surgeons in different surgical subspecialties and provide support to women surgeons (Table 11.1).

In 1981, Dr. Patricia Numann founded the Association of Women Surgeons (AWS) a not-for-profit educational and professional organization whose mission is to inspire, encourage, and enable women surgeons to realize their professional and personal goals. It has the aim to promote improvements in the workforce conditions for surgeons now and in the future. Since then, several other women's surgical societies have been founded as a testimony to the fact that women are facing similar problems at different timeframes and with some regional and cultural peculiarities. The aims of all these society include:

- promote surgery as a career for women and to enable women who have chosen a career in surgery to realize their professional goals,
- educate medical students and professionals (including men) and the society as a whole support of women surgeons,
- develop guidelines and policies to combat the numerous issues faced by all individuals in the surgical field,
- facilitate and support mentorship for women in surgical training and for undergraduates in medical schools,

Table 11.1 Surgical society

Society	Year	Country
Association of Women Surgeons (AWS)	1981	USA
Women in surgery (WinS)	1991	UK
Japan association of women surgeons	2007	Japan
Royal Australasian college of surgeons (RACS) women in surgery	2011	Australia and New Zealand
Women in surgery Italia (WIS Italia)	2015	Italy
Women in surgery Africa (WISA)	2015	Africa
Women surgeons Kuwait	2018	Kuwait
Women association surgeons Pakistan (WASP)	2019	Pakistan

- protect rights during maternity and issues related to it. Help to create balance between family and work, including options for flexible hours in training,
- action as intermediary if issues of harassment and discrimination become concerning.

A wind of change in Italy started in 2015 when Drs Isabella Frigerio and Gaya Spolverato founded Women in Surgery Italia (WIS Italia, www.womeninsurgeryitalia.it), with the progressive increase in female surgeons. This society is open to all surgeons, women, and men and wants to be the starting point for promoting initiatives aimed at achieving gender equality in surgery.

WIS Italia aims:

- to enable women of all ages and surgical specialties to pursue their profession and to develop their skills,
- to promote a workplace able to enhance: involvement, respect, growth, professional and human satisfaction,
- to encourage female surgeons' leadership,
- to create a network of contacts to increase training and professional opportunities.

Overall, the dedication of a few women pioneers paved the way for young women surgeons, and their will to share their invaluable experience is key to the development of a new generation of female leaders in the surgical field.

Women in Surgery: Statistics

The gender and equity analysis of the global health and social workforce outlined how women deliver global health whereas men lead it⁹. In particular, women represent 70% of global health workforce but hold only 25% of senior roles. Sixty-nine percent of global health organizations are headed by men and 80% of board chairs are men. Only 20% of global health organizations were found to have gender parity on their boards, and 25% had gender parity at senior management level. Furthermore, gender stereotypes have driven occupational segregation, sorting men and women into different kind of jobs. Men hold the majority of jobs in the surgical field whereas they account for only 10% of those entering nursing school. This horizontal segregation leads to the feminization of certain medical specialties such as pediatrics, pediatric surgery, obstetrics, gynecology, oncology, and dermatology [9].

Women face sexual harassment in greater measure; 30% of female medical academics in the USA reported sexual harassment compared with 4% of males [9].

The gender pay gap in health is 26–29%, higher than average for other sectors. This remains nearly universal and largely unexplained with a lifelong impact contributing to female poverty in old age [9].

According to the data reported by the Health Ministry in Italy at the beginning of 2020 [10], female medical doctors who works in Italy as attending were 51,199, representing 48.1% of the total compared to the 38.4% of 2010. They are on average

Table 11.2 Admissions in Italian universities. Academic Year 2019–2020 [11]

Residency	Total admissions	F%
Cardiac surgery	249	51.8
General surgery	2023	48.8
Maxillofacial surgery	167	59.8
Oral surgery	297	59
Pediatric surgery	146	28.7
Plastic surgery	288	66.6
Thoracic surgery	186	50.5
Vascular surgery	360	47.2
Neurosurgery	335	63.5
Total	4051	49.7

Table 11.3 General Surgery Residency admissions [11]

Academic Year	Total (M + F)	F%
1999–2000	1157	31.0
2006–2007	1291	39.0
2013–2014	1604	48.0
2019–2020	2023	48.9

younger than the male counterpart (48.9 years vs. 53.8 years) and they represent almost 63.5% of doctors younger than 45 years as opposed to those older than 45 years, underlying the generational change.

The increase in the female proportion does not correspond to an increase in leadership: only 17% of departments and 34.7% of units are led by women [10]. To confirm the horizontal segregation highlighted by the WHO [9], women represent only the 30.2% of surgeons in hospitals and 15% in academia. Even though there is a trend toward the increase of new female employees (59.9% of new hiring), again, there is still horizontal segregation. Only 25–26% are females in general, vascular and thoracic surgery and only 14–17% in subspecialties such as urology, orthopedics and neurosurgery (Table 11.2). In Italy, only 3.3% of full professors of surgery and 3% of chief of surgery are women.

According to the data of the Education Ministry in Italy, the percent of women entering general surgery residency was 48.9% in the academic year 2019/2020 compared to the 31% of 1999/2000. As depicted in Tables 11.3 and 11.4, it seems that some kind of bottleneck still exists as even though the women entering the residency in general surgery in 2013/2014 were 48%, the specialized female surgeons working in surgical departments in 2020 were 24.4% [11].

Type of Gender Discrimination

In 1984 Nora Frenkiel coined the term “glass ceiling” [12], and then Carol Hymowitz and Timothy Schellhardt in a 1986 defined this as “an invisible but impenetrable barrier between women and the executive suite preventing them from reaching the highest levels of the business world regardless of their accomplishments and

Table 11.4 Female Surgeons working as staff in Surgical Units, year 2020¹⁰

Specialty	N°	%
Cardiac surgery	115	15.8
Orthopedic surgery	606	15.2
Maxillofacial surgery	55	15.0
Urology	259	14.1
Pediatric surgery	152	36.5
Ophthalmology	652	32.1
Plastic surgery	152	27.8
ENT surgery	437	24.9
Vascular surgery	213	24.9
General surgery	1606	24.4
Thoracic surgery	98	23.4
Neurosurgery	220	22.8

merits.” The increasing number of women entering medical school does not reflect the rate of females pursuing surgical careers, even if a constant rise has been noted [13]. This slow but steady growth has opened a debate on gender inequality in surgery. Currently, in the USA [14] and most Western countries [15], the ratio of women in surgical training is far less than that of women in medical school, and surgical specialties are still facing difficulties in recruiting and retaining female surgeons. Different types of gender discrimination have been identified affected female surgeons at different stages of their career creating both evident and more subtle barriers. The reasons that hinder women from pursuing a surgical career include sexual and verbal harassment, implicit forms of verbal discrimination [16–19], discrimination in academic surgery [20], in surgical leadership [21] and in surgical society leadership [22]. Moreover, some studies showed that gender income gap appears to exist in surgery, where rigorous training, lengthy procedures, and significant on-call responsibilities are undeniable parts of the working routine and continuous dedication is a key to success. In this scenario, achieving and maintaining a state of balance between professional and personal life can become even more challenging especially for female surgeons [23].

Gender-Based Discrimination

Gender discrimination in modern working settings are deemed unacceptable and violate women’s rights, harms their health, and damages careers [24–26]. Many studies have showed that women who are victims of discrimination have anxiety, depression, and post-traumatic stress disorder [24, 27]. Moreover, these symptoms translate into damaged team dynamics, decreased job satisfaction, decreased productivity at the workplace, abandoning surgical training or retiring early [16].

An uncomfortable truth is that surgery and surgical training have a problem with sexual harassment, sexual assault, and rape. Some studies [12, 28–31] identified different types of gender discrimination that affect female surgeons' career at different stages. Explicit gender bias included sexual and verbal harassment, workplace marginalization, and bias in hiring and for promotions. Recent studies showed that 20–70% of female surgeons experienced sexual harassment [32, 33] in the form of unwanted verbal or physical conduct. Such conduct has been reported to come more frequently from attending surgeons, and the risk of being a victim was four times higher for residents and fellows compared to attending physicians [32]. Among women who experienced sexual harassment, only 5–15% filed a formal complaint [34]; and 50% of them reported that no action was taken after the reporting of their complaint.

A survey by Crebbling et al. [35] reports the prevalence in Australia and New Zealand of discrimination, bullying and sexual harassment in surgery. They showed that, among 3516 (47.8%) participants, 1516 (49.2%) respondents indicated that they had experienced one or more harassment. During the last 5 years, more than 70% of the participating hospitals reported episodes of discrimination, bullying or sexual harassment by a surgeon. Surgical directors or surgical consultants were by far the most frequently reported perpetrators. Moreover, females were more likely to experience discrimination (41%), bullying (58%), sexual harassment (36%) than males. The highest frequency of behaviors was sexually explicit or offensive jokes (59%), unwelcome sexual flirtations (56%), inappropriate physical contact (53%), and questions or insinuations about sexual or private life (52%).

A cross-sectional national survey from the USA [33] investigated the occurrence, nature, and reporting of sexual harassment in surgical training and to understand why surgical trainees who experience harassment might not report it. Among 7409, sexual harassment was reported by 10.3% (19.9% of female trainees overall). Of those women that did report, the perpetrators were most frequently patients or patients' families (31.2%) and consultant surgeons (30.9%), followed by trainees (15.4%) and nurses or staff (11.7%). The most cited reasons for not reporting were believing that the action was harmless (62.1%) and believing reporting would be a waste of time (47.7%).

Other surveys [12, 25, 36] analyzed the presence of sexual harassment in different surgical specialties. Whicker et al. [36] found that 68% of orthopedic surgeons experienced sexual harassment during their orthopedic training, without significant difference between current and past trainees (59% current vs. 71% past, $p = 0.10$). Similar findings have been reported by Ceppa et al. [25] in cardiothoracic surgery with 81% of female attending surgeons and 46% of males reporting that they had been sexually harassed ($P < 0.001$).

Nowadays, a subconscious form of discrimination based on previous social and psychological experiences and interactions is more common [30, 37, 38]. These are often forms of bias that individuals are not aware of, or unable to control. Different factors contribute to this form of discrimination [31]:

- Workplace discrimination such as lack of flexibility, long work hours, leave policy, role models, lack of mentorship, and exclusion from networks.
- Epistemic injustice (unfair assessments of women's' surgeons' credibility by patients and colleagues. Misrecognition by patients who assume that women are not surgeons).
- Stereotyped roles (colleagues' expectations about being friendly and caring domestic tasks and paperwork, patients' expectations to be empathetic and having high level of communications style).
- Objectification (feeling objectified by colleagues and patients about physical appearance and clothes).

Salles et al. [30] collected data among health-care professionals and surgeons about the presence of conscious and unconscious gender bias using "The Implicit Association Test," a validated tool used to measure implicit biases, which are mental associations shaped by one's environment that influence interactions with others. Results showed that healthcare professionals associated men with career and women with family, whereas surgeons associated men with surgery and women with family medicine. Ross et al. [39] queried 190 men surgeons about attitudes toward women surgeons utilizing a validated questionnaire. They found a bias of male surgeons against female colleagues: 10% considered female colleagues less capable to perform competent surgery, although 21% thought that male surgeons handle job stress better and 45% of responders recognized that discrimination against women in the field of surgery exists and that there is a negative attitude toward women being surgeons.

A large cross-sectional population-based study that compared the proportion of referrals made by male and female physicians to male and female surgeons, was to determine whether physicians' referrals to surgeons are influenced by the sex of the referring physician. This study found that male physicians referred a greater proportion of patients to male surgeons than to female surgeons and female surgeons received greater fractions of nonoperative referrals. These differences have not attenuated over time and were greatest in surgical specialties with the highest representation of female surgeons, suggesting that disparities will persist, even widen, as more women enter the field of surgery [40].

Discrimination in Leadership Positions

In the last century, the number of women entering medical schools has grown so much that they now represent more than 50% of medical students in Western countries [15]. However, there was not an equivalent increase in the number of women joining surgical specialties, and they are still underrepresented in leadership and academic positions [41]. Some reasons have contributed to this, including different types of discrimination, inequities in promotion, and lack of mentorship.

Several studies have been published to investigate gender discrimination in surgical leadership [21, 42, 43]. Although a great progress has been made in the advancement of women into leadership positions in surgery, there are still significant rooms for improvement. A persistent gender gap remains among leadership positions in US academic surgical departments despite increasing equality in trainee gender demographics. Currently, 29 (7.6%) of 379 chairs of surgical departments across the USA are held by women as of 31st December, 2021 [44]. In 2018, women filled 2 (8.3%) of the UK's corresponding presidential positions, 3 (11.8%) of vice-presidential positions and 18.1% of the executive committees, despite accounting for almost 27% of the workforce and 24% of surgical society members [45].

Weiss et al. [21] analyzed numbers of female medical students, residents, and faculty members in the USA obtained from the 2011 to 2012 Biannual Benchmark Report from the Association of American Medical Colleges, with the goal of this study is to evaluate the percentage of women in Chair, Program Director, Chief, and Associate Director positions in the USA, at academic and community-based programs. Authors found that there was a considerable higher female representation in the Program Director position than Chair position in General Surgery as compared with men. There was greater female representation in Associate Director role than Chief role in General Surgery, and there were significantly more women in the Chief versus Chair role, as well as a higher female percentage in the Associate Director position than Program Director position.

Moreover, Filiberto et al. [46] analyzed data of 811 US surgery fellowship programs across 14 specialties, with the aim of showed data regarding sex and academic rank of the leadership of fellowship programs are lacking. They showed that women are underrepresented among surgery fellowship program directors (18%), and that the percentage of women program directors was greatest in breast surgery (65%) and least in minimally invasive surgery (6%).

An international survey including female surgeons from USA, Japan, Finland, Hong Kong, and China, showed that female surgeons agreed that their representation in leadership positions should be increased. Different factors were considered responsible for impeding their advancement depending on the country. Japanese female surgeons identified a lack of a family support system as a main factor, whereas American female surgeons felt that latent gender discrimination played the main role [47].

Discrimination in Academia: Authorship, Research Productivity, Founding

Some studies showed that women are underrepresented in the surgical literature by means of either less publications or less citations than their male counterparts [48–51].

Xiao et al. [51] in a bibliometric analysis of research articles found that among 3604 authors of 1802 articles included, 22.6% first and senior authors were female. Similar results were found by Taira et al. [48] who evaluated first authorship among 664 original research articles, with 78.6% first authors being male surgeons. Also, two manuscripts [52, 53] showed that the paper presented at 2002, 2003, and 2004 annual meetings of the Association for Academic surgery and Society of University surgeons women authored only 9.1% of abstracts and 11.8% of resulting publications.

Gender bias exist also in funding received [54–56]. Atkinson et al. [55] found that among 1642 awards distributed in 20 years by different surgical societies, 74.3% were received by males and only 25.5% by females. Gender discrimination exists also for grant awarded within National Institutes of Health (NIH) funding, with mean NIH funding per grant for men higher than for women (\$365,760 men vs. \$292,912 women) [56].

Nevertheless, studies suggested that gender biases relating to academic leadership positions should be considered responsible of differences in publication rates between male and female surgeons [50]. Bernardi et al. [50] showed that women publish at rates proportional to their involvement in each specialty, and that female progress in academic surgery seems to be far more multifactorial and might depend on an amalgam of institutional policies and cultures, interactions with mentors, superiors, and colleagues as well as personal traits such as ambitions, perseverance, and perception of success.

Discrimination in Surgical Societies

A persistent gender gap remains among leadership positions in surgical societies and representation during conferences [57–59]. Among factors that may hinder women's surgical careers there is the low rate of women at surgical conferences [59].

Gerull et al. [59] determined the representation of women at surgical conferences among 14 US surgical societies in 2011 and 2016, to assess change over time. Women represented 23.8% of members (28,591/120,351), 19.4% of plenary speakers (25/129), 21.7% sessions speakers (1120/5161); 39.5% of the panels (353/893) were “all male panels.” There are relatively few opportunities for women to be plenary speakers, and there has not been a significant increase in the proportion of women selected to be plenary speakers over the two timepoints that we examined. However, there has been some improvement in the representation of women as session speakers and the number of all-male sessions over time.

Similar results have been showed by two study conducted during 2017 [58, 60], in which no increased in female authorship was observed between 2015 and 2018. These biases were even more pronounced in neurosurgical society conferences organized by three main American neurosurgical organizations between 2014 and

2018 [61]. There was no significant increase in female participation across the study period. There was no female presidents or honored guest at any academic meetings analyzed; 53.8% of executive committees comprised all men. Women often constituted a minority (<15%) of speakers and moderators.

Moreover, the number of female surgeons in leadership positions in surgical societies is still consistent low. Among 18 UK surgical societies only 8.3% had female residents, 15.2% had women in committee positions and 13.5% had a woman on the executive committee in 2018. Women as Committee Members have registered a slow but significant increase in the Society of American Gastrointestinal and Endoscopic Surgery between 1992 and 2018 from 3% in 1992 to 27% in 2018 [57]. A marginal change among women occupying leadership positions in the Society of Thoracic Surgeons (STS) and Annals of Thoracic Surgery Editorial Board was observed also comparing 2018 and 2015 archives from STS Annual Meetings (12.3% vs. 9.1%, $p = 0.092$ and 15.7% vs. 45.4%, $p = 0.029$) [60]. Similar results were demonstrated by Butler et al. analyzing female representation between 2014 and 2020 in the American College of Surgeons, the American Surgeons Association, and by McCoullough et al. [62] analyzing women representation between 2014 and 2018 in the American Society for Surgery of the Hand.

Work-Life Imbalance

In medical and especially surgical specialties, work-life balance is often discussed and difficult to achieve [23]. For surgeons, work can encompass many different tasks such as on-call responsibilities, operating, clinic, paperwork, teaching responsibilities, grant and paper writing, presentations, traveling to conferences, and journal reading. Life is generally everything else like physical needs (exercise, nutrition, personal health, sleep) and especially family and children. In any case, work-life conflict seems to affect women more strongly, as manifests their lower likelihood, in many settings, of having a spouse, getting married or having children than their male contemporaries. The reason why this might be occurring, is to be found in a society that is still very patriarchal, where men and women did not have equal opportunities for career progression in the surgical field, and female surgeons are responsible for the majority of housework and childcare, while the perception that having children and domestic duties were barriers to their professional development [63]. To increase the number of women enrolled in surgical specialties and balance lives of female surgeons, some interventions such as more flexible working hours, as well as adequate parental leave and childcare policies may be needed [64, 65].

An international survey involved 1111 surgeons from 53 countries [66] draws attention to the dramatic variation in leave policies and illustrates the need to define optimal policies for the support of a reliable surgical force while maintaining workplace safety and professional contributions. Respondents were asked who

determined policy regarding pregnancy and maternity leave in their country. In the USA, most respondents answered that their hospital or employer/administrator created policy (72%), followed by national government (29.8%) and individual supervisor (23.2%). National government was the most common response for participants from England, Ireland, Finland, and Italy. Surgeons in Italy were the most likely to be required to stop taking night call and operating and timing of reduction of work activity was upon declaration of pregnancy or first trimester (83%).

Work-life imbalance also include the topics of fertility, pregnancy, and motherhood. Female surgeons seem to face high rates of infertility as well as pregnancy complications [67, 68]. The reasons could include the physically demanding nature of surgery, and the difficulty of integrating pregnancy and motherhood into training or daily practice along with inadequate or indefinite parental leave, breastfeeding and childcare plans may result in perceiving pregnancy as stigma. Moreover, female surgeons deliberately delay first pregnancy or avoid it through elective abortions, to preserve concentration on surgical training and simultaneously prevent the negative attitude of their male and female peers and superiors.

Gender Pay Gap

A gender pay gap appears to exist in surgery. Pay gap may begin with how starting salaries are negotiated, creating a gap that continues to widen over time. Another factor may be pregnancy and childbearing; however, a study found that this discrepancy is maintained even after adjusting for seniority [69], suggesting that the gender pay gap existence is probably far more multifactorial.

A recent report of the Association of Women Surgeons declared that female surgeons earn nearly \$20,000 less annually than male surgeons, and this wage gap begins on entry into the workforce and widens over time: Women surgeons will earn 90% of what men are paid until age 35, and then that number drops to around 82% [70]. A large difference in salary was actually observed in the USA in surgery (\$329,097 versus \$285,369) [69], and among surgical specialties in orthopedic surgery were female make an average of \$491,770 a year (vs \$614,447 a year for male orthopedic surgeons). Moreover, Greys et al. [71] in their study of 407 residents across 19 U.S. general surgery programs, found that female general surgery residents expected their minimum acceptable starting salary to be \$18,198 less than men predicted theirs would be (\$249,502 vs \$267,700). They also reported their ideal starting salary to be \$29,954 less than their male counterparts (\$334,709 vs. \$364,663).

This gender pay gap may also be influenced by a referral bias that affects how quickly female surgeons can build up their practice, as showed by Dossa F. et al [40] that found that male physicians referred a greater proportion of patients to male surgeons than to female surgeons and female surgeons received greater fractions of nonoperative referrals.

How Can the Gender Gap in Surgery Be Minimized?

Manifest and occult barriers still prevent young women from enrolment, promotion, training opportunities, and career progression in surgical departments [31]. Some steps have been made to bridge the gender gap in surgery; however, gender imbalance remains prevalent in surgery. Despite discrimination and obstacles, no significant differences were shown between males and females in learning surgical skills, among neither medical students nor surgical trainee [72].

Some possible solutions have been proposed to overcome gender bias in surgery. The possibility to obtain flexible training and career options, the promotion of a less masculine image of surgery itself, the implementation of initiatives to improve work-life balance, the valorization of same sex mentors and role models have all been proposed as means to make surgery a woman-friendly career [73].

Constant controlling and reporting of incidents of harassment is required to reduce the rate of explicit gender bias. Moreover, to overcome implicit gender bias women need more autonomy in the operating room, also to perform more complex surgeries, and equal distribution of clinical tasks. Discrimination in academia needs equal chances for authorship and founding, easier female access to the full professor rank and meritocracy-based selection and promotion processes, especially during training. Residency program directors should understand the necessity of establishing gender equality through fair interview and selection processes [74]. Moreover, mentorship in surgery has been recognized to significantly contribute to career satisfaction, inclusion, and retention, and have a favorable effect on implementing research productivity, achieving personal development, and to pursue young surgeons to superior position. Mentorship has been widely acknowledged to play a crucial role during three distinct phases of surgical career: surgical training, the transition from trainee to attending in the first 3–5 years of practice, and the mid-career phase [75]. The different needs of mentees during their surgical training and practice require more than one mentor, and this phenomenon is described as “mosaic mentoring” and involves seeking mentors to match specific and sometimes short-term personal or career goals [76]. Women in surgery are less likely to have mentors, mainly due to the paucity of female surgeons who could be potential mentors. However, this group of surgeons might benefit the most from having same-gender mentors to gain a sense of inclusion and advance their careers. Social media is an important instrument for networking, mentoring and sponsorship [77] among female surgeons, partially overcoming the difficulties in finding same-gender mentors within single institutions. Social media represent a modern system to create a global network and help by sharing common experiences, enabling a connection between people around the world.

Structured mentorship programs have not been formally established in many countries; however, sporadic initiatives have been created in the form of pilot studies, with the aim to guide future structured systems [78]. Women in Surgery Italia (WIS Italia), the Italian association of women in surgery, along with the University of Padova, recently presented a project aimed to help female medical students with

an interest in surgery and female residents to find mentors among selected world-class institutions. The pilot project selected 25 mentors and 25 mentees and had its presentation meeting on June 29, 2022. In the future, online meetings between matched mentor and mentee will be organized with the aim to create support in training opportunities, role models, career advancement, and work-life balance.

All these efforts are inadequate without the active implementation of consensus-based policies for minimization of work-life imbalance, including the introduction of more concise training programs, more flexible working schedules, longer maternity leaves, even paternity leaves for spouses. Supportive measures could be applied not only for childcare but also for peers and faculty during maternity leaves. Finally, work modifications especially during late phases of pregnancy are required.

In everyday life of female surgeons, technology could represent a powerful mean to overcome inequities and could help remove some of the barriers that female surgeons face during their professional lives. Acknowledging this, artificial intelligence (AI) applied to the surgical field could have a potential role as an equalizer for women in surgery [79]. AI is currently being tested in clinical practice to aid preoperative diagnosis, staging, to predict response to treatment, and to support clinical decision-making during surgery. The widespread adoption of robotic surgery and its latest developments could be of great support for female surgeons, reducing the need for traveling, and contributing to a better work-life balance in a world where women are often both professionals and caregivers. Besides, robotic surgery contributes to remove physical strength barriers and could allow for female surgeons to continue performing surgery during pregnancy and childbearing. This is particularly relevant, since female surgeons have been reported to postpone pregnancy for various reasons, such as their training and career, which can result in negative impacts on infertility rates and obstetrical complications [80]. Another important application of AI is in the field of surgical training. Training and surgical mentoring could be provided remotely to surgeons residing in rural areas, which has already been successfully achieved. Again, the possibility to train anywhere and anytime could substantially contribute to ameliorating a female surgeon's work-life balance, allowing them to train during pregnancy and to maintain their role as caregivers without sacrificing their careers, and, ultimately, reducing the number of female surgeons who actually quit their job due to the difficulty in balancing their career and family life [67, 81].

Conclusions

Worldwide women in surgery still represent a small percentage, however, significant measures are required to respond to the increasing number of women joining surgical specialties. To achieve parity in surgery the first step is recognition of the issues and causes of discrimination of female surgeons. Further action is needed in combating such disparities and establishing a culture of equity for women in surgery. We also need a constant controlling and reporting of explicit and implicit gender bias and concrete intervention to break down disparities in academia, such

as investment in continuous surgical training, education to become lecturers, researchers, and scientists. Moreover, those surgeons currently in leadership positions play an important role in this fight for fairness and equality, contributing to career satisfaction, inclusion, and retention, and have a favorable effect on implementing research productivity, achieving personal development, and to pursue young surgeons to superior position.

References

1. Wirtzfeld DA. The history of women in surgery. *Can J Surg*. 2009;52(4):317–20.
2. Hospitals and Asylums of the World. *Hospital (Lond 1886)*. 1893;13(331):287–8.
3. Hacker C. Jennie Trout: an indomitable lady doctor whose history was lost for a half-century. *Can Med Assoc J*. 1974;110(7):841–3.
4. Baker R. Elizabeth Blackwell, the first woman doctor. *J Am Med Womens Assoc*. 1947;2(3):136–8.
5. Verdi D, Ferrari L, Capelli G, Mari V, Parini S, Tacconi G, et al. Women surgeons: how can we shape the future of new leaders? A celebration of the past with a glimpse of the future. *Surgery*. 2022;172(2):633–8.
6. Hartz RS. “The XX files”: demographics of women cardiothoracic surgeons. *Ann Thorac Surg*. 2001;71(2 Suppl):S8–13.
7. Ali AM, McVay CL. Women in surgery: a history of adversity, resilience, and accomplishment. *J Am Coll Surg*. 2016;223(4):670–3.
8. Blackmon SH, Carpenter AJ. Nina Starr Braunwald’s career, legacy, and awards: results of a survey of the thoracic surgery foundation award recipients. *Ann Thorac Surg*. 2018;106(2):633–6.
9. Delivered by women. Led by men: a gender and equity analysis of the global health and social workforce. Geneva: World Health Organization. Human Resources for Health Observer Series; 2019. p. 24.
10. <https://www.dati.salute.gov.it/dati/dettaglioDataset.jsp?menu=dati&idPag=62>.
11. <http://ustat.miur.it/dati/>.
12. Longo P, Straehley CJ. Whack! I’ve hit the glass ceiling! Women’s efforts to gain status in surgery. *Gend Med*. 2008;5(1):88–100.
13. Calise F, Spolverato G, Piccoli M. Gender gap or gender bias? That is the question. *Updat Surg*. 2021;73(1):3–5.
14. Association of American Medical Colleges. Women Were Majority of U.S. Medical school applicants in 2018. [Internet] 2021. <https://www.aamc.org/news-insights/press-releases/women-were-majority-us-medical-school-applicants-2018>.
15. Xepoleas MD, Munabi NCO, Auslander A, Magee WP, Yao CA. The experiences of female surgeons around the world: a scoping review. *Hum Resour Health*. 2020;18(1):80.
16. Liang R, Dornan T, Nestel D. Why do women leave surgical training? A qualitative and feminist study. *Lancet*. 2019;393(10171):541–9.
17. Acai A, Mahetaji K, Reid SE, Sonnadara RR. The role of gender in the decision to pursue a surgical career: a qualitative, interview-based study. *Can Med Educ J*. 2020;11(4):e51–61.
18. Janjua MB, Inam H, Martins RS, Zahid N, Sattar AK, Khan SM, et al. Gender discrimination against female surgeons: a cross-sectional study in a lower-middle-income country. *Ann Med Surg (Lond)*. 2020;57:157–62.
19. Barnes KL, McGuire L, Dunivan G, Sussman AL, McKee R. Gender bias experiences of female surgical trainees. *J Surg Educ*. 2019;76(6):e1–14.
20. Schroen AT, Brownstein MR, Sheldon GF. Women in academic general surgery. *Acad Med*. 2004;79(4):310–8.

21. Weiss A, Lee KC, Tapia V, Chang D, Freischlag J, Blair SL, et al. Equity in surgical leadership for women: more work to do. *Am J Surg.* 2014;208(3):494–8.
22. Butler PD, Pugh CM, Meer E, Lett E, Tilahun ED, Sanfey HA, et al. Benchmarking accomplishments of leaders in American surgery and justification for enhancing diversity and inclusion. *Ann Surg.* 2020;272(6):897–903.
23. Hill E, Solomon Y, Dornan T, Stalmeijer R. “You become a man in a man’s world”: is there discursive space for women in surgery? *Med Educ.* 2015;49(12):1207–18.
24. Cortina LM, Jagsi R. What can medicine learn from social science studies of sexual harassment? *Ann Intern Med.* 2018;169(10):716–7.
25. Ceppa DP, Dolejs SC, Boden N, Phelan S, Yost KJ, Donington J, et al. Sexual harassment and cardiothoracic surgery: #UsToo? *Ann Thorac Surg.* 2020;109(4):1283–8.
26. Lancet T. Time’s up for sexual harassment in medicine. *Lancet.* 2018;391(10140):2576.
27. Dzau VJ, Johnson PA. Ending sexual harassment in academic medicine. *N Engl J Med.* 2018;379(17):1589–91.
28. Parini S, Lucidi D, Azzolina D, Verdi D, Frigerio I, Gumbs AA, et al. Women in surgery Italia: National Survey Assessing Gender-Related Challenges. *J Am Coll Surg.* 2021;233(5):583. https://journals.lww.com/journalacs/Fulltext/2021/11000/Women_in_Surgery_Italia__National_Survey_Assessing.1.aspx.
29. Schlick CJR, Ellis RJ, Etkin CD, Greenberg CC, Greenberg JA, Turner PL, et al. Experiences of gender discrimination and sexual harassment among residents in general surgery programs across the US. *JAMA Surg.* 2021;156(10):942–52.
30. Salles A, Awad M, Goldin L, Krus K, Lee JV, Schwabe MT, et al. Estimating implicit and explicit gender bias among health care professionals and surgeons. *JAMA Netw Open.* 2019;2(7):e196545.
31. Ferrari L, Mari V, Parini S, Capelli G, Tacconi G, Chessa A, et al. Discrimination toward women in surgery: a systematic scoping review. *Ann Surg.* 2022;276(1):1–8.
32. Hu YY, Ellis RJ, Hewitt DB, Yang AD, Cheung EO, Moskowitz JT, et al. Discrimination, abuse, harassment, and burnout in surgical residency training. *N Engl J Med.* 2019;381(18):1741–52.
33. Freedman-Weiss MR, Chiu AS, Heller DR, Cutler AS, Longo WE, Ahuja N, et al. Understanding the barriers to reporting sexual harassment in surgical training. *Ann Surg.* 2020;271(4):608–13.
34. Nayyar AKKG. A National Survey of sexual harassment among surgeons. 2019.
35. Crebbin W, Campbell G, Hillis DA, Watters DA. Prevalence of bullying, discrimination and sexual harassment in surgery in Australasia. *ANZ J Surg.* 2015;85(12):905–9.
36. Whicker E, Williams C, Kirchner G, Khalsa A, Mulcahey MK. What proportion of women orthopaedic surgeons report having been sexually harassed during residency training? A survey study. *Clin Orthop Relat Res.* 2020;478(11):2598–606.
37. Hutchison K. Four types of gender bias affecting women surgeons and their cumulative impact. *J Med Ethics.* 2020;46(4):236–41.
38. Brownstein M, Saul J. Implicit bias and philosophy. In: *Metaphysics and epistemology*, vol. 1. Oxford: Oxford University Press; 2016.
39. Ross SB, Jadick MF, Spence J, DeReus H, Sucandy I, Rosemurgy AS. Men surgeons’ perceptions of women surgeons: is there a bias against women in surgery? *Surg Endosc.* 2020;34(11):5122–31.
40. Dossa F, Zeltzer D, Sutradhar R, Simpson AN, Baxter NN. Sex differences in the pattern of patient referrals to male and female surgeons. *JAMA Surg.* 2022;157(2):95–103.
41. Epstein NE. Discrimination against female surgeons is still alive: where are the full professorships and chairs of departments? *Surg Neurol Int.* 2017;8:93.
42. Battaglia F, Farhan SA, Narmeen M, Karimuddin AA, Jalal S, Tse M, et al. Does gender influence leadership roles in academic surgery in The United States of America? A cross-sectional study. *Int J Surg.* 2020;83:67–74.
43. Carpenter AM, Tan SA, Costopoulos K, Cooper LA, Sarosi GA, Shaw CM. Gender diversity in general surgery residency leadership. *J Surg Educ.* 2018;75(6):e68–71.

44. American Association of Medical Colleges Table C: department chairs by department, sex, and race/ethnicity, 2019. [Internet]. 2020. <https://www.aamc.org/system/files/2020-01/2019%20Supplemental%20Table%20C.pdf>.
45. Skinner H, Burke JR, Young AL, Adair RA, Smith AM. Gender representation in leadership roles in UK surgical societies. *Int J Surg*. 2019;67:32–6.
46. Filiberto AC, Le CB, Loftus TJ, Cooper LA, Shaw C, Sarosi GAJ, et al. Gender differences among surgical fellowship program directors. *Surgery*. 2019;166(5):735–7.
47. Kawase K, Carpelan-Holmström M, Kwong A, Sanfey H. Factors that can promote or impede the advancement of women as leaders in surgery: results from an international survey. *World J Surg*. 2016;40(2):258–66.
48. Taira BR, Jahnes K, Singer AJ, McLarty AJ. Does reported funding differ by gender in the surgical literature? *Ann Surg*. 2008;247(6):1069–73.
49. Mayer EN, Lenherr SM, Hanson HA, Jessop TC, Lowrance WT. Gender differences in publication productivity among academic urologists in the United States. *Urology*. 2017;103:39–46.
50. Bernardi K, Lyons NB, Huang L, Holihan JL, Olavarria OA, Loor MM, et al. Gender disparity among surgical peer-reviewed literature. *J Surg Res*. 2020;248:117–22.
51. Xiao N, Mansukhani NA, Mendes de Oliveira DF, Kibbe MR. Association of author gender with sex Bias in surgical research. *JAMA Surg*. 2018;153(7):663–70.
52. Sharkey MS, Feinn RS, Cahill SV, Batter A, Nduaguba AM, Cassese T, et al. Abstract submission and acceptance rates for men and women in Academic Pediatric Orthopaedic Surgery: an analysis of POSNA annual meeting abstract submissions 2012–2015. *J Pediatr Orthop*. 2019;39(1):e77. https://journals.lww.com/pedorthopaedics/Fulltext/2019/01000/Abstract_Submission_and_Acceptance_Rates_for_Men.25.aspx.
53. Housri N, Cheung MC, Koniaris LG, Zimmers TA. Scientific impact of women in academic surgery. *J Surg Res*. 2008;148(1):13–6.
54. Krebs ED, Narahari AK, Cook-Armstrong IO, Chandrabhatla AS, Mehaffey JH, Upchurch GR, et al. The changing face of academic surgery: overrepresentation of women among surgeon-scientists with R01 funding. *J Am Coll Surg*. 2020;231(4):427–33.
55. Atkinson R, Lu P, Cho NL, Melnitchouk N, Kuo LE. Gender disparities in award recipients from surgical specialty societies. *Surgery*. 2019;166(3):423–8.
56. Silva NA, Cerasiello SY, Herendeen JS, Sotayo A, Say I, Mazzola CA, et al. Gender differences in NIH grant funding in neurological surgery. *J Clin Neurosci*. 2020;80:43–9.
57. Dumitra TC, Alam R, Fiore JF, Mata J, Fried GM, Vassiliou MC, et al. Is there a gender bias in the advancement to SAGES leadership? *Surg Endosc*. 2020;34(1):458–63.
58. Davids JS, Lyu HG, Hoang CM, Daniel VT, Scully RE, Xu TY, Phatak UR, Damle A, Melnitchouk N. Female representation and implicit gender bias at the 2017 American Society of Colon and Rectal Surgeons' Annual Scientific and Tripartite Meeting. *Dis Colon Rectum*. 2019;62:357.
59. Gerull KM, Wahba BM, Goldin LM, McAllister J, Wright A, Cochran A, et al. Representation of women in speaking roles at surgical conferences. *Am J Surg*. 2020;220(1):20–6.
60. Olive JK, Preventza OA, Blackmon SH, Antonoff MB. Representation of women in the Society of Thoracic Surgeons authorship and leadership positions. *Ann Thorac Surg*. 2020;109(5):1598–604.
61. Silva N, Cerasiello S, Semonche A, Sotayo A, Luis J, Shao B, et al. Gender representation at neurological surgery conferences. *World Neurosurg*. 2019;129:453–9.
62. McCullough M, Willacy RA, Luong M, Abzug JM, Poon S. A 5-year review of the designated leadership positions of the American Society for Surgery of the Hand (ASSH). *J Hand Surg Am*. 2021;46(2):151.e1–5.
63. Crompton R, Lyonette C. Women's career success and work–life adaptations in the accountancy and medical professions in Britain. *Gend Work Org*. 2011;18(2):231–54.
64. Rangel EL, Lyu H, Haider AH, Castillo-Angeles M, Doherty GM, Smink DS. Factors associated with residency and career dissatisfaction in childbearing surgical residents. *JAMA Surg*. 2018;153(11):1004–11.

65. Acai A, Steyn C, Reid SE, Sonnadara RR. A solution to gender inequity in surgery? Better caregiving policies. *Can J Surg.* 2018;61(1):6.
66. Walsh DS, Gantt NL, Irish W, Sanfey HA, Stein SL. Policies and practice regarding pregnancy and maternity leave: an international survey. *Am J Surg.* 2019;218(4):798–802.
67. Rogers AC, Wren SM, McNamara DA. Gender and specialty influences on personal and professional life among trainees. *Ann Surg.* 2019;269(2):383. https://journals.lww.com/annalsofsurgery/Fulltext/2019/02000/Gender_and_Specialty_Influences_on_Personal_and.31.aspx.
68. Phillips EA, Nimeh T, Braga J, Lerner LB. Does a surgical career affect a Woman's child-bearing and fertility? A report on pregnancy and fertility trends among female surgeons. *J Am Coll Surg.* 2014;219(5):944. https://journals.lww.com/journalacs/Fulltext/2014/11000/Does_a_Surgical_Career_Affect_a_Woman_s.11.aspx.
69. Jena AB, Olenski AR, Blumenthal DM. Sex differences in physician salary in US public medical schools. *JAMA Intern Med.* 2016;176(9):1294–304.
70. Statement on gender salary equity. <https://www.womensurgeons.org/page/SalaryStatement>.
71. Gray K, Neville A, Kaji AH, Wolfe M, Calhoun K, Amersi F, et al. Career goals, salary expectations, and salary negotiation among male and female general surgery residents. *JAMA Surg.* 2019;154(11):1023–9.
72. Ali A, Subhi Y, Ringsted C, Konge L. Gender differences in the acquisition of surgical skills: a systematic review. *Surg Endosc.* 2015;29(11):3065–73.
73. Bellini MI, Graham Y, Hayes C, Zakeri R, Parks R, Papalois V. A woman's place is in theatre: women's perceptions and experiences of working in surgery from the Association of Surgeons of Great Britain and Ireland women in surgery working group. *BMJ Open.* 2019;9(1):e024349.
74. Beasley SW, Khor SL, Boakes C, Jenkins D. Paradox of meritocracy in surgical selection, and of variation in the attractiveness of individual specialties: to what extent are women still disadvantaged? *ANZ J Surg.* 2019;89(3):171–5.
75. Ferrari L, Mari V, Capelli G, Spolverato G. Mentorship and early career mentorship. *Art Int Surg.* 2022;2:177–85.
76. Bettis J, Thrush CR, Slotcavage RL, Stephenson K, Petersen E, Kimbrough MK. What makes them different? An exploration of mentoring for female faculty, residents, and medical students pursuing a career in surgery. *Am J Surg.* 2019;218(4):767–71.
77. Corsini EM, Boeck M, Hughes KA, Logghe HJ, Pitt SC, Stamp N, et al. Global impact of social media on women in surgery. *Am Surg.* 2020;86(2):152–7.
78. Ullrich LA, Jordan RM, Bannon J, Stella J, Oxenberg J. The mentor match: a new approach to implementing formal mentorship in general surgery residency. *Am J Surg.* 2020;220(3):589–92.
79. Spolverato G, Capelli G, Majidi D, Frigerio I. Statement on artificial intelligence surgery by women-in-surgery—Italia: can artificial intelligence be the great equalizer in surgery? *Art Int Surg.* 2021.
80. Gumbs AA, Frigerio I, Spolverato G, Croner R, Illanes A, Chouillard E, et al. Artificial intelligence surgery: how do we get to autonomous actions in surgery? *Sensors.* 2021;21(16):5526.
81. Park J, Minor S, Taylor RA, Vikis E, Poenaru D. Why are women deterred from general surgery training? *Am J Surg.* 2005;190(1):141–6.

Chapter 12

Shared Decision-Making and Coproduction in Surgery: The Patient Is the Cure



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Coproduction and Shared Decision-Making in the Modern Healthcare Scenario

The modern healthcare ecosystem sees a patient-centric perspective [1]. Not only should healthcare institutions promote adequate knowledge translation processes to ensure that the patient is fully aware of what is going on [2], but the patient is often called to codesign his or her care path [3].

Healthcare coproduction (or coproduction) is the process in which patients, as users who benefit from the healthcare service, cooperate along with clinicians in defining their care path [4–6]. Patients actively engaged in the coproduction of their care are supposed

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to be fully aware of the pros and cons of their choices, the consequences, and those behaviors that may favor the clinical outcome or the healing process [7].

Coproduction may also mean sharing the responsibility with the clinician, which is why full coproduction may not be feasible for every one [5]. The variety of the patients (young vs. elderly, level of education, knowledge on healthcare-related issues, the possibility of being supported by family members or patients' associations, ...) may largely affect the patient's attitude to understanding his or her condition, making decisions, and sticking to a chosen treatment path. To facilitate such a process and bridge the gaps between healthcare professionals and patients, the literature and practice [8, 9] recommend that adequate knowledge translation mechanisms and tools be implemented [10].

Among these facilitators, we may name technology-based tools like mobile electronic records [11] and web portals [12]. Technical skills-based tools are represented by cases [13], guidelines [14], journal publications [15], evidence based-methods [16], among others. Also, non-technical or soft skills-based tools are helpful in facilitating the cooperation between patients and medical teams, for instance, the use of interpersonal skills [17, 18], simple language [19], metaphors and examples [20], and ethics [21, 22]. Education also stands as a powerful facilitator in enhancing the translation of knowledge through webinars [23], training [24], leaflets and brochures [25], lessons learned and best practices [9]. Tools based on creativity may also be employed, for instance, through design [26]. Last but not least, social activities may also be valuable, for example, multistakeholder engagement approaches [27], committees and meetings [28], multidisciplinary teams [29, 30], discussions [31], and communities of practices [18].

All in all, clinicians and healthcare institutions are encouraged to promote coproduction dynamics with their patients whenever possible or feasible, enhancing patients' satisfaction.

One of the processes that are considered part of coproduction is shared-decision making (SDM). SDM has been defined by the literature as "a collaborative process in which patients and healthcare professionals make healthcare decisions based on the best available evidence and on patients' priorities" [32]. When engaging in SDM, clinicians and patients collaborate to make medical decisions based on the best available evidence but also consider the patients' treatment preferences, wishes, and values. Like coproduction, SDM is expected to increase patients' adherence to treatment and, as a result, the clinical outcome. Sometimes clinical decisions are preference-sensitive, meaning that two or more feasible choices exist, and the preferred option should be valued based on how the patient assesses and values the risks and potential advantages [33, 34].

Shared Decision-Making in Complex Surgical Contexts

SDM is a standard paradigm in elective surgery [35], when multiple reasonable options arise. Still, there are some surgical contexts in which engaging in SDM practices may be challenging for surgeons, like in trauma and emergency settings [33, 34].

Trauma and emergency teams are made up of various clinical professionals with different expertise, including emergency physicians, surgeons, anesthesiologists, and nurses. Such team members are required to collaborate to provide high-quality care in the face of challenging conditions that often comprise stressful situations with time constraints and limited knowledge regarding the causes of the trauma, the patient's identity, current circumstances or conditions, or care preferences [14]. In such cases, trauma and emergency professionals may not have enough time to discuss with their patients and their dear ones the severity of the situation, the feasible treatment choices, or what they may expect in the short and long post-treatment period [36].

Recent investigations conducted among Dutch trauma and emergency surgeons highlighted several barriers and difficulties in applying and measuring SDM practices [34]. In some trauma or emergency contexts, physicians need to make a decision quickly as the patient's life may be in danger. Still, there are other clinical situations which may provide emergency doctors several hours or more before treatment begins. In such cases, physicians should ensure to give the patients enough time to learn about their alternatives and make an informed decision about the next clinical steps.

A literature review of the topic of SDM in trauma and emergency settings conducted on 20 articles grabbed from Scopus depicted some exciting results [37], reported as follows.

- Most studies were conducted in the USA and the Netherlands, meaning that those two countries are more sensitive toward the topic, as the supporting literature recalls;
- Regarding the specific surgical specialties, most articles refer to emergency general surgery (46% of the sample) and orthopedics (30% of the sample), with hip and knee surgery as the most mentioned surgery type [32, 38, 39];
- Scholars did engage in multiple research methodologies to analyze such a complex topic, including qualitative semi-structured interviews, scoring, retrospective analysis of registry data, quantitative cross-sectional, expert opinions, narrative reviews, quantitative logistic regression, and quantitative observational studies,
- Several decision aids can be employed to support the dialogue between trauma and emergency surgeons and their patients or families, including empathy, high-quality communication, upfront and open communication, multidisciplinary collaborations, checklists, scoring methods, open-access datasets, patient and family handbooks, but also videos and clinical vignettes;
- Many positive impacts can be named, including better clinical outcomes, as SDM can “facilitate and enhance the quality of patient recovery after surgery, illness, or trauma” [40]. Other benefits include better management of patients' expectations [41], exclude or limit surgery when not necessary [42], more effective and efficient patient management [43] with effects on patient-centric approaches [38] and coproduction dynamics [44] with an overall more satisfying hospital experience [45]. Moreover, SDM can lead to cost reductions [38] and better adherence to ethical norms [32];

- Several barriers to the practical application of SDM can arise, including non-technical skill-based barriers, resource-based barriers, process-based barriers, and situation-based barriers. Some examples are a misunderstanding between patients and professionals, time constraints in managing communication, high patient and work loads, the fear of unnecessarily frightening patients, insufficient multidisciplinary collaboration, the lack of studies and training, and cultural issues and mindsets.

Results from the World Society of Emergency Surgery Experience

Starting from these premises, the World Society of Emergency Surgery (WSES) launched an initiative within its Team Dynamics Study Group [14, 46] to investigate the barriers, facilitators, and dynamics of SDM in trauma and emergency settings by employing a multi-national survey [47].

The questionnaire, launched in November 2021 and kept open until August 2022, was filled in by 650 surgeons. Questions were built on the recent literature and comprised both 5-point Likert scale enquires and some open questions, which were manually analyzed by the research team. Participants came from 71 countries on the five continents.

Fascinating results, in line with the Dutch experience [34], were gathered from the investigation:

- While the majority of surgeons claimed to be familiar with the term “SDM,” only 45% of the participants, in fact, were able to offer a definition that matched the idea of the patient being involved in the clinical decisions. More than 11% of the participants were unaware of what SDM was, and another 30% thought it meant something else different and incorrect. Multiple times, the term “multidisciplinary” was used to emphasize the effort to work together by speaking with colleagues who have various backgrounds or areas of expertise. The procedure of clinical decision-making was still perceived as a “doctors-only” task, with the patient not being able to contribute, and several surgeons mentioned the necessity to find a solution “in the best patient’s interests” to demonstrate how much they care about their patients’ outcomes. However, it appears that involving the patients and their families in the decision-making process is neither feasible nor beneficial. According to the majority of participants, clinical teams are skilled at what they do, and they can collaborate to choose the optimal clinical course of action given the circumstances. The team’s effective knowledge translation and communication processes, which also involve non-technical abilities like leadership, are the focus of all efforts, which still remains within the boundaries of the clinical working team;
- Several obstacles and barriers associated with participating in SDM procedures arise. While surgeons seem to value the patient’s wishes when they appear clear, they are less willing to “explore” such preferences when they are not openly

expressed or perhaps when patient engagement requires a conversation with time and communication efforts.

- When asked about potential scenarios or circumstances in which SDM might be successfully employed, surgeons did offer a number of instances, including appendicitis/diverticular disease, acute abdomen, acute cholecystitis, bowel obstruction, colon cancer, and fracture;
- In accordance with the results grabbed from the recent literature [37], participants named clinical guidelines and training as supportive factors for such practices, but surgeons appear to place less faith in technological advancements and online resources.

Implications and Future Research Avenues

Both literature and practice have recognized the importance of coproduction and SDM in the modern patient-centric healthcare and surgical system [48]. Sharing knowledge with the patients and their families and supporting them in co-decide about multiple reasonable clinical options stands today as a relevant ethical and moral duty for the surgeons and medical team involved.

Although SDM practices are pretty common in surgery, not all surgical specialties seem ideal and suitable for SDM. The challenging contexts in which trauma and emergency surgeons operate represent a sound example. The recent literature [14, 34, 37] has reported several issues for trauma and emergency surgeons to employ SDM with their patients, even when the time or diagnosis would allow them to do so.

Cutting-edge research should deepen and share the decision aids and knowledge translation tools to facilitate such a process, especially those based on soft or non-technical skills. Interestingly enough, more technical tools such as checklists and scores that are employed by surgeons are little related to modern technologies such as artificial intelligence (AI)-based applications, which today represent sound decision-making supports for surgeons [46, 49–52]. New research avenues should investigate how web-based applications and other high-tech means may support and facilitate the relationship between clinical teams and patients, even in emergency settings, and the degree of technology acceptance.

Identifying facilitators and barriers is also valuable to both scholars and practitioners. While training and education stand as the most valued strategies, time and resource constraints limit the possibility of the surgeon in charge to discuss profitably with the patient, due to the high workload. Counseling may represent a good facilitator for physicians to learn how to translate knowledge for their patients to manage their expectations and guide them in their informed choice, as well as an increasingly important role of nurses as case managers to act between the surgeon's technical input and the patient's feelings, wishes, and fears [53, 54].

Scientific societies and universities engaged in surgical research should further promote such cutting-edge topics through dedicated tracks at conferences and workshops and through calls for papers in academic journals.

Bibliography

1. Barach P, Johnson JK. Assessing risk and preventing harm in the clinical microsystem. In: Johnson J, Sollecito WA, editors. *McLaughlin & Kaluzny's continuous quality improvement in health care*. Burlington: Jones & Barlett Learning; 2020. p. 235–52.
2. Graham ID, Logan J, Harrison MB, Straus SE, Tetroe J, Caswell W, et al. Lost in knowledge translation: time for a map? *J Contin Educ Heal Prof*. 2006;26(1):13–24.
3. Branco RM, Quental J, Ribeiro Ó. Personalised participation: an approach to involve people with dementia and their families in a participatory design project. *CoDesign [Internet]*. 2017;13(2):127–43. Available from: <https://doi.org/10.1080/15710882.2017.1310903>.
4. Petersson C, Batalden P, Fritzell P, Borst S, Hedberg B. Exploring the meaning of coproduction as described by patients after spinal surgery interventions. *Open Nurs J*. 2019;13(1):85–91.
5. Batalden M, Batalden P, Margolis P, Seid M, Armstrong G, Oipari-arrigan L, et al. Coproduction of healthcare service. *BMJ Qual Saf*. 2016;25(7):509–17.
6. Elwyn G, Nelson E, Hager A, Price A. Coproduction: when users define quality. *BMJ Qual Saf*. 2020;29(9):711–6.
7. Palumbo R. Contextualizing co-production of health care: a systematic literature review. *Lars Tummers prof. Yvonne Brunetto, Dr PST, editor. Int J Public Sect Manag*. 2016;29(1):72–90.
8. Lemire N, Souffez K, Laurendeau MC. Facilitating a knowledge Translation process. Knowledge review and facilitation tool. Quebec: Institut Publique de Santé du Quebec; 2013.
9. Brunoro-Kadash C, Kadash N. Time to care: a patient-centered quality improvement strategy. *Leadersh Health Serv*. 2013;26(3):220–31.
10. Dal Mas F, Garcia-Perez A, Sousa MJ, Lopes da Costa R, Cobianchi L. Knowledge Translation in the Healthcare Sector. A structured literature review. *Electron J Knowl Manag*. 2020;18(3):198–211.
11. Baigorri A, Villadangos J, Astrain JJ, Córdoba A. A medical knowledge management system based on expert tagging (MKMST). *WIT Trans Inf Commun Technol*. 2013;45:221–31.
12. Dadich A, Abbott P, Hosseinzadeh H. Strategies to promote practice nurse capacity to deliver evidence-based care: an example from sexual healthcare. *J Health Organ Manag*. 2015;29(7):988–1010.
13. Karimi J, Walter Z. Corporate entrepreneurship, disruptive business model innovation adoption, and its performance: the case of the newspaper industry. *Long Range Plan*. 2016;49(3):342–60.
14. Cobianchi L, Dal Mas F, Massaro M, Fugazzola P, Coccolini F, Kluger Y, et al. Team dynamics in emergency surgery teams: results from a first international survey. *World J Emerg Surg*. 2021;16:47.
15. D'Andrea D, Marabelli M, Newell S, Scarbrough H, Swan J. Dominant cognitive frames and the innovative power of social networks. *Organ Stud*. 2016;37(3):293–321.
16. Savory C. Translating knowledge to build technological competence. *Manag Decis*. 2006;44(8):1052–75.
17. Radaelli G, Lettieri E, Mura M, Spiller N. Knowledge sharing and innovative work behaviour in healthcare: a micro-level investigation of direct and indirect effects. *Creat Innov Manag*. 2014;23(4):400–14.
18. Savory C. Building knowledge translation capability into public-sector innovation processes. *Technol Anal Strateg Manag*. 2009;21(2):149–71.
19. Ware C, Buckwell C, Small S, Wood R. Activation of evidence: a new approach to knowledge translation and closing the clinical care gap. *J Med Mark*. 2008;8(2):127–36.
20. Conway A, Dowling M, Devane D. Implementing an initiative promote evidence-informed practice: part 2 - Healthcare professionals' perspectives of the evidence rounds programme. *BMC Med Educ*. 2019;19(1):1–17.
21. Jull J, Petticrew M, Kristjansson E, Yoganathan M, Petkovic J, Tugwell P, et al. Engaging knowledge users in development of the CONSORT-equity 2017 reporting guideline: a qualitative study using in-depth interviews. *Res Involv Engagem*. 2018;4(1):34. <https://doi.org/10.1186/s40900-018-0118-y>.

22. Greenwood M, Lindsay N, King J, Loewen D. Ethical spaces and places: indigenous cultural safety in British Columbia health care. *Altern An Int J Indig Peoples*. 2017;13(3):179–89. <https://doi.org/10.1177/1177180117714411>.
23. Ruta F, Gallo G, Ferrara P, Terzoni S, Della Monica A, Dal Mas F, et al. Translating knowledge about organs and tissues donation using webinars. An exploratory study in Italy. *Transplant Proc*. 2021;53(6):1792–7.
24. Ioannidis JPA. A fiasco in the making? As the coronavirus pandemic takes hold, we are making decisions without reliable data [internet]. *STAT+*. 2020. [cited 2020 Mar 24]. <https://www.statnews.com/2020/03/17/a-fiasco-in-the-making-as-the-coronavirus-pandemic-takes-hold-we-are-making-decisions-without-reliable-data/>.
25. Biancuzzi H, Dal Mas F, Miceli L, Bednarova R. Post breast cancer coaching path: a co-production experience for women. In: Paoloni P, Lombardi R, editors. *Gender studies, entrepreneurship and human capital IPAZIA 2019 springer proceedings in business and economics*. Cham: Springer; 2020. p. 11–23.
26. Dal Mas F, Biancuzzi H, Massaro M, Miceli L. Adopting a knowledge translation approach in healthcare co-production. A case study. *Manag Decis*. 2020;58(9):1841–62.
27. Cobianchi L, Dal Mas F, Massaro M, Bednarova R, Biancuzzi H, Filisetti C, et al. Hand in hand: a multistakeholder approach for co-production of surgical care. *Am J Surg*. 2022;223(1):214–5.
28. Currie J, Mateer J, Weston D, Anderson E, Harding J. Implementation of a clinical governance framework to 17 combat service support brigade, Australian Army. *Int J Heal Gov*. 2017;22(1):15–24.
29. Cobianchi L, Dal Mas F, Barcellini A, Vitolo V, Facchetti A, Peloso A, et al. Knowledge translation in challenging healthcare environments: The PLOPPO experience at the National Centre of Oncological Hadrontherapy (CNAO Foundation). In: Garcia-Perez A, Simkin L, editors. *Proceedings of the 21st European Conference on Knowledge Management - ECKM2020*. Coventry: Academic Conferences & Publishing International Ltd; 2020. p. 124–32.
30. Cobianchi L, Dal Mas F, Piccolo D, Peloso A, Secundo G, Massaro M, et al. Digital transformation in healthcare. The challenges of translating knowledge in a primary research, educational and clinical Centre. In: Soliman KS, editor. *International business information management conference (35th IBIMA)*. Seville: IBIMA; 2020. p. 6877–88.
31. Fulop L. Leadership, clinician managers and a thing called “hybridity”. *J Health Organ Manag*. 2012;26:578.
32. Abbasgholizadeh Rahimi S, Rodriguez C, Croteau J, Sadeghpour A, Navali AM, Légaré F. Continuing professional education of Iranian healthcare professionals in shared decision-making: lessons learned. *BMC Health Serv Res*. 2021;21(1):1–9.
33. Mathijssen EGE, Van Den Bemt BJB, Wielsma S, Van Den Hoogen FHJ, Vriezekolk JE. Exploring healthcare professionals’ knowledge, attitudes and experiences of shared decision making in rheumatology. *RMD Open*. 2020;6(1):1–9.
34. Woltz S, Krijnen P, Pieterse AH, Schipper IB. Surgeons’ perspective on shared decision making in trauma surgery. A national survey. *Patient Educ Couns*. 2018;101(10):1748–52. <https://doi.org/10.1016/j.pec.2018.06.002>.
35. Politi MC, Saunders CH, Grabinski VF, Yen RW, Cyr AE, Durand M-A, et al. An absence of equipoise: Examining surgeons’ decision talk during encounters with women considering breast cancer surgery. *PLoS One*. 2021;16(12):e0260704. <https://doi.org/10.1371/journal.pone.0260704>.
36. Stahel PF, Cobianchi L, Dal Mas F, Paterson-Brown S, Sakakushev BE, Nguyen C, et al. The role of teamwork and non-technical skills for improving emergency surgical outcomes: an international perspective. *Patient Saf Surg*. 2022;16(1):1–10. <https://doi.org/10.1186/s13037-022-00317-w>.
37. Dal Mas F, Massaro M, Woltz S, Ruta F, Catena F, Fugazzola P, et al. Shared decision-making in trauma and emergency surgery settings. A literature review. In: Cerchione R, Centobelli P, editors. *Proceedings of the 23rd European Conference on Knowledge Management - ECKM*. Naples: Academic Conferences & Publishing International Ltd; 2022. p. 278–88.

38. Brown TT, Hurley VB, Rodriguez HP. Association of patient engagement strategies with utilisation and spending for musculoskeletal problems in the USA: a cross-sectional analysis of Medicare patients and physician practices. *BMJ Open*. 2021;11(11):e053121.
39. Bottle A, Parikh S, Aylin P, Loeffler M. Risk factors for early revision after total hip and knee arthroplasty: national observational study from a surgeon and population perspective. *PLoS One*. 2019;14(4):1–15.
40. Tighe P, Buckenmaier CC, Boezaart AP, Carr DB, Clark LL, Herring AA, et al. Acute pain medicine in the United States: a status report. *Pain Med (United States)*. 2015;16(9):1806–26.
41. Thunnissen FM, Drager LD, Braak B, Drenth JPH, Van Laarhoven CJHM, Schers HJ, et al. Healthcare utilisation of patients with cholecystolithiasis in primary care: a multipractice comparative analysis. *BMJ Open*. 2021;11(11):1–8.
42. Parmar AD, Coutin MD, Vargas GM, Tamirisa NP, Sheffield KM, Riall TS. Cost-effectiveness of elective laparoscopic cholecystectomy versus observation in older patients presenting with mild biliary disease. *J Gastrointest Surg*. 2014;18(9):1616–22.
43. Heiss KF, Raval MV. Patient engagement to enhance recovery for children undergoing surgery. *Semin Pediatr Surg*. 2018;27(2):86–91. <https://doi.org/10.1053/j.sempedsurg.2018.02.005>.
44. Janssen SJ, Teunis T, Guitton TG, Ring D, Spoor AB, Chauhan A, et al. Do surgeons treat their patients like they would treat themselves? *Clin Orthop Relat Res*. 2015;473(11):3564–72.
45. Newcomb AB, Allred C, Grove C, Newcomb H, Mohess D, Griffen MM, et al. Surgeon communication and family understanding of patient prognosis in critically ill surgical patients: a qualitative investigation informs resident training. *J Surg Educ*. 2019;76(6):e77–91. <https://doi.org/10.1016/j.jsurg.2019.05.017>.
46. Cobianchi L, Piccolo D, Mas FD, Agnoletti V, Ansaloni L, Balch J, et al. Surgeons' perspectives on artificial intelligence to support clinical decision—making in trauma and emergency contexts: results from an international survey. *World J Emerg Surg*. 2023:1–17.
47. Cobianchi L, Dal Mas F, Agnoletti V, Ansaloni A, Biffi V, Butturini G, et al. Time for a paradigm shift in shared decision-making in trauma and emergency surgery? Results from an international survey. *World J Emerg Surg*. 2023;18(1):14.
48. Osei-Frimpong K, Wilson A, Lemke F. Patient co-creation activities in healthcare service delivery at the micro level: the influence of online access to healthcare information. *Technol Forecast Soc Change*. 2018;126:14–27.
49. Loftus TJ, Tighe PJ, Filiberto AC, Efron PA, Brakenridge SC, Mohr AM, et al. Artificial intelligence and surgical decision-making. *JAMA Surg*. 2020;155(2):148–58.
50. Bertsimas D, Dunn J, Velmahos GC, Kaafarani HMA. Surgical risk is not linear: derivation and validation of a novel, user-friendly, and machine-learning-based predictive OpTimal trees in emergency surgery risk (POTTER) calculator. *Ann Surg*. 2018;268(4):574. https://journals.lww.com/annalsofsurgery/Fulltext/2018/10000/Surgical_Risk_Is_Not_Linear__Derivation_and.4.aspx.
51. Maurer LR, Bertsimas D, Bouardi HT, El Hechi M, El Moheb M, Giannoutsou K, et al. Trauma outcome predictor: an artificial intelligence interactive smartphone tool to predict outcomes in trauma patients. *J Trauma Acute Care Surg*. 2021;91(1):93. https://journals.lww.com/jtrauma/Fulltext/2021/07000/Trauma_outcome_predictor__An_artificial.15.aspx.
52. Cobianchi L, Verde JM, Loftus TJ, Piccolo D, Dal Mas F, Mascagni P, et al. Artificial intelligence and surgery: ethical dilemmas and open issues. *J Am Coll Surg*. 2022;235(2):268–75. https://journals.lww.com/journalacs/Fulltext/9900/Artificial_Intelligence_and_Surgery__Ethical.215.aspx.
53. Stanojević S, Čartolovni A. Moral distress and moral injury and their interplay as a challenge for leadership and management: the case of Croatia. *J Nurs Manag*. 2022;30(7):2335–45. <https://doi.org/10.1111/jonm.13835>.
54. Steenbergen M, de Vries J, Arts R, Beerepoot LV, Traa MJ. Barriers and facilitators for shared decision-making in oncology inpatient practice: an explorative study of the healthcare providers' perspective. *Support Care Cancer [Internet]*. 2022;30(5):3925–31. <https://doi.org/10.1007/s00520-022-06820-1>.

Chapter 13

A Multidisciplinary Approach to Surgical Care: The Case of Disease Units. A Delphi Consensus on the Newly-Born Pancreas Units



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Introduction

The Need for a Multidisciplinary Approach to Pancreatic Cancer Care

Pancreatic cancer stands as a malignancy with a dismal prognosis, with the highest mortality. More aggressive forms like pancreatic ductal adenocarcinoma (PDAC) represent the world's 14th most frequent malignancy and the seventh major cause of cancer-related mortality [1, 2]. In 2018, PDAC was the second most significant cause of cancer deaths in the USA, and it is anticipated to become the second leading cause of cancer deaths by 2030 [3].

Although clinical research has improved the chances of cure in recent years, the diagnostic and therapeutic path remains particularly complex. Novel integrated protocols combining chemotherapy, radiation therapy, and surgery have been developed in response to the need for new therapeutic techniques for treating pancreatic cancer [3]. Allowing patients with pancreatic cancer to qualify for surgery is one of the most challenging tasks facing clinicians and researchers, given surgery appears to be the only long-term cure. Still, for most patients diagnosed with pancreatic cancer, the treatment journey may result in palliative and end-of-life care [1, 2].

Each stage of the clinical path requires specific skills, from the treatment of complications such as jaundice or duodenal obstruction to the surgical approach, which often brings high mortality risks and requires advanced interventional radiology and endoscopy. The centres highly specialised in pancreatic surgery have proved to lead to better clinical outcomes [4–6]. Still, each patient is unique, with peculiar nutritional or psychological issues to be addressed. Other specific skills are required when it comes to a correct histopathological diagnosis, the choice of the proper medical treatment, the need to apply and manage chemotherapy, and the right timing of radiotherapy. The integration with simultaneous and palliative care, from the earliest stages up to the end-of-life care, are all aspects that require a multidisciplinary approach for a path that provides a continuity of care.

Multidisciplinarity is not new to oncological care. The most prominent example is that of breast units for the care of breast-related cancers [7, 8]. Several studies have underlined how such multidisciplinary units are able to lead to better clinical outcomes for their patients (+18% survival rate), and also a better quality of life [9, 10]. Recent experiences have included the presence of non-traditional specialists, including physiotherapists, physiatrists, and fitness professionals [11, 12]. Even if breast cancer differs from pancreatic cancer under several circumstances—including the survival rates and the importance of prevention, a multidisciplinary approach has been defined as the key care strategy in a patient-centric scenario.

The Pancreas Units as Defined by the Lombardy Region in Italy

The Lombardy Region in Italy has ruled the creation, within the Regional Healthcare System, of a network of Pancreas Units. The organisational model described within the regulation XI/6241 [13] sees the presence of a long list of different professionals, some mandatory tangible requirements which must be met to qualify as a “Pancreas Unit”, and a “hub and spokes” organisational approach to care. The management and organisational model sees the presence of an integrated journey for the patient, who is taken care of by a case manager, and who is required to attend a hub for more specialised activities (like endoscopy, histological examination, and surgery), and a spoke closer to home for computed tomography (CT) scan or chemotherapy. According to the Lombardy Region, a patient association should be involved in the Pancreas Unit with the aim of assessing the quality of care. Moreover, all the Pancreas Units should participate in a network to join clinical and research efforts.

A Multi-Stakeholder Approach to Pancreatic Cancer Care

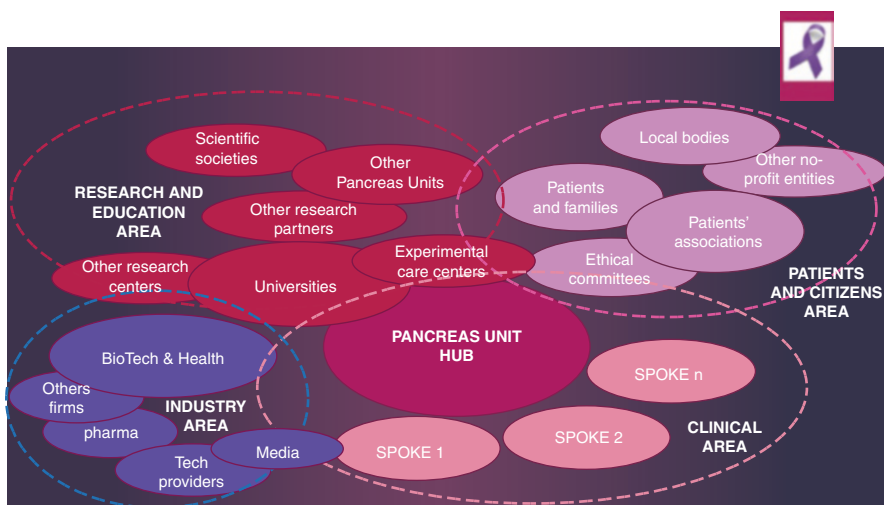
The regulation XI/6241 of the Lombardy Region offers new inputs for a multidisciplinary and integrated approach to pancreatic cancer care. Among its innovations, we can underline the presence of non (or less) traditional clinical professionals (like psychologists), the assessment by an association of patients, and a “hub and spokes” approach. Still, according to the latest trends in the clinical literature, more stakeholders could be included in the picture [14].

Figure 13.1 Reports our stakeholders’ model.

According to the model, the stakeholders’ map identifies four meaningful areas according to the stakeholders involved, their characteristics, and the major issues.

The first area involves the clinical institutions identified in the “hub and spokes” model. In such an area, we recognise the presence of multiple professionals with different expertise, backgrounds, and tasks. Such professionals are required to work together in a coordinated way to reach the preferred clinical outcome from a patient-centric perspective. A knowledge translation issue emerges [15–17], as such professionals will need to employ the best fitting tools and facilitators to exchange, share, and create new knowledge in the patient’s best interest. In doing so, several facilitators can be used, including non-technical skills like leadership, teamwork, and the ability to communicate [18, 19].

The second area involves the patients’ world, which comprises not only the patient and the family or caregiver but a wider ecosystem which also encompasses the patient’s associations, other no-profit entities supporting the patients, the local bodies, and the ethical committees. In a patient-centric approach to care, the patients



Source: Authors' elaboration

Fig. 13.1 An integrated stakeholders model. (Source: Authors' elaboration)

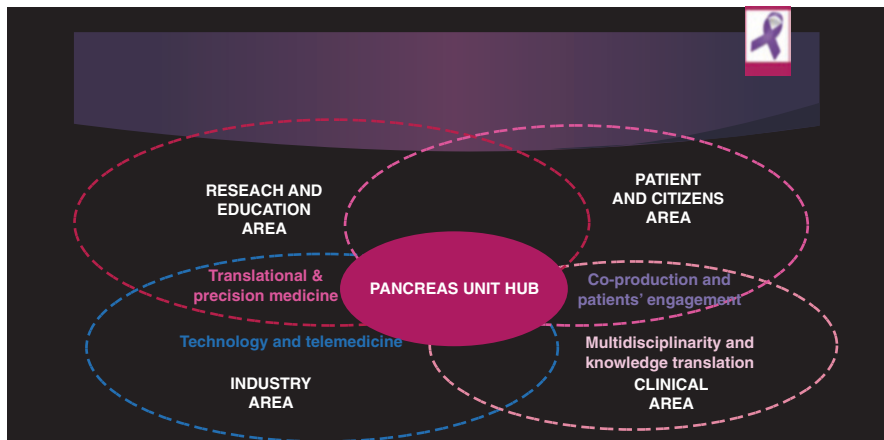
are required to actively participate in the co-design of their oncological care. Shared-decision making [20] requires clinicians to “speak less and listen more” [21] to address the patients’ wishes, aims, and feelings. Moreover, patient engagement and co-production dynamics [14, 22, 23] should be stimulated to increase the treatment outcomes and patients’ satisfaction [24, 25].

The third area concerns those stakeholders involved in the educational and research arena. Such stakeholders have a great responsibility in the management of innovation by employing experimental trials [15, 26, 27] and tailored approaches [28]. Moreover, medical schools should translate such new clinical and organisational approaches into their modules for undergraduate students and residents, but also in the lifelong learning journeys of physicians.

Last but not least, the fourth area is represented by the private industry. Biotech companies, pharmaceutical multinationals and R&D firms, and tech providers can be game-changers when it comes to new treatments and care. While their relationships with clinical institutions are vital, they may carry on relevant investments in new drugs or care paradigms. Innovation may also come in the delivery and follow-up phases through new technologies, like in the case of telemedicine [29–32], which would allow patients to receive monitoring and care in the cozy and safe environment of their residences, or while in nursing homes or hospices.

Figure 13.2 Reports the main topics connected to the four areas.

The aim of the chapter is to test the model by reaching an expert consensus through a Delphi survey.



Source: Authors' elaboration

Fig. 13.2 Main topics. (Source: Authors' elaboration)

Methodology

A Delphi survey [33] has been designed starting from the recent literature on healthcare organisation science, stakeholders' engagement [14], knowledge translation [16], and non-technical skills [19, 34–36].

The Delphi survey was conceived in English and then translated into Italian. The survey in both languages is reported in Appendix 1.

The experts included in the panel were gathered from the Executive Master of Strategic Management and Leadership of Healthcare Organization (Executive Master in Management strategico e Leadership delle Organizzazioni Sanitarie - EMMLOS) carried on by the University of Pavia, Lombardy, Italy. All the participants have executive roles in primary healthcare institutions within the Lombardy Region (21 panelists) and Piedmont Region (3 panelists), ranging from general to clinical and administrative directorship.

The Delphi survey included some descriptive statistics and four sections, namely the organisational factors (14 items), the stakeholders (18 items), the non-technical skills (1 + 16 items), and the processes and knowledge translation facilitators (32 items). All items had to be voted by the expert panel on a scale from 1 (not important) to 9 (very important). A positive consensus (inclusion) was gathered for those items voted with a mean of over 7. A negative consensus (exclusion) was defined for those items voted with a mean of 3 or below. Another round of discussion had to be made for those items voted from 3.1 to 6.9 as the average.

The Delphi survey was conducted in June, 2022 using Google Forms, and consensus was reached through two Delphi rounds. 24 fully filled questionnaires were gathered, with a 100% response rate in both rounds.

Results

Section 0. Descriptive Statistics

Out of 24 participants, 13 (54% of the sample) declared a business and management background, 5 (20%) a clinical background, and 2 of them a legal background. The remaining four participants claimed a different field of education (engineering, ICT, ...).

The following Table 13.1 lists the roles covered by panelists.

Among the gender, 14 participants were men and the remaining 10 women.

Regarding the age, the most declared ranges were 41 to 50 (10 participants) and 51 to 60 (10 participants). Two participants were under 40, and two were over 60.

Section 1. Organisational Factors

Table 13.2 reports the results of section. 1—Organisational factors.

Out of 14 items, a positive consensus (inclusion) was reached for 11 of them in round 1. Among the most voted items, the participants recognised the most significant importance of sharing knowledge and cases within the network of Pancreas Units, the presence of a case manager, and covering the entire patient's journey, from the early diagnosis to the complete healing or end-of-life care.

Three items were brought to Round 2 for discussion. In particular, the participants discussed the importance of having dedicated spaces for the Unit. In the end, the panel agreed on having spaces for the patients (reception and welcoming, ...),

Table 13.1 Panelists' role

Role	Number of panelist
Manager (areas: Purchasing department 2, higher education 1, institutional relations 1)	4
Administrative director	3
General director	3
Clinical director	3
Social and Healthcare director	3
Engineering manager	3
Medical doctor	2
Healthcare professions director	1
Analysist	1
Human resource director	1
Total	24

Source: Authors' elaboration

Table 13.2 Section 1—Organisational factors

Items	Results Round 1		Results Round 2
Organising frequent meetings among multidisciplinary clinical professionals	7.67	Inclusion	
The presence of metrics/KPI assessing all steps of the patient journey	7.00	Inclusion	
Having spaces fully dedicated to the pancreas unit	5.46	Discussion round 2	Inclusion when it comes to dedicated spaces for the patients - exclusion when it comes to clinical spaces
Defining team leaders for each clinical and organisational function	7.67	Inclusion	
Using new technologies in managing collaboration and work relations within the unit's staff	7.29	Inclusion	
Using new technologies in managing the relations with the patients	7.00	Inclusion	
Sharing knowledge, cases, ... with other pancreas units	8.71	Inclusion	
Disseminate knowledge by being present on the local press	4.67	Discussion round 2	Exclusion
Disseminate knowledge by being present on social media	5.83	Discussion round 2	Exclusion
Defining multidisciplinary clinical training paths for all the unit's staff members	7.96	Inclusion	
Defining multidisciplinary management/organisational training paths for all the unit's staff members	7.46	Inclusion	
Integrating data across clinical and administrative unit	7.38	Inclusion	
Introducing "case managers", in charge to follow the patient & the case over different clinic departments/expertise	8.46	Inclusion	
Covering all the patient journey, in an "extended view", starting from prevention (whenever possible) and early diagnosis	8.54	Inclusion	

Source: Authors' elaboration

especially in the context of a Hub. They excluded the presence of joint spaces to carry on the clinical activities, mainly due to their technical content and the need to use specific medical equipment.

In Round 2, participants discussed the importance of disseminating the Pancreas Unit's activities and events on the local press and social media networks. The panel excluded both items because of the technical content of the matter and the absence of prevention activities to be brought to the attention of citizens.

Section 2. Stakeholders

Table 13.3 reports the results of Section 2—Stakeholders.

Among the stakeholders, half of the items (9 out of 18) got a positive consensus on Round 1. The highest agreement was gathered for the involvement of more “traditional” and “non-traditional” multidisciplinary clinical professionals, the patients, the partner institutions, and other Pancreas Units belonging to the network.

Nine items were discussed in Round 2. Most of them were included, with the exception of the companies active in the media field. Concerning the involvement of other public bodies, the participants underlined the need to select those institutions closer to the healthcare mission.

Table 13.3 Section 2—Stakeholders

Items	Results Round 1		Results Round 2
Involving traditional clinical professionals (e.g., surgeons, oncologists, radiation therapists, palliative care specialists, ...)	8.33	Inclusion	
Involving non-traditional clinical professionals (physiotherapists, psychologists, ...)	8.38	Inclusion	
Involving clinicians from partner institutions according to a hub/spokes model	8.17	Inclusion	
Involving the patient	8.50	Inclusion	
Involving the patient’s family	7.83	Inclusion	
Involving the patients’ associations	7.50	Inclusion	
Involving other NGOs or no-profit entities	6.67	Discussion round 2	Inclusion
Involving other public sector entities	6.25	Discussion round 2	Inclusion only for specific bodies
Involving ethical committees	6.92	Discussion round 2	Inclusion
Involving clinicians from international institutions	6.96	Discussion round 2	Inclusion
Involving scientific societies	6.79	Discussion round 2	Inclusion
Involving other pancreas units	8.13	Inclusion	
Involving pure research institutions and universities	7.67	Inclusion	
Involving private firms/companies active in the pharma sector	6.83	Discussion round 2	Inclusion
Involving private firms/companies active in the biotech sector	7.29	Inclusion	
Involving private firms/companies active in the surgical technology sector	6.96	Discussion round 2	Inclusion
Involving private firms/companies active in the media sector	5.33	Discussion round 2	Exclusion
Involving colleagues characterised by diverse features	6.88	Discussion round 2	Inclusion

Source: Authors’ elaboration

Section 3. Non-technical Skills

Table 13.4 reports the results of section 3—Non-technical skills.

Concerning the non-technical skills, the panel agreed on their importance in Round 1. Assessing the specific 16 items, a positive consensus was gathered for 14 of them, and the remaining two (copying with fatigue and multicultural ability) were included after a short discussion in Round 2. Interesting enough, the item with the highest positive consensus was Teamwork (8.58/9).

Section 4. Processes and Knowledge translation Facilitators

Table 13.5 reports the results of section 4—Processes and knowledge translation facilitators.

Among the 32 items belonging to the processes and knowledge translation facilitators, 22 of them received a positive consensus in Round 1, 2 of them received a negative consensus, and 8 of them were discussed in Round 2. Among the most voted items, we may mention co-production and the establishment of mixed teams (8.38/9) and lessons learned and best practices (8.21/9). The panel excluded the use of tensions and prototyping (considered out of context).

Table 13.4 Section 3—Non-technical skills

Items	Results Round 1		Results Round 2
Non-technical or soft skills in general terms	7.83	Inclusion	
Decision-making	8.21	Inclusion	
Coping with fatigue	6.63	Discussion round 2	Inclusion
Communication	7.46	Inclusion	
Leadership	7.50	Inclusion	
Situational awareness	7.63	Inclusion	
Managing stress	7.29	Inclusion	
Team working	8.58	Inclusion	
Ideas creation ability	7.13	Inclusion	
Coordination ability	8.08	Inclusion	
Multicultural ability	6.79	Discussion round 2	Inclusion
Planning ability	7.13	Inclusion	
Learning ability	7.75	Inclusion	
Professionalism	7.58	Inclusion	
Information management ability	7.54	Inclusion	
Agility	7.29	Inclusion	
Ethics	8.17	Inclusion	

Source: Authors' elaboration

Table 13.5 Section 5—Processes and knowledge translation facilitators

Items	Results Round 1		Results Round 2
The pathogenesis and mechanisms behind diseases	7.92	Inclusion	
Mobile electronic medical records and online tools	7.96	Inclusion	
Design	6.88	Discussion round 2	Inclusion
Web portals	6.38	Discussion round 2	Inclusion
Image tagging	7.63	Inclusion	
Lesson learned and best practices	8.21	Inclusion	
Tours to share experiences with others	6.83	Discussion round 2	Inclusion
Committees and meetings	6.29	Discussion round 2	Inclusion
Journal publications	6.75	Discussion round 2	Inclusion
In-person visit and talking	7.13	Inclusion	
Establishment of mixed teams	8.38	Inclusion	
Co-production	8.38	Inclusion	
Leaflets and brochures	7.04	Inclusion	
Training	7.83	Inclusion	
Clinical cases	8.17	Inclusion	
Clinical guidelines	7.96	Inclusion	
Use of interpersonal skills	8.17	Inclusion	
Discussions, debates, curiosity	6.33	Discussion round 2	Inclusion
New technological tools	7.50	Inclusion	
Mentoring and leadership	7.33	Inclusion	
Testimonials	7.25	Inclusion	
Engaging with the patient's family	7.42	Inclusion	
Empowerment	7.88	Inclusion	
Tensions	3.00	Exclusion	
Community of practice	6.88	Discussion round 2	Inclusion
Multidisciplinary people (e.g., Degree in medicine + IT)	7.38	Inclusion	
Use of evidence-based methods	7.79	Inclusion	
Quality assessment by stakeholders	7.79	Inclusion	
Prototyping	3.00	Exclusion	
Simulations	6.83	Discussion round 2	Inclusion
Self-assessment	7.00	Inclusion	
Use of a simple language	7.42	Inclusion	

Source: Authors' elaboration

Discussion

The Lombardy region in Italy started to rule the creation of formalised Pancreas Unit in early 2022, with the aim of improving the care of one of the worst cancers. A multidisciplinary approach to care sees the involvement of a variety of clinical professionals with different roles and the engagement of an association of patients to ensure the quality of standards not only in the clinical outcomes but also in the general wellbeing of patients undertaking such a challenging path.

The need to go beyond the mandatory inputs of the regulation XI/6241 [13] triggered the creation of a Delphi panel to survey healthcare managers operating in the Lombardy region. The questionnaire sought expert consensus on four different key strategic themes, namely organisational factors, stakeholder engagement, non-technical skills, and processes and knowledge translation facilitators.

Consensus about the importance of most items identified in the key areas was reached during Round 1. Still, different opinions emerge.

Among the organisational factors, participants recognised the strategic role of knowledge sharing among the Pancreas Units operating in the regional network. In accordance with the aims stated in the regulation XI/6241, the experts underlined the importance of joining forces within the network, sharing data and experiences, and analysing aggregated data about the clinical results. The expert consensus on such a strategic topic leads to the need to set up and formalise adequate procedures to facilitate the exchange of information and the creation of new knowledge. The patient-centric approach stated by the regional regulation was well-received by the experts, who underlined the importance of a case manager following all the steps with the patient, and the need for a complete journey, from the diagnosis to the follow-ups and eventual end-of-life care. Even in this case, setting up procedures and a sound training program for the case managers looks vital, as those case managers (nurses) will need to support the patient on a very tough journey. Still, according to the experts, the role of the Pancreas Unit remains technical. Therefore, the technical content can hardly be linked to the use of press or social media to disseminate information. Still, in a world which sees an increasing digitalisation and the search for medical information and tips through the use of “Dr. Google” [37, 38], the potential of clinical-related content disseminated via the web remains a “hot” topic in the current scenario. The technical approach led to the exclusion of common spaces devoted only to the Pancreas Unit’s clinical activities. Still, the experts agree on the importance of setting up “welcoming” areas for patients, especially in hubs. As in other studies grabbed from the oncological literature [14, 39], the “visual” effect remains influential in guiding patients through their journey.

Regarding the second key area, that of stakeholders, the experts agreed on the importance of engaging a variety of different actors within an open ecosystem. Although almost all the stakeholders reported in the model got a positive consensus, priorities are different, as some actors were considered more relevant or strategic than others. Going beyond some “natural” options like the patients, attention was paid, for example, to the importance of having in the care team less “traditional”

clinical professionals like psychologists and physiotherapists, as reported in other studies [25]. Again, networking among the Pancreas Units is seen as the best strategy to enhance the outcome of the initiative. Therefore, the need for dedicated tools and procedures should be on the agenda of policymakers.

Concerning the non-technical skills theme, general interest emerges, with teamwork appearing as the top-rated soft competence. Given the nature of non-technical skills, which can hardly be learned but fostered [34], particular attention should be paid by hospital managers and policymakers (especially those operating in hubs) to set up the teams while establishing the Pancreas Unit. Although the assessment of such non-technical skills may be challenging, their crucial role in the success of the initiative must be acknowledged. The formal establishment of Pancreas Units should, therefore, reward those clinical professionals more in line with the needed soft skills—especially teamwork, decision-making, coordination, and ethics.

The last area allowed the experts to raise their voices about the most valuable knowledge translation tools to facilitate the work of clinicians in the management of their multidisciplinary teams, the relationship with the patients and the other meaningful stakeholders. The technical content of the matter led the experts to concentrate more on equally specialised tools, like case studies and best practices. Still, co-production dynamics emerge as equally valuable, but they must be accompanied by dedicated procedures and facilitators. Training was rated as a central strategy to bridge the competencies and knowledge gaps.

Conclusions

In concluding our work, we wish to recall the premise that inspired it. The formal establishment of a network of recognised Pancreas Units in the Lombardy region of Italy poses a series of open issues to be addressed. Employing a Delphi survey among some multidisciplinary healthcare managers operating in the same region, we sought an expert consensus on the most relevant topics. All in all, our results depict a busy agenda for policymakers in setting up the “rules of the game” to get the best out of such a valuable initiative, which has the aim and the potential to improve the care of one of the worst cancer worldwide. Our study underlines, therefore, some practical implications and “food for thought” for healthcare managers and policymakers engaged in the matter.

As with all pieces of research, ours is not without limitation. Although relevant, our sample size is rather small and self-selected through the participation of the experts as executive students of the EMMLOS course within the University of Pavia. Given the importance of the topic in terms of clinical and organisational issues, more experts should be enquired to foster the dialogue at a national and international level. Such a limitation may represent a valuable future research avenue. Authors' Contributions FD and LC conceived the idea of the study; PP, FD, SD, StCa and LC wrote the research protocol; FD, SD and LC took care of data collection; SD, EC, SaCu, MF, AF, MG, PI, SM, GM, IM, FM, DM, BN, GR, MR, KR,

SR, MS, RS, AS, ET and IV participated in the Delphi panel; FD, SD and LC took care of data collection and wrote the first manuscript's draft, PP, StCa, AV, SD, EC, SaCu, MF, AF, MG, PI, SM, GM, IM, FM, DM, BN, GR, MR, KR, SR, MS, RS, AS, ET and IV critically review the manuscript. All authors approved the latest version of the manuscript.

Appendix 1

Delphi Protocol (English Version)

Section 0—Descriptive Statistics

1. What is your background?
 - (a) Business/management.
 - (b) Law.
 - (c) Clinical.
 - (d) Other.
2. What is your role?
 - (a) General Director.
 - (b) Scientific Director.
 - (c) Medical Director.
 - (d) Administrative Director.
 - (e) Physician/GP.
 - (f) Manager.
 - (g) Other.
3. What is your gender?
 - (a) Male.
 - (b) Female.
 - (c) Prefer not to answer.
4. What is your age group?
 - (a) Under 40.
 - (b) 41 to 50
 - (c) 50 to 60
 - (d) Over 60.
5. Do you agree to be an author in the scientific publication(s) reporting the Delphi results?
 - (a) Yes.

In a pancreas unit, how would you rate the importance of the following items from 1 to 9, where: 1 = not important at all 9 = very important when it comes to facilitators in pancreatic cancer care		Importance								
		1	2	3	4	5	6	7	8	9
18	Discussions, debates, curiosity									
19	New technological tools									
20	Mentoring and leadership									
21	Testimonials									
22	Engaging with the patient's family									
23	Empowerment									
24	Tensions									
25	Community of practice									
26	Multidisciplinary people (Eg. Degree in medicine + IT)									
27	Use of evidence-based methods									
28	Quality assessment by stakeholders									
29	Prototyping									
30	Simulations									
31	Self-assessment									
32	Use of a simple language									

Delphi protocol (Italian version)

Sezione 0—Statistiche Descrittive

1. Qual è il Suo background formativo?
 - (a) Economia/Amministrazione.
 - (b) Diritto/Giurisprudenza.
 - (c) Medicina.
 - (d) Altro.

2. Qual è il Suo attuale ruolo lavorativo?
 - (a) Direttore Generale.
 - (b) Direttore Scientifico.
 - (c) Direttore Sanitario.
 - (d) Direttore Amministrativo.
 - (e) Medico/Medico di base.
 - (f) Funzionario.
 - (g) Altro.

In una pancreas unit, come valuterebbe l'importanza dei seguenti elementi da 1 a 9, dove: 1 = per niente importante 9 = molto importante quando si tratta della presenza di fattori che possano facilitare la cura del cancro del pancreas?	Importanza								
	1	2	3	4	5	6	7	8	9
25	Communities of practices di supporto								
26	Presenza di personale con attitudini multidisciplinari (es. Laurea in medicina + informatica)								
27	Uso di metodi basati sull'evidenza (evidence-based)								
28	Procedure di monitoraggio della qualità del servizio								
29	Prototipazione								
30	Simulazioni								
31	Autovalutazione (self-assessment)								
32	Uso di un linguaggio semplice/non tecnico								

References

1. Frassini S, Calabretto F, Granieri S, Fugazzola P, Viganò J, Fazzini N, et al. Intraperitoneal chemotherapy in the management of pancreatic adenocarcinoma: a systematic review and meta-analysis. *Eur J Surg Oncol.* 2022;48:1911. <https://doi.org/10.1016/j.ejso.2022.05.030>.
2. Barcellini A, Peloso A, Pugliese L, Vitolo V, Cobiانchi L. Locally advanced pancreatic ductal adenocarcinoma: challenges and progress. *Onco Targets Ther.* 2020;13:12705–20.
3. Cobiانchi L, Dal MF. New perspectives for pancreatic cancer treatment. Will we be able to ensure equity to care? *Surg Innov.* 2021;29(3):313–4. <https://doi.org/10.1177/15533506211062398>.
4. Vonlanthen R, Lodge P, Barkun JS, Farges O, Rogiers X, Soreide K, et al. Toward a consensus on centralisation in surgery. *Ann Surg.* 2018;268(5):712–24.
5. Balzano G, Guarneri G, Pecorelli N, Paiella S, Rancoita PMV, Bassi C, et al. Modelling centralisation of pancreatic surgery in a nationwide analysis. *Br J Surg.* 2020;107(11):1510–9.
6. Balzano G, Guarneri G, Pecorelli N, Reni M, Capurso G, Falconi M. A four-step method to centralise pancreatic surgery, accounting for volume, performance and access to care. *HPB.* 2021;23(7):1095–104.
7. Plate S, Emilsson L, Söderberg M, Brandberg Y, Wärnberg F. High experienced continuity in breast cancer care is associated with high health related quality of life. *BMC Health Serv Res.* 2018;18(1):1–8.
8. Wilson ARM, Marotti L, Bianchi S, Biganzoli L, Claassen S, Decker T, et al. The requirements of a specialist breast Centre. *Eur J Cancer.* 2013;49(17):3579–87.
9. Kalager M, Haldorsen T, Bretthauer M, Hoff G, Thoresen SO, Adami HO. Improved breast cancer survival following introduction of an organised mammography screening program among both screened and unscreened women: a population-based cohort study. *Breast Cancer Res.* 2009;11(4):1–9.
10. Biancuzzi H, Dal Mas F, Miceli L, Bednarova R. Post breast cancer coaching path: a co-production experience for women. In: Paoloni P, Lombardi R, editors. *Gender studies, entrepreneurship and human capital IPAZIA 2019 springer proceedings in business and economics.* Cham: Springer; 2020. p. 11–23.
11. Browall M, Mijwel S, Rundqvist H, Wengström Y. Physical activity during and after adjuvant treatment for breast cancer: an integrative review of Women's experiences. *Integr Cancer Ther.* 2018;17(1):16–30.

12. Bednarova R, Biancuzzi H, Rizzardo A, Dal Mas F, Massaro M, Cobianchi L, et al. Cancer rehabilitation and physical activity: the “oncology in motion” project. *J Cancer Educ.* 2020;37:1066–8.
13. Lombardia R. Determinazioni in merito all’attivazione della rete regionale dei centri di diagnosi e cura dei tumori al pancreas (Pancreas Unit). Milano: Regione Lombardia; 2022. Deliberazione XI/6241.
14. Cobianchi L, Dal Mas F, Massaro M, Bednarova R, Biancuzzi H, Filisetti C, et al. Hand in hand: a multistakeholder approach for co-production of surgical care. *Am J Surg.* 2022;223(1):214–5.
15. Cobianchi L, Dal Mas F, Barcellini A, Vitolo V, Facoetti A, Peloso A, et al. Knowledge translation in challenging healthcare environments: The PIOPPO experience at the National Centre of Oncological Hadrontherapy (CNAO Foundation). In: Garcia-Perez A, Simkin L, editors. *Proceedings of the 21st European conference on knowledge management—ECKM2020.* Coventry, Academic Conferences & Publishing International Ltd; 2020. p. 124–32.
16. Dal Mas F, Garcia-Perez A, Sousa MJ, Lopes da Costa R, Cobianchi L. Knowledge translation in the healthcare sector. A structured literature review. *Electron J Knowl Manag.* 2020;18(3):198–211.
17. Cobianchi L, Dal Mas F, Angelos P. One size does not fit all—translating knowledge to bridge the gaps to diversity and inclusion of surgical teams. *Ann Surg.* 2021;273(2):e34–6.
18. Stahel PF, Cobianchi L, Dal Mas F, Paterson-Brown S, Sakakushev BE, Nguyen C, et al. The role of teamwork and non-technical skills for improving emergency surgical outcomes: an international perspective. *Patient Saf Surg.* 2022;16(1):1–10. <https://doi.org/10.1186/s13037-022-00317-w>.
19. Cobianchi L, Dal Mas F, Massaro M, Fugazzola P, Coccolini F, Kluger Y, et al. Team dynamics in emergency surgery teams: results from a first international survey. *World J Emerg Surg.* 2021;16:47.
20. Woltz S, Krijnen P, Pieterse AH, Schipper IB. Surgeons’ perspective on shared decision making in trauma surgery. A national survey. *Patient Educ Couns.* 2018;101(10):1748–52. <https://doi.org/10.1016/j.pec.2018.06.002>.
21. Angelos P. Interventions to improve informed consent perhaps surgeons should speak less and listen more. *JAMA Surg.* 2020;155(1):13–4.
22. Petersson C, Batalden P, Fritzell P, Borst S, Hedberg B. Exploring the meaning of coproduction as described by patients after spinal surgery interventions. *Open Nurs J.* 2019;13(1):85–91.
23. Batalden M, Batalden P, Margolis P, Seid M, Armstrong G, Opiari-arrigan L, et al. Coproduction of healthcare service. *BMJ Qual Saf.* 2016;25(7):509–17.
24. Elwyn G, Nelson E, Hager A, Price A. Coproduction: when users define quality. *BMJ Qual Saf.* 2020;29(9):711–6.
25. Dal Mas F, Biancuzzi H, Massaro M, Miceli L. Adopting a knowledge translation approach in healthcare co-production. A case study. *Manag Decis.* 2020;58(9):1841–62.
26. Vitolo V, Cobianchi L, Brugnattelli S, Barcellini A, Peloso A, Facoetti A, et al. Preoperative chemotherapy and carbon ions therapy for treatment of resectable and borderline resectable pancreatic adenocarcinoma: a prospective , phase II, multicentre, single-arm study. *BMC Cancer.* 2019;19(922):1–7.
27. Takahashi S, Ohno I, Ikeda M, Konishi M, Kobayashi T, Akimoto T, et al. Neoadjuvant S-1 with concurrent radiotherapy followed by surgery for borderline Resectable pancreatic cancer: a phase II open-label multicenter prospective trial (JASPAC05). *Ann Surg.* 2020;276:e510.
28. Denicolai S, Previtali P. Precision medicine: implications for value chains and business models in life sciences. *Technol Forecast Soc Change.* 2020;151:119767. <https://www.sciencedirect.com/science/article/pii/S0040162519311023>.
29. Biancone P, Secinaro S, Marseglia R, Calandra D. E-health for the future. Managerial perspectives using a multiple case study approach. *Technovation.* 2021;120:102406. <https://www.sciencedirect.com/science/article/pii/S0166497221001875>.
30. Bhaskar S, Bradley S, Chattu VK, Adisesh A, Nurtazina A, Kyrkybayeva S, et al. Telemedicine across the globe-position paper from the COVID-19 pandemic health system resilience

- PROGRAM (REPROGRAM) International Consortium (Part 1). *Front Public Health*. 2020;8:556720. <https://doi.org/10.3389/fpubh.2020.556720>.
31. Sorensen MJ, Bessen S, Danford J, Fleischer C, Wong SL. Telemedicine for surgical consultations—pandemic response or here to stay? *Ann Surg*. 2020;272(3):e174–80.
 32. Miceli L, Dal Mas F, Biancuzzi H, Bednarova R, Rizzardo A, Cobianchi L, et al. Doctor@ Home: through a telemedicine co-production and co-learning journey. *J Cancer Educ*. 2021;37:1236.
 33. Linstone HA, Turoff M. Delphi: a brief look backward and forward. *Technol Forecast Soc Change*. 2010;78(9):1712–9.
 34. Dal Mas F, Biancuzzi H, Miceli L. The importance of soft skills in the co-production of health-care services in the public sector: the oncology in motion experience. In: Lepeley MT, Beutell N, Abarca N, Majluf N, editors. *Soft skills for human centered management and global sustainability*. New York: Routledge; 2021.
 35. Dal Mas F, Bagarotto EM, Cobianchi L. Soft skills effects on Knowledge Translation in health-care. Evidence from the field. In: Lepeley MT, Beutell N, Abarca N, Majluf N, editors. *Soft skills for human centered management and global sustainability*. New York: Routledge; 2021. p. 95–109.
 36. Lepeley MT. Soft skills: the language of human centered management. In: Lepeley MT, Beutell N, Abarca N, Majluf N, editors. *Soft skills for human centered management and global sustainability*. London: Routledge; 2021.
 37. Gualtieri LN. The doctor as the second opinion and the internet as the first. In: CHI '09 extended abstracts on human factors in computing systems [internet]. New York, NY: Association for Computing Machinery; 2009. p. 2489–98. <https://doi.org/10.1145/1520340.1520352>.
 38. Miceli L, Bednarova R, Bednarova I, Rizzardo A, Cobianchi L, Dal Mas F, et al. What people search for when browsing “Doctor Google.” An analysis of search trends in Italy after the law on pain. *J Pain Palliat Care Pharmacother*. 2021;35(1):23–30.
 39. Dal Mas F, Biancuzzi H, Massaro M, Barcellini A, Cobianchi L, Miceli L. Knowledge translation in oncology. A case study. *Electron J Knowl Manag*. 2020;18(3):212–23.

Part V
Healthcare Management

Chapter 14

Dr Surgeon & Mr. Manager: The Hybrid Role of Surgeons



Helena Biancuzzi, Francesca Dal Mas , and Jacopo Martellucci 

Introduction

New Public Management (NPM) is generally considered to be the driving force behind the largest public sector reform agenda [1], although its spread has not been homogeneous across countries. It is possible, in fact, to classify the different realities as “core- NPM countries” (USA, United Kingdom, and Australia) and “NPM -laggard countries” (among others, Germany, Italy, and other southern European countries) [2]. Some authors add a third group, which actually coincides with the “Bric” countries (Brazil, Russia, India, China) [3].

The public sector has, however, been neglected by the scholars of Human research management (HRM), and more generally by those of management, especially when compared with the private sector, and specifically that of firms and corporations [4]. This led, even within the overall reform plan, to the uncritical adoption of abstract HRM models, not sufficiently robust to grasp the peculiar characteristics of public administrations, with often negative repercussions for organisations [3]. This has happened, in particular, since the 1990s, when the governments of almost all advanced economies, starting with the United Kingdom, have initiated

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major structural reforms aimed at making bureaucratic organisations more efficient. The management of human resources, like all managerial processes [5], cannot, in fact, ignore the specific context of reference (contingency perspective) which, in the case of the public administration, presents strong levels of bureaucracy and the technicality of the processes, on the one hand, and, as a consequence, sees the use of highly specialised figures, not infrequently placed in managerial roles, on the other. Moreover, the rigid access rules and career rules typical of the public administration have led to a specific physiognomy of human resources [6], which today appear as a monolithic reality. It is, in fact, a professional body with wide margins of decision-making autonomy [7], which has ended up occupying specific enclaves of power, experienced as self-referential quasi-organisations [8], resistant to change [9].

The scarce contextualisation of the models of management and development of human resources, associated with the strong characterisation of the professionalism present in the public sphere, leads to the question of what was, in practice, the substantial effectiveness of the innovations introduced by the NPM and, more generally, by those related to the modernisation of the public sector.

All this, also in consideration of two further reasons. For almost 20 years now, the strong powers (and, with them, those of the bureaucracy professionals) have been under increasing pressure from service users [10] from new management figs [3, 11], politicians, and the media. Moreover, the results of some pieces of research show, with increasing evidence, that NPM policies have led to periods of austerity, with limited budget allocation for management training, decision support, work by objectives and communication policies. Still, such concepts are widely recognised as fundamental pillars of change [12].

In most European countries, National Healthcare Systems (NHS) operate under the public management rules and umbrella. For such a reason, they need to reply to those regulations and policies set for the public administration in terms of budget allocation, results and outcomes, recruitment, HRM, salaries, and so on.

In NHSs, as well as in the public administration in general terms, new professional figures emerge under the name of hybrid managers (HMs). An HM is a highly technical professional called to manage more or less complex organisational units within a public administration with the task of interpreting and governing change in a managerial sense. An HM should, therefore, employ not only his/her professional role but also that of a manager with expertise and skills in administrative and organisational topics [13]. The concept of HM also applies to medical doctors, especially those in charge of a unit or department. While clinical department chiefs are usually appointed because of their medical expertise in the subject matter, they are required to hold managerial roles, too, in terms of budgeting, investments, hiring, HRM, team dynamics, reporting, and so on, needing to make decisions other than clinical, participating into management committees and meetings, and so on. Such a hybrid role may end up in some chief medical doctors being highly qualified as physicians but not as managers, with a misalignment of the required skills to be a good management executive.

This chapter employs a structured literature review [14], on the role and characteristics of HMs within the healthcare sector. Physicians and surgeons, as HMs, are now required to possess skills which may be far from those in which they were trained. The aim of the chapter is to address the following Research Questions (RQs):

RQs: What are the managerial skills required of healthcare professionals, and especially surgeons, after the NPM reforms? What are the impacts of these new skills required? What are the difficulties and potentialities resulting from this change?

Methodology

This chapter employs a structured review protocol like the one described by Massaro and colleagues [14]. Starting from the meaningful literature on HMs in the healthcare sector, the goal is to identify what managerial skills are gradually required for health professionals, especially medical chiefs. Specifically, we want to investigate what are the impacts of these necessary new skills on the work of physicians and surgeons, the difficulties and perplexities that emerge from the reform period, and what are the possible strengths and opportunities for improvement.

In order to select and analyse the meaningful literature on the topic, the Scopus-Elsevier database was used, representing the largest database of abstracts and citations of peer-reviewed literature in the fields of science, technology, medicine, social sciences, arts and humanities [15].

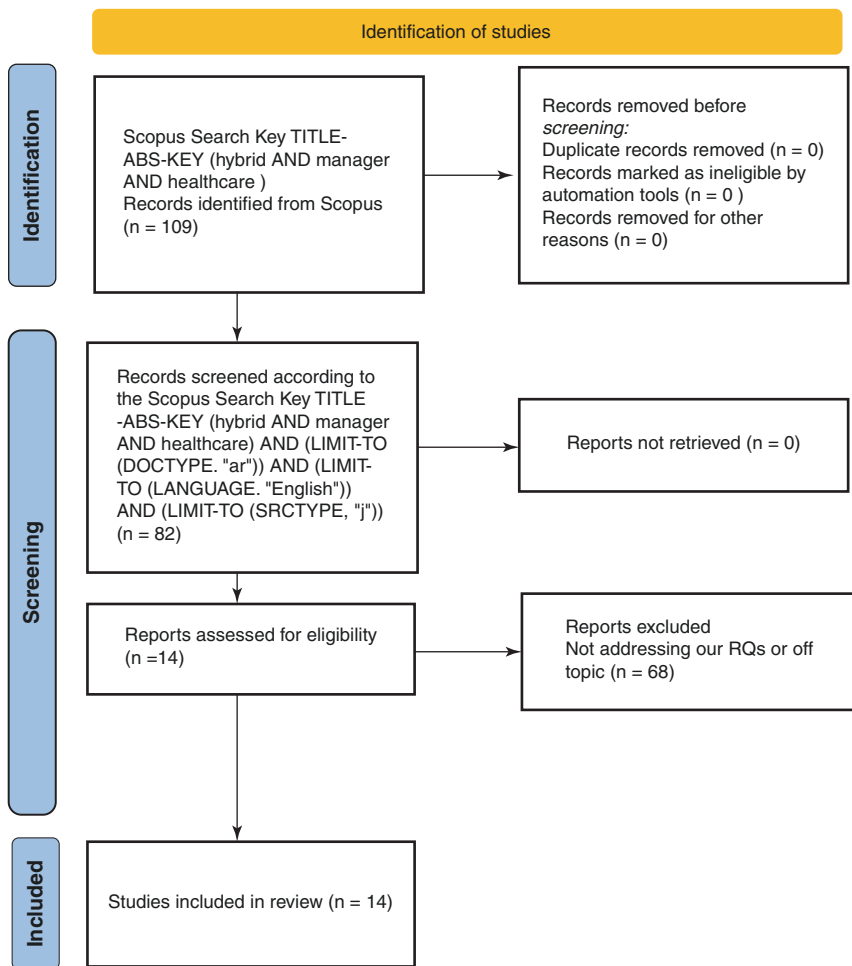
More in detail on the search techniques, Scopus-Elsevier was questioned by keywords in the fields “Title, Abstract and Keywords”. The search algorithm included the terms “hybrid”, “manager”, and “healthcare”. The search, performed in the month of June 2022, returned 109 document results. To further refine the search, only journal articles written in English were selected, thus eliminating other sources like conference proceedings, books, and book chapters. The new search led to 82 document results. All 82 abstracts were retrieved, read, and analysed. In such a phase, the work grid became even more selective by identifying only those articles that expressly examined HMs’ role in the health sector, describing the impacts, perceptions, and effects generated by the NPM reform. Particular attention was paid to the interventions that emerged in the field of surgery. In the end, 14 papers were selected and included in the analysis.

Fig. 14.1 reports the identification and selection process according to the PRISMA methodology [16–18].

The list of selected articles is reported in Table 14.1.

The selected articles were coded and analysed using the Nvivo software (version 12), following a specially identified framework, which included the following variables:

1. Year of publication, in order to analyse the chronological development of the literature on the subject under investigation;
2. Geographical area analysed, aimed at verifying how the phenomenon has spread geographically (for example, the trend in the diffusion of contributions in the first movers’ countries of the NPM reforms compared to the distribution in other countries);
3. Declared impacts;



Source: Authors' elaboration

Fig. 14.1 The selection process of studies. Source: Authors' elaboration

4. New skills required;
5. Emerging difficulties;
6. Strengths/opportunities for improvement.
7. The framework aimed to answer the research questions, focusing its attention on the change in the role of clinicians following the introduction of HMs.

Table 14.1 Articles included in the sample

#	Authors	Journal	Title	Year	References
1	Kuhlmann et al.	BMC health services research	Medicine and management: Looking inside the box of changing hospital governance	2016	[19]
2	T. Forbes, N. Prime	Health services management research	Changing domains in the management process: Imaging services managers in the post-1990 National Health Service	2000	[20]
3	Kuhlmann et al.	BMC health services research	“A manager in the minds of doctors:” a comparison of new modes of control in European hospitals	2013	[21]
4	Liz Fulop	Journal of health organization and management	Leadership, clinician managers and a thing called “hybridity”	2012	[22]
5	Lega F., Sartirana M.	BMC health services research	Making doctors manage... but how? Recent developments in the Italian NHS	2016	[23]
6	M. S. Macinati, G. Cantaluppi, M. G. Rizzo	Health services management research	Medical managers’ managerial self-efficacy and role clarity: How do they bridge the budgetary participation–performance link?	2016	[24]
7	L. Kippist, A. Fitzgerald	Journal of health organization and management	Organisational professional conflict and hybrid clinician managers: The effects of dual roles in Australian health care organisations	2009	[25]
8	I.Spehar et al.	Journal of health organization and management	Professional identity and role transitions in clinical managers	2015	[26]
9	A. Morinière, I. Georgescu	Accounting, auditing and accountability journal	Hybridity and the use of performance measurement: Facilitating compromises or creating moral struggles? Insights from healthcare organisations	2021	[27]
10	Prenestini et al.	BMC health services research	Involving clinicians in management: Assessing views of doctors and nurses on hybrid professionalism in clinical directorates	2021	[28]
11	Giacomelli G. Et al.	Health services management research	Involving hybrid professionals in top management decision-making: How managerial training can make the difference	2019	[29]

(continued)

Table 14.1 (continued)

#	Authors	Journal	Title	Year	References
12	Sartirana M.	BMC health services research	Beyond hybrid professionals: Evidence from the hospital sector	2019	[30]
13	Bresnen M. Et al.	Human relations	Hybrid managers, career narratives and identity work: A contextual analysis of UK healthcare organisations	2018	[31]
14	Nzinga J. Et al.	Journal of health organization and management	Hybrid clinical-managers in Kenyan hospitals Navigating between professional, official and practical norms	2019	[32]

Source: Authors' elaboration

Results

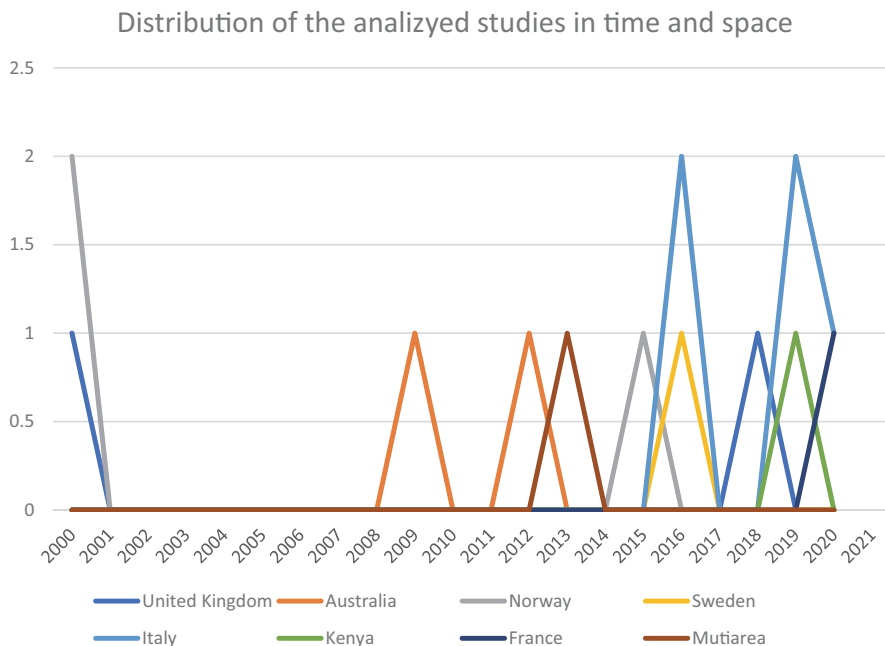
Taking into consideration the 14 selected articles, it emerges that the first contributions come from the first mover countries, namely those where NPM was first implemented. Contributions from NPM-laggard countries began to appear only in 2015. Fig. 14.2 reports the geographic distribution of studies from 2000 to 2021.

The contents of the selected documents were analysed on the basis of the investigation objectives of this work and, in particular: the declared impacts (A); the new skills required (B); the emerging difficulties (C); the strengths and opportunities for improvement identified (D). Moreover, some specific insights about surgeons as HMs were retrieved from the selected contributions (E).

Impacts Claimed

The impacts reported in the papers were numerous, both positive and negative. The HMs who encountered problems first noted that the changes required by the NPM reforms have hardly translated into micro-level changes [19], and in any case, where present, have taken root slowly and with difficulties [23]. Another observation is by Kippist et [25], who note that hybrid clinical managers tend to prioritise their clinical work, which can lead to delays in decision-making. These delays have the direct consequence of tensions among the members of the organisation.

There are also studies that bring out positive impacts. First of all, numerous contributions underline that the creation of this hybrid role has allowed the widespread and greater knowledge of the system [29–32]. As reported by Bresnen and colleagues [31]:



Source: Authors' elaboration

Fig. 14.2 Geographic distribution of the selected articles. Source: Authors' elaboration

I became the manager of medicine and that was an incredibly operational role. I did that for two years and that was very much the classical bed pressures, getting people out of A&E, [etc.]. But I did other things as well, like introduce proper governance arrangements in medicine ... and we turned medicine round. It was a good experience, and it certainly gives you an insight into organisations and the challenges.

The positive learning impact is underlined by Nzinga and colleagues as well [32].

I learnt a lot of the administrative things [...] when I became a manager in this hospital. I was just learning from the Medical Superintendent, who has been here for a longer time [...].

Furthermore, several contributions argue that the shift to a hybrid approach has led to a greater sharing of knowledge among professionals [28], but above all, an improvement in relations between work groups [28], dialogue between professionals [28–30], and a reduction in conflicts between professionals and managers [28]. As reported by Sartirana [30]:

...now it is different ... we are responsible for administrative and financial matters, and this has greatly improved our relationship with the top managers.

Finally, some contributions underline more efficient cost management [28, 30]. As underlined by Prenestini [28]:

..they agreed that their work was subject to greater control (64%), that budgets were now more easily managed (64%), and that cost management was more effective (58%).

New Skills Required

HMs are asked for numerous new skills, which are not part of the medical background, and for which professionals often have no training. Still, this can be a starting point for improving their skills. Interesting enough, the selected studies report the need for both technical and non-technical skills. Indeed, while controlling and organising resources or participating in the budget are technical skills related to general management and accounting, problem-solving stands as a soft skill [33–35] that is related more to the individual than the educational background.

Table 14.2 reports the most cited skills required among the various contributions.

Table 14.2 Required skills

New skills required	Quotes	References
Control and organisation of resources	<i>“When asked follow-up questions for further details on the radiographer managers understanding of the terms ‘manager’ and ‘management’, most agreed on what the terms meant. For most it conjured up concepts of controlling and organising resources”</i>	[20]
	<i>“Therefore, the hybrid role requires a range of skills and knowledge drawn traditionally from the business of health. (...) people skills required to manage subordinates”</i>	[25]
Strategic and operational management	<i>“My mission is to motivate people to achieve difficult goals, to have people that come to work every day and think, ‘what can I do for patients and the hospital?’”</i>	[30]
Streamline management	<i>“I think my key role is facilitating, both between the directorate and other directorates, and between the various consultant staff who have been at war for god knows how long, and to try and ensure that the whole system is running as smoothly as it can (...)”</i>	[20]
Problem-solving	<i>“One example that cannot be detailed related to an accident that resulted in extensive water damage that was seen to be resolved by a clever re-framing of the incident by the clinician in the study so that the unit, and the person who caused the mishap, did not become the focus of the incident or blamed for it, and it came to be seen as an act of defiance against the bureaucracy”</i>	[22]
Participation in the budget	<i>“Therefore, the hybrid role requires a range of skills and knowledge drawn traditionally from the business of health. Knowledge and understanding of budgets and forecasts for their department; (...)”</i>	[25]

Source: Authors' elaboration

Emerging Difficulties

Numerous difficulties emerge from the selected contributions due to the lack of the technical skills required to fill the new role and the frequent unwillingness to work in position which is far from the initial background. Table 14.3 summarises the main difficulties identified by the various contributions analysed.

Table 14.3 Emerging difficulties

Emerging difficulties	Quotes	Ref.
Inappropriate workload	<i>“(….)participants were frustrated with the managerial role. They experienced little freedom in how they could enact the role, because of a high amount of administrative work and a lack of support staff”</i>	[26]
	<i>“Some days it’s administration and administration and administration and administration. And then you have to (emphasised by the participant) sit here (in the office). (….)”</i>	
	<i>“At the beginning, it is new and unknown, it is a challenge ... but then you realise that it interferes with your clinical practice ... it is a difficult choice for those who have clinical activity, and sometimes I think that I’d have more fun doing other things”</i>	[30]
Feeling of lack of support	<i>“Some experienced the job as lonely and told that they would have liked to have a mentor or colleagues with whom they could share their experiences. They described a sense of being left to themselves in the managerial role, with few social arenas for meeting other clinical managers”</i>	[26]
Strength of the role not perceived/not respected/not remunerated	<i>“Managing physicians is extremely difficult ... they really don’t want to be managed. ... I’m actually a specialist in [other medical specialty not present at this clinic], I mean that I couldn’t go out there in the ward and say something like “all right my friends, you have to stop doing that”. That would probably not be accepted very well at all. And even if I did have the same specialty as they do ... if I can’t point to a systematic review or something like that, showing that this, this isn’t good... you know, it’s part of the physician’s role to decide and choose what you yourself think is right ...as department manager it’s pretty hard to influence this, actually very difficult. You have to stand on an immensely solid base to do that”</i>	[19]
	<i>“In this hospital you are called an “in charge”, you are called a “deputy in charge” [...] [but] there is no official communication, as in if you go to my file there is nothing that indicates that I’m in charge or a deputy in charge. At least it’s my hope that the hospital recognises such positions through promotion (...). Being a head of department doesn’t come with anything in your pocket. It just gives you more work and more responsibilities but there is nothing you would benefit from as a person”</i>	[32]

(continued)

Table 14.3 (continued)

Emerging difficulties	Quotes	Ref.
Willingness to be recognised as medical doctors	<i>“I think the biggest shock that I had when I came here was that the staff regarded me as not a radiographer. In the last two posts that I had been in I was a working radiographer and a manager, and when I came here-there is quite a lot of hostility towards my post. I would hate to think that it is towards me, although sometimes by paranoia is such that it feels as though it is towards me - but I am seen as a manager and they feel that because I don’t actually go out and work in the general area, I can’t understand and appreciate the problems they are having. I find that very hard to reconcile because I have been a radiographer for a long time and I don’t think that my skills are diminished by the fact that my role is different”</i>	[20]
Pressure, disappointment, dissatisfaction	<i>“When I took my management role... I used to go home and think: God what have I done today. What am I being paid for, this is just ridiculous... [it was] about six months until I really got into it. This is just silly, I should be with patients ... I still did have a bit of clinical work initially, but in the end you just couldn’t do either effectively”</i>	[31]
Lack of specific training, skills, personality	<i>“We are not even trained to be administrators [...] you are suddenly dumped in that office [...] you start learning from scratch. We are not real managers [...] we didn’t go to school anywhere to learn managerial skills”</i>	[32]
Lack of guidelines and/or protocols	<i>“There isn’t really a job description [...] a medical officer’s role is general, so whatever you find at your [work] station it is within your capacity and you should be able to do it. So, what I got was an orientation of the place, what goes on every day, and then the rest is what is expected of me as the doctor”</i>	[32]

Source: Authors’ elaboration

Strengths and Opportunities Identified for Improvement

While some contributions underline several difficulties or shortcomings of the hybrid role, other papers note several positive aspects. First of all, many contributions highlighted the pride of professionals in obtaining this new role [20, 26, 31], especially with great concentration among nurses [26, 28, 31]. Getting this new hybrid role produced greater awareness on both a financial and organisational level [20, 24, 32], as well as an improvement in efficiency thanks to participation in the budget [24]. Finally, the growth of skills and abilities [24, 30] often leads to a better communication style [20] and to greater interest and ease in managing one’s work environment [20].

Surgeons as HMs

Surgery and surgeons are mentioned in some of the selected articles [26, 27, 32]. In particular, Spehar and colleagues [26] underline the difficulties in merging the roles of a manager and a clinician, with surgeons not willing to apply as chiefs when the

administrative duties surpass the medical ones. They report a case of a surgeon who kept the job as a department chief only “not to let the others down”, with no colleagues willing to replace him. Morinière and Georgescu [27] highlight how, in an NPM approach, profitability is sought, and surgical interventions can be charged at high fees. Therefore, the need to increase the number of surgical operations to maximise profits may contradict the logic of public services. Nzinga and colleagues [32] shed light on the appointment criteria of surgical chiefs and department heads, which are primarily based on seniority rather than the presence of the right competencies.

Discussion and Conclusions

NPM reforms affecting public administrations around the globe have radically changed some HRM practices. More in detail, specialists with backgrounds different from their original studies are still required to possess and use management and organisational skills. Such competencies include general management, human resource management, accounting, and organisation. This new trend also affects physicians and surgeons, who are now required to fill a hybrid role, which includes their original medical background and management responsibilities.

A structured literature review has been conducted to shed light on some key topics regarding HMs in healthcare, including the impacts, the opportunities, the needed skills, and the primary difficulties for surgeons and medical doctors in their hybrid roles.

Results underline a misalignment between the original skills possessed by medical doctors and the ones required in the role, especially for higher positions like chiefs of surgery or department chiefs. Such misalignment is perceived as a problem for most professionals. While, on the one hand, this may refer to the lack of training, other contributions underline that some clinicians may refuse to hold a different job role than the one they studied for. If they love medicine, they may struggle or be bored by administrative procedures like budgeting, reporting, hiring, and so on.

The lack of training stands as a major issue. Still, training and educational paths should be aligned to the needed skills. Interestingly, the selected articles name several competencies required according to the reported cases. While some of such competencies are purely technical and related to the job description (e.g., the active participation in the creation of the departmental budget), others are non-technical or “soft”, like featuring a problem-solving attitude. According to the literature, non-technical or soft skills cannot be learned [36, 37], as they refer to personal traits that people may or may not have. Still, they can be fostered, especially when they can be considered essential in some jobs, like in the case of trauma and acute care surgical teams [35, 38]. Cases reported in the selected articles underline that some professionals may be more willing to work as HMs than others [26], and that the hiring process of chiefs should follow different criteria than only historical clinical results or seniority [32].

While the individual's attitudes and will to cover a specific job or role is for sure essential, we cannot deny that today, we experience the need for all medical professionals to know at least some basic management concepts. Examples may include, for surgeons, the need to assess the potential of a new surgical technique, the feasibility study about the request to acquire a new surgical instrument and the impact in terms of investments, costs, and revenues, the need to measure the quality of the healthcare outcomes beyond the purely technical medical output, and the need to manage teams in terms of competencies assessment, among many more. Therefore, every Dr. Surgeon should also encompass the role of a Mr. Manager. While management topics are on the agenda of top medical journals, some basic training on such themes should be included in medical schools and the lifelong learning journeys of experienced physicians. Scientific societies should also take the lead in merging such new topics and competencies through discussions at medical congresses and dedicated tracks and editorials in clinical journals. A multidisciplinary dialogue with healthcare specialists could support and facilitate the knowledge translation process [39] for surgeons and medical doctors to acquire the needed competencies in a facilitated way.

References

1. Kuipers BS, Higgs M, Kickert W, Tummers L, Grandia J, Van der Voet J. The management of change in public organizations: a literature review. *Public Adm.* 2014;92(1):1–20.
2. Pollitt CBG. Public management reform: a comparative analysis—new public management, governance, and the neo-weberian state. *Int Rev Adm Sci.* 2011;78(1):180–2.
3. Brunetto Y, Xerri M, Trincherio E, Beattie R, Shacklock K, Farr-Wharton R, et al. Comparing the impact of management on public and private sector nurses in the UK, Italy, and Australia. *Public Manag Rev.* 2018;20(4):525–44.
4. Rona S, Beattie JW. Human resource management in public service organizations. In: *Masters in public management*. London: Routledge; 2018.
5. Lawrence PR, Lorsch J. *Organization and environment: managing differentiation and integration*. Boston: Harvard Business School; 1986.
6. Brown AD. Identities and identity work in organizations. *Int J Manag Rev.* 2015;17(1):20–40.
7. Farr-Wharton R, Brunetto Y, Shacklock K. Professionals' supervisor–subordinate relationships, autonomy and commitment in Australia: a leader–member exchange theory perspective. *Int J Hum Resour Manag.* 2011;22(17):3496–512.
8. Ackroyd S. Organization contra organizations: professions and organizational change in the United Kingdom. *Organ Stud.* 1996;17(4):599–621.
9. Noordegraaf M. From “pure” to “hybrid” professionalism: Present-day professionalism in ambiguous public domains. *Adm Soc.* 2007;39(6):761–85.
10. Dudau A, Kominiš G, Szocs M. Innovation failure in the eye of the beholder: towards a theory of innovation shaped by competing agendas within higher education. *Public Manag Rev.* 2018;20(2):254–72.
11. Brunetto Y, Beattie R. Changing role of HRM in the public sector. *Public Manag Rev.* 2020;22(1):1–5. <https://doi.org/10.1080/14719037.2019.1645876>.
12. Diefenbach T. New public management in public sector organizations: the dark sides of managerialistic ‘enlightenment’. *Public Adm.* 2009;87(4):892–909.


13. Biancuzzi H, Lombrano A. L'hybrid management nel processo di ammodernamento della pubblica amministrazione. I risultati di una revisione strutturata della letteratura. *Polit Sanit.* 2021;22(2):1–8.
14. Massaro M, Dumay JC, Guthrie J. On the shoulders of giants: undertaking a structured literature review in accounting. *Accounting Audit Account J.* 2016;29(5):767–901.
15. Palumbo R. Contextualizing co-production of health care: a systematic literature review. Lars Tummers Prof. Yvonne Brunetto, Dr PST, editor. *Int J Public Sect Manag.* 2016;29(1):72–90.
16. Prisma Statement. Prisma Transparent Reporting of Systematic Reviews and Meta Analysis [Internet]. 2021 [cited 2021 May 23]. <http://www.prisma-statement.org/>.
17. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, Ioannidis JPA, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *J Clin Epidemiol.* 2009;62(10):e1–34.
18. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 Statement: an updated guideline for reporting systematic reviews. *BMJ.* 2021;372:372. <https://www.bmj.com/content/372/bmj.n71>.
19. Kuhlmann E, Rangnitt Y, von Knorring M. Medicine and management: looking inside the box of changing hospital governance. *BMC Health Serv Res.* 2016;16(2):57–64.
20. Forbes T, Prime N. Changing domains in the management process: imaging services managers in the post-1990 National Health Service. *Heal Serv Manag Res.* 2000;13(3):178–86.
21. Kuhlmann E, Burau V, Correia T, Lewandowski R, Lionis C, Noordegraaf M, et al. “A manager in the minds of doctors:” a comparison of new modes of control in European hospitals. *BMC Health Serv Res.* 2013;13(1):1–11.
22. Fulop L. Leadership, clinician managers and a thing called “hybridity”. *J Health Organ Manag.* 2012;26:578.
23. Lega F, Sartirana M. Making doctors manage... but how? Recent developments in the Italian NHS. *BMC Health Serv Res.* 2016;16(2):65–72.
24. Macinati MS, Cantaluppi G, Rizzo MG. Medical managers’ managerial self-efficacy and role clarity: how do they bridge the budgetary participation–performance link? *Heal Serv Manag Res.* 2017;30(1):47–60.
25. Kippist L, Fitzgerald A. Organisational professional conflict and hybrid clinician managers: the effects of dual roles in Australian health care organisations. *J Health Organ Manag.* 2009;23:642.
26. Spehar I, Frich JC, Kjekshus LE. Professional identity and role transitions in clinical managers. *J Health Organ Manag.* 2015;29:353.
27. Morinière A, Georgescu I. Hybridity and the use of performance measurement: facilitating compromises or creating moral struggles? Insights from healthcare organizations. *Accounting Audit Account J.* 2021;35:801.
28. Prenestini A, Sartirana M, Lega F. Involving clinicians in management: assessing views of doctors and nurses on hybrid professionalism in clinical directorates. *BMC Health Serv Res.* 2021;21(1):1–11.
29. Giacomelli G, Ferré F, Furlan M, Nuti S. Involving hybrid professionals in top management decision-making: how managerial training can make the difference. *Heal Serv Manag Res.* 2019;32(4):168–79.
30. Sartirana M. Beyond hybrid professionals: evidence from the hospital sector. *BMC Health Serv Res.* 2019;19(1):1–10.
31. Bresnen M, Hodgson D, Bailey S, Hassard J, Hyde P. Hybrid managers, career narratives and identity work: a contextual analysis of UK healthcare organizations. *Hum Relations.* 2019;72(8):1341–68.
32. Nzinga J, McGivern G, English M. Hybrid clinical-managers in Kenyan hospitals: navigating between professional, official and practical norms. *J Health Organ Manag.* 2019;33:173.
33. Hassan A, Maharoff M, Zainal Abiddin N, et al. Soft skills competency tool for secondary teachers in strengthening effective. Univ Portland, USA. 2013;2:146–55. <https://doi.org/10.1080/03797720802522627%5>.

34. Lepeley MT. Soft skills: The language of human centered management. In: Lepeley MT, Beutell N, Abarca N, Majluf N, editors. *Soft skills for human centered management and global sustainability*. London: Routledge; 2021.
35. Cobianchi L, Dal Mas F, Massaro M, Fugazzola P, Coccolini F, Kluger Y, et al. Team dynamics in emergency surgery teams: results from a first international survey. *World J Emerg Surg*. 2021;16:47.
36. Massaro M, Bardy R, Lepeley MT, Dal Mas F. Intellectual capital development in Business Schools. The role of “soft skills” in Italian Business Schools. In: *Proceedings of the 5th European conference on intellectual capital*. Oxfordshire: Academic Publishing Limited; 2014. p. 1–8.
37. Dal Mas F, Renaudin M, Garlatti A, Massaro M. Towards a social knowledge management in a knowledge-intensive public organization. In: *Proceedings of the international conference on intellectual capital, knowledge management and organisational learning, ICICKM*. Oxfordshire: Academic Conferences & Publishing International Ltd; 2018. p. 40–8.
38. Stahel PF, Cobianchi L, Dal Mas F, Paterson-Brown S, Sakakushev BE, Nguyen C, et al. The role of teamwork and non-technical skills for improving emergency surgical outcomes: an international perspective. *Patient Saf Surg* [Internet]. 2022;16(1):1–10. <https://doi.org/10.1186/s13037-022-00317-w>.
39. Dal Mas F, Garcia-Perez A, Sousa MJ, Lopes da Costa R, Cobianchi L. Knowledge Translation in the Healthcare Sector. A structured literature review. *Electron J Knowl Manag*. 2020;18(3):198–211.

Chapter 15

Towards the Healthcare of the Future. A Delphi Consensus on Environmental Sustainability Issues



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Introduction

The concept of sustainability is gaining traction in both academic literature and practice. The literature recognizes that sustainability includes three nuances: environmental, social, and economic (or financial) [1]. Several efforts have been made worldwide to promote sustainable development, namely, the ability to solve today's issues without compromising the resources needed to solve tomorrow's problems [2]. In 2015, the United Nations adopted the Sustainable Development Goals (SDGs) as the 17 worldwide objectives to be attained by 2030 [3]. Firms are increasingly pursuing some of these goals related to environmental sustainability by implementing practices within the circular economy umbrella, with the aim to narrow, slow, and close resource loops, thus preventing the waste of resources [4, 5].

Starting from the global definition of sustainability, we can say that sustainability in healthcare refers to the ability to ensure good quality healthcare today without compromising the ability of future generations to provide good quality healthcare. Healthcare is appropriately positioned within the SDGs, being the protagonist of SDG #3, which states the comprehensive goal to "Ensure healthy lives and promote wellbeing for all at all ages." Healthcare disparities represent discrepancies in the quality of care received by individuals with equal access to care and no differences in treatment preferences or requirements [6]. While the majority of the research has demonstrated that ethnic minorities do endure healthcare disparities and inferior clinical outcomes [7], inequalities also exist according to gender, age, socioeconomic position, sexual orientation, areas and rural locations, and disability status [6, 8, 9]. Most global efforts on sustainability in healthcare have referred to the social aspects of care, including offering care to everyone [10] ensuring inclusion [8] and reducing disparities [11] in the access [12] and quality of care, including technologies, pharmaceutical treatments, vaccines, and trials [13].

Economic (or financial) sustainability has also been at the center of the debate due to frequent budget cuts, especially in developed countries, which are characterized by an aging population with chronic diseases and an increasing demand for more healthcare services [14].

Environmental sustainability has often been left behind in the healthcare sector, given the priority granted to the social and economic aspects of sustainability issues related to health and diseases. However, in a global scenario that sees enormous environmental problems like climate change, desertification, air pollution, and

increasing waste produced by factories all over the world, the healthcare sector could not be overlooked, as it represents a vast industry with millions of employees, a massive number of stakeholders, facilities, refined operations, and extensive supply chains, involving both the public and the private sector in all the continents.

The UK National Healthcare System (NHS) took the lead in the direction towards sustainability [15], intending to reduce its carbon footprint by 80% within three decades from the 2008 Climate Change Act [16] as the NHS accounts for 4.6% of the UK's total carbon footprint and approximately 25% of the public sector's footprint [16]. An analysis of the NHS carbon footprint showed that working on buildings and premises would not have been enough. Indeed, even if hospitals had been entirely powered by renewable energy, total emissions would only have been reduced by one-fifth. Other interventions would include reducing carbon arising from staff and patient travel and promoting greener practices and products for purchased goods and services (especially in terms of pharmaceuticals and medical supplies). However, the study shows that to reach the 80% goal, a translation into clinical practice was needed, meaning clinicians should take environmental sustainability aspects into account when considering their treatment options or making their medical decisions. In May 2022, the Royal College of Surgeons of England published the "Sustainability in the operating theatre Guide to good practice," [17] containing suggestions to reduce solid waste, stimulate environmentally friendly purchases and water conservation, reduce travel through telemedicine, and in general terms, endorse a cultural change towards greener clinical and surgical practices. In November 2022, the Royal College of Surgeons of Edinburgh, the Royal College of Surgeons of England, and the Royal College of Physicians and Surgeons of Glasgow published the "Intercollegiate Green Theatre Checklist Compendium of Evidence," [18] a checklist of 16 items covering all the surgical journeys, from anesthesia, surgical preparation, intraoperative equipment, and after the operation. According to the Royal Colleges, surgery is particularly carbon-intensive [19], with a typical single operation estimated to generate between 150 and 170 kgCO₂e, equivalent to driving 450 miles in an average petrol car [20].

The recent NHS studies and the inputs from the Royal Colleges contribute to stimulating the debate about environmental sustainability in medicine and surgery, which is probably one of the most promising healthcare topics in research, practice, and policies of the next few years. One first step is to understand the environmental practices, either in clinical processes or in the management of buildings, especially hospitals, and the perception and attitude of healthcare workers (being them executives, clinicians, or part of the technical and administrative staff) towards change management and environmental practices directly related to their daily tasks and operations.

Starting from these premises, this study aims to pave the way to understanding the environmental practices in hospitals and healthcare institutions as well as the attitude of healthcare employees towards these practices by involving a sample of healthcare executives with managerial roles. This first pilot study was conducted in March 2023 by employing a Delphi survey to a group of 27 healthcare managers enrolled in an executive program held by the University of Pavia, Italy.

Methodology

A multidisciplinary panel, comprising scholars from business and management, statistics, medicine, and engineering designed the Delphi survey [21]. The questionnaire was designed starting from the recent documents published by The Royal Colleges of the UK [18, 20], and from the literature on sustainability practices and circular economy, stakeholders engagement [22], and knowledge translation [23], also following previous studies [24].

The Delphi survey was conceived in English and then translated into Italian. The English version of the survey is reported in the Appendix.

Like in previous studies [25] the experts included in the panel were gathered from the Executive Master of Strategic Management and Leadership of Healthcare Organization (Executive Master in Management strategico e Leadership delle Organizzazioni Sanitarie—EMMLOS) of the University of Pavia, Lombardy, Italy, home to the best ranked medical school in Italy. All the participants hold executive roles in primary healthcare institutions within the Lombardy Region (25 panelists), Liguria, and Marche Regions (1 panelist each), ranging from general to clinical and administrative directorship.

The Delphi survey included some descriptive statistics gathered from previous studies [25] and four major questions divided into two sections. The first section was about sustainability acceptance and change management, and it included 26 items. The second section was about sustainability habits in clinical practice, comprising 3 questions of 23, 10, and 6 items, respectively. As recommended by the literature [26], all items had to be voted on by the expert panel on a Likert scale from 1 (not important) to 9 (very important). A positive consensus (inclusion) was gathered for those items voted with a mean of over 7. A negative consensus (exclusion) was defined for those items voted with a mean of 3 or below. Those items voted from 3.1 to 6.9 as the average had to be discussed further.

The Delphi survey was conducted in March 2023 using Google Forms for the first round. Two Delphi rounds were made, with a 100% response rate both times. Consensus was reached for 44 out of 65 items (68%).

Results

Section 0: Descriptive Statistics

The 27 panelists had different backgrounds, ranging from Business and Management, Law, and Clinical Sciences. Almost half of them were female. Most of them (almost 60%) were between 51 and 60 years old. All of them held executive positions in public or private healthcare institutions, hospitals, and agencies. A summary of the descriptive statistics of the sample is reported in Table 15.1.

Table 15.1 Descriptive statistics

Background	Number	%
Business and management	9	33.33%
Law	8	29.63%
Medicine	6	22.22%
Nursing	3	11.11%
Humanities	1	3.70%
<i>Total</i>	27	100.00%
Gender	Number	%
Female	13	48.15%
Male	14	51.85%
<i>Total</i>	27	100.00%
Age	Number	%
Under 40	6	22.22%
From 41 to 50	3	11.11%
From 51 to 60	16	59.26%
Over 60	2	7.41%
<i>Total</i>	27	100.00%
Role	Number	%
Manager	5	18.52%
Health and Social Director	3	11.11%
Health Director	2	7.41%
General Director	2	7.41%
Administrative Director	2	7.41%
Administrative Manager	2	7.41%
Purchasing Director	1	3.70%
Healthcare Professions Director	1	3.70%
Medical Director	1	3.70%
Operations Director	1	3.70%
Human Resources Director	1	3.70%
Physician/General Practitioner	1	3.70%
President	1	3.70%
Administrator	1	3.70%
Legal office Director	1	3.70%
Financial Director	1	3.70%
Pharmacy Manager	1	3.70%
<i>Total</i>	27	100.00%

Section 1: Sustainability Acceptance and Change Management

Section 1 was about the concept of sustainability acceptance and change management, and it included only one question with 26 items to be rated. Table 15.2 reports the findings, listing the items according to the highest ranking in terms of their mean.

Table 15.2 Sustainability acceptance and change management—findings

Think of the clinical practice within your hospital/ institution/health agency/organization. On a scale from 1 to 9, where 1 = strongly disagree and 9 = strongly agree, how would you rate the following statements?	Mean	SD ^a	Round 1	Round 2
The end-of-life of clinical equipment should be managed by implementing recycling practices	8.44	1.22	Inclusion	
Technology can lead to more sustainable clinical practices	8.30	1.23	Inclusion	
The end of lifecycle of products sourced from external suppliers should be managed implementing recycling practices	8.30	1.30	Inclusion	
Medical instruments should consider environmental efforts (e.g., limiting the use of energy, non-recyclable materials and the creation of waste) and their end of lifecycle should be managed implementing recycling practices	8.22	1.28	Inclusion	
Green management should be a priority in all the industrial sectors	8.19	1.42	Inclusion	
Greener clinical practices should be properly reported	8.11	1.37	Inclusion	
It would be important to introduce sustainability practices also in procurement, selecting more sustainable products and suppliers	8.00	1.41	Inclusion	
Governments should incentivize greener clinical practices	7.89	1.40	Inclusion	
Greener clinical practices should be embedded into guidelines	7.85	1.43	Inclusion	
Ratios and indexes connected to clinical practices should be calculated to measure and report sustainability in all medical department	7.70	1.41	Inclusion	
Clinicians should be educated about environmental issues and outcomes connected with clinical activities and choices	7.67	1.59	Inclusion	
Non-technical skills can lead to more sustainable clinical practices	7.56	1.34	Inclusion	
Greener clinical practices should be prioritized on the agenda of hospitals and other stakeholders (e.g., financing institutions and governments)	7.41	1.62	Inclusion	
Greener clinical practices should be prioritized on the agenda of scientific societies	7.33	1.64	Inclusion	
Grants and awards should prioritize greener clinical practices	7.22	2.15	Inclusion	
Greener clinical practices should be prioritized on the agenda of top healthcare managers	7.19	1.64	Inclusion	
Patients should be educated about environmental issues and outcomes connected with clinical activities and choices	7.07	1.69	Inclusion	

(continued)

Table 15.2 (continued)

Think of the clinical practice within your hospital/institution/health agency/organization. On a scale from 1 to 9, where 1 = strongly disagree and 9 = strongly agree, how would you rate the following statements?	Mean	SD ^a	Round 1	Round 2
Patients should be aware of the most sustainable clinical options when co-deciding with their physician	6.93	2.02	Discussion in round 2	Inclusion
Green management should be a priority in clinical practice	6.89	2.19	Discussion in round 2	Inclusion
Greener clinical practices should be preferred even if they are more expensive	6.67	1.80	Discussion in round 2	Inclusion
Hospitals and other stakeholders (e.g., financing institutions and governments) will appreciate greener clinical practices	6.63	1.88	Discussion in round 2	Inclusion
Sustainability issues are particularly relevant in my hospital/institution/health agency/organization	5.89	2.22	Discussion in round 2	No consensus reached
Patients will appreciate greener clinical practices	5.85	2.23	Discussion in round 2	No consensus reached
Changing clinical practices can lead to fewer issues than traditional practices	5.48	1.97	Discussion in round 2	No consensus reached
Greener management of clinical practice can lead to better medical outcomes	5.11	1.89	Discussion in round 2	No consensus reached
Patients will have more trust in greener clinical practices	5.04	1.91	Discussion in round 2	No consensus reached

^a *SD* standard deviation

Consensus was reached in Round 1 for 17 out of 26 items (65%). Of the remaining nine items, consensus was gathered in Round 2 for only 4 of them, while no agreement was reached for the remaining five items.

More specifically, panelists fully agreed on the need to implement recycling practices for end-of-life equipment and implement clinical instruments and tools that are fully compliant with sustainability standards, including energy efficiency and waste creation. They also believed in the potential of new technologies to lead to greener management. Panelists also agreed on the need to report such results and practices using dedicated ratios to be disclosed outside the institution. To better manage and stimulate green management, panelists agreed on the importance of tailored education, non-technical skills, and promotion activities carried on by scientific societies.

A brief debate allowed the participants to agree on the importance of discussing the sustainability impacts of some feasible clinical choices with the patients and to consider greener clinical practices even if they are more expensive.

No consensus was reached on the outcome of greener practices when compared to traditional clinical choices, as the topic was considered too general. Moreover, several doubts arose about patients' trust in greener clinical practice, as the topic was considered still in its infancy, and patients usually have other health priorities.

Section 2: Sustainability Habits in Clinical Practice

Section 2 included three major questions: one about the clinical practices, one about the potential tools to promote sustainability practices among the staff and users (patients, families, citizens), and one about the tangible impacts of sustainable management.

Table 15.3 reports the results of the question about clinical practices.

Interestingly, only one out of 23 items obtained positive consensus in Round 1, namely, the practice of leasing instruments. A discussion on practices was carried on in Round 2, and the participants shared their experiences in their own institutions/working places. While some general good practices emerge (for instance, considering sustainability as one of the winning criteria in deciding the suppliers),

Table 15.3 Sustainability habits—findings about clinical practices

Think of the clinical practice within your hospital/institution/health agency/organization. On a scale from 1 to 9, where 1 = strongly disagree and 9 = strongly agree, how would you rate the following statements? Please note that all the elements should be rated according to your knowledge	Mean	SD ^a	Round 1	Round 2
My hospital/institution uses more leased equipment	7.12	1.86	Inclusion	
My hospital/institution recommends arranging metals/battery collection where possible	6.88	2.40	Discussion in round 2	Inclusion
My hospital/institution encourages equipment to be shared among different clinical departments	6.76	2.24	Discussion in round 2	Inclusion
My hospital/institution recommends avoiding clinically unnecessary interventions (e.g., antibiotics, catheterization, histological examinations)	6.68	2.90	Discussion in round 2	Inclusion
My hospital/institution recommends powering off lights, computers, ventilation, AGSS, and temperature control when the theater is empty	6.68	2.46	Discussion in round 2	Inclusion
My hospital/institution recommends that damaged reusable equipment is repaired, encouraging active maintenance	6.56	2.53	Discussion in round 2	Inclusion
My hospital/institution endorses the reduction of water and energy consumption	6.32	2.66	Discussion in round 2	Inclusion
My hospital/institution recommends using domestic or recycling waste streams for all packaging	5.85	2.81	Discussion in round 2	No consensus reached
My hospital/institution shares equipment with other hospitals/institutions	5.77	2.64	Discussion in round 2	No consensus reached
My hospital/institution uses reusable textiles (including theater hats, sterile gowns, patient drapes, and trolley covers)	5.48	2.46	Discussion in round 2	No consensus reached

(continued)

Table 15.3 (continued)

Think of the clinical practice within your hospital/institution/health agency/organization. On a scale from 1 to 9, where 1 = strongly disagree and 9 = strongly agree, how would you rate the following statements? Please note that all the elements should be rated according to your knowledge	Mean	SD ^a	Round 1	Round 2
My hospital/institution accurately measures operating room sterile supply waste	5.42	2.69	Discussion in round 2	No consensus reached
My hospital/institution is supplied by firms adopting sustainable practices	5.37	2.34	Discussion in round 2	No consensus reached
My hospital/institution recommends avoiding all unnecessary equipment (e.g., swabs, single-use gloves)	5.35	2.74	Discussion in round 2	No consensus reached
My hospital/institution promotes greener clinical practices in general terms	5.26	2.22	Discussion in round 2	No consensus reached
My hospital/institution recommends opening only those sets that are needed and, when they are needed, by integrating supplementary items into sets	5.21	2.59	Discussion in round 2	No consensus reached
My hospital/institution recommends the creation of clinical preference lists for each operation—separate essential vs. optional items to have ready on side	5.00	2.59	Discussion in round 2	No consensus reached
My hospital/institution employs sustainable “inputs” (e.g., from renewable sources, and/or made of biodegradable materials, and/or coming from recycling processes)	5.00	2.59	Discussion in round 2	No consensus reached
My hospital/institution recommends recycling or using lowest carbon-appropriate waste streams as appropriate	4.81	2.79	Discussion in round 2	No consensus reached
My hospital/institution installed several automatic or pedal-controlled water taps	4.44	2.83	Discussion in round 2	No consensus reached
I have a clear understanding and picture about greener clinical practices adopted my hospital/institution	4.41	2.48	Discussion in round 2	No consensus reached
My hospital/institution recommends switching to low-carbon alternatives (e.g., skin sutures vs. clips, loose prep in gallipots)	4.38	2.68	Discussion in round 2	No consensus reached
My hospital/institution recommends avoiding the use of single-use surgical packs	4.35	2.16	Discussion in round 2	No consensus reached
My hospital/institution recommends opting for reusables, hybrid, or remanufactured equipment instead of single-use (e.g., diathermy, gallipots, kidney-dishes, light handles, quivers, staplers, energy devices)	4.20	2.60	Discussion in round 2	No consensus reached

^a SD standard deviation

many claimed that, for instance, they felt discouraged in using different bins for waste, as the cleaning staff would throw away all the garbage into one basket. Therefore, despite the fruitful conversation, panelists could not reach a consensus about the perceived relevance of certain clinical habits.

Table 15.4 underlines the potential tools to promote sustainability practices among the staff and users (patients, families, and citizens).

Only three out of ten items received a positive consensus during the first round, namely, using newsletters, participating in congresses or events to share best practices, and training courses. After a discussion in Round 2, all the items received a positive consensus, except for leaflets, which were excluded as they were considered against environmental sustainability and could be easily replaced by e-brochures.

Table 15.5 reports the findings related to the tangible impact of greener clinical practice, according to the participants' perceptions.

Two items obtained a positive consensus in Round 1, namely, the institution's reputation and the positive contribution to the environment. The other items (someone's personal commitment, cost reduction, patient engagement, and quality of care) got full consensus after discussion in Round 2, with all participants agreeing on their importance.

Table 15.4 Sustainability habits—findings about the tools to promote sustainability practices

Think of the clinical practice within your hospital/institution/health agency/organization. Which of the following tools should be used to promote sustainability/greener clinical practices?	Mean	SD ^a	Round 1	Round 2
Newsletters	7.44	2.01	Inclusion	
Invitation to report best practices at congresses or events	7.30	2.05	Inclusion	
Invitation to attend specific training courses	7.11	2.03	Inclusion	
Digital solutions (e.g., APPs, sensors, smart grid, ...)	6.96	2.41	Discussion in round 2	Inclusion
Multidisciplinary Green Teams	6.85	2.14	Discussion in round 2	Inclusion
Corporate reports	6.78	2.36	Discussion in round 2	Inclusion
Websites	6.70	2.23	Discussion in round 2	Inclusion
Billboards	6.04	2.31	Discussion in round 2	Inclusion
Illuminated signs and meters (e.g., reporting energy consumption or other data)	5.93	2.70	Discussion in round 2	Inclusion
Leaflets	4.56	2.41	Discussion in round 2	Exclusion

^a SD standard deviation

Table 15.5 Tangible impact of greener clinical practice

Accordingly to your knowledge and/or perception, what is the tangible impact of greener clinical practice WITHIN your hospital/institution? On a scale from 1 to 9, where 1 = low, and 9 = remarkable, how would you rate the following statements?	Mean	SD ^a	Round 1	Round 2
Reputation of the hospital/institution	8.15	1.38	Inclusion	
Positive contribution for the environment	7.85	1.49	Inclusion	
My personal commitment	6.85	2.09	Discussion in round 2	Inclusion
Cost reduction	6.48	1.81	Discussion in round 2	Inclusion
More engagement of the patient	6.26	1.99	Discussion in round 2	Inclusion
Better quality of care	6.19	1.42	Discussion in round 2	Inclusion

^a *SD* Standard Deviation

Discussion

Environmental sustainability is becoming a debated theme in healthcare, as the healthcare industry enormously impacts upon the planet and its resources. Therefore, engaging in greener practices will need to become a priority not only for healthcare policymakers and executives but also for clinicians, who should consider sustainability aspects while making their clinical decisions. A cultural shift is therefore required, as environmental sustainability should be equally important to the social and economic aspects of sustainability in healthcare.

The aim of the study was to enquire a group of healthcare executives about the current sustainability practices and their perceptions about the topic through a Delphi survey. Our first pilot study leads to some exciting results.

First of all, several items did not get a consensus, despite an open discussion among the participants. Although all the panelists came from the same country (so no major differences emerged in the healthcare system), and even from the same area (North-western Italy), a variety of different practices were named.

While panelists recognize the general value of environmental sustainability, most of them do not feel that their home institutions are embracing and endorsing such principles.

Among the accepted factors, it should be recognized that recycling is considered a good practice. Interestingly enough, participants focused more on end-of-life equipment than everyday's waste. It should be noted that the end-life issue is easier to deal with and "solve" than day-by-day waste, which instead has enormous potential especially for its duration over time [15].

According to the panelists, there is a feeling that technology can support some aspects of environmental sustainability, for example, in the case of the virtual hospital model of care [27] and, in more general terms, e-health and telemedicine tools [28]. Accountability and reporting also get a full consensus as a means of disseminating good practices and results, and participants underlined the key role of institutional stakeholders like governments and scientific societies, who should take the lead in promoting environmentally friendly practices, even embedding these into their guidelines. However, when it comes to a single institution/hospital or a patient, the common feeling is that environmental sustainability is not (yet) a priority. Indeed, hospitals should cope with the management of complex issues like budget cut [14] new technological shifts [29], a lack of personnel [30], and the need to reorganize some processes following the post-pandemic “new normal” [31]. Patients, on their side, are usually concerned about their health and the need to find a feasible clinical solution to get better. Again, environmental sustainability can represent a nice “bonus,” but not a priority under these circumstances. Therefore, in the current scenario, sustainability issues look more interesting for science than for real life.

Panelists were also unsure about the clinical outcomes coming from (more) environmentally friendly clinical practices than traditional ones. Such a result may be explained by the fact that just a few executives had a medical or nursing background. This issue remains open to further investigation.

Concerning the general practices, participants were pretty negative when rating the implementation of those practices or habits that are recommended by the Royal Colleges’ latest checklists and guides. Indeed, the only course which got a full consensus in Round 1 was the acquisition of medical equipment through leasing contracts rather than full ownership. It should be noted that the leasing formula is now popular among technology providers as technological paradigms and innovation move fast, and this is a way to allow the replacement of older instruments with new ones. Therefore, this stands more as a common business model than a virtuous sustainable practice. In the discussion, panelists underlined how green sustainability has been included as one of the legal criteria to select suppliers, and they emphasized that there are regulations to avoid, for instance, certain environmentally dangerous materials, for example, in cleaning detergents. Again, we should note that some green aspects in procurement come from the law rather than from a single institution’s virtuous behavior or independent initiative.

Other recommended practices find huge barriers of several kinds in their implementation. For example, physicians are not encouraged to avoid unnecessary tests due to legal responsibilities. In case of a medical trial in court, medical doctors may be considered guilty if they did not evaluate all the possible clinical options. Therefore, they prefer to run more tests, even if they look unnecessary or are not included in the guidelines.

General recycling is also a debated issue. Several participants complained about the fact that, although different bins are present throughout the buildings, all the trash seems to be finally included in a single basket. From this, we can deduce that there is a general lack of waste disposal policies, and that recycling is not sufficiently promoted.

All in all, most of the recommended practices are not in place, thus calling for more extensive mapping of habits, organizational changes, and dissemination among staff and users (patients and visitors).

When it comes to knowledge translation and dissemination tools, participants agreed on newsletters, congresses and events, and training modules as preferred options. All the other proposed tools (including multidisciplinary green [32]) were later debated and accepted, with the exception of printed leaflets, even if their importance was recognized by the recent literature on patient engagement [33].

Last but not least, participants recognized the general importance of environmental sustainability in healthcare, and they stressed its role in boosting the hospital's reputation.

Conclusions

This study was aimed at enquiring about environmental sustainability in healthcare. The analyzed panel, albeit still limited, underlined the general importance of the topic, which currently seems more theoretical than applied in practice. The results show that, although the general principles of environmental sustainability are considered valuable, clinical practice and hospital processes follow other rules, with a few exceptions. Barriers to the full adoption of more environmentally friendly practices emerge, including a general lack of knowledge, the presence of other working priorities, scarce guidance by institutional actors and scientific societies, an insufficient perceived commitment by institutions, and legal constraints, especially linked to the clinical profession. More efforts on a global scale are needed to promote environmental practices. Governments and institutions, scientific societies, industry leaders, and scholars should join forces to study solutions, share best practices that have been applied in some contexts, and promote knowledge translation dynamics to all the involved actors, especially clinicians, and users.

As with all the studies, ours presents some limitations. The main issue is related to the very limited sample made of healthcare executives who work under similar circumstances. Despite several hospitals and institutions being represented, results are linked to a specific context, namely, the Italian one, and cannot be generalized. Still, our investigation allowed us to develop some general considerations to pave the way into a fertile phenomenon within the healthcare domain, which will probably represent one of the most promising topics for research, practice, and policy in the next few years.

Authors' Contributions FD and LC conceived the idea of the study; PP, FD, SD, MA, HB, StCa, SaCu, GG, GiMa, BR, AR, AV, and LC wrote the research protocol; AGA, GBo, GBr, GiCa, GaCa, AC, RC, TC, CC, GC, GD, CD, MFG, SL, IM, MM, GiMo, MCM, GioPa, GiuPa, SP, MP, LR, EMR, AS, PS, EAT, SV took care of data collection, FD, SD and LC took care of data analysis, FD wrote the first manuscript's draft. All authors critically reviewed the manuscript and approved the latest version of the manuscript.

Appendix

Delphi Protocol (English Version)

Section 0: Descriptive Statistics

1. What is your background?
 - Business/management
 - Law
 - Clinical
 - Other
2. What is your role?
 - General Director
 - Scientific Director
 - Medical Director
 - Administrative Director
 - Physician/GP
 - Manager
 - Other
3. What is your gender?
 - Male
 - Female
 - Prefer not to answer
4. What is your age group?
 - Under 40
 - 41–50
 - 50–60
 - Over 60
5. Do you agree to be an author in the scientific publication(s) reporting the Delphi results?
 - Yes

Think of the clinical practice within your hospital/institution/health agency/organization. Which of the following tools should be used to promote sustainability/greener clinical practices?		Importance								
		1	2	3	4	5	6	7	8	9
9	Illuminated signs and meters (e.g., reporting energy consumption or other data)									
10	Digital solutions (e.g., APPs, sensors, smart grid, ...)									

Accordingly to your knowledge and/or perception, what is the tangible impact of greener clinical practice WITHIN your hospital/institution? On a scale from 1 to 9, where 1 = low, and 9 = remarkable, how would you rate the following statements? Please note that all the elements should be rated according to your knowledge		Importance								
		1	2	3	4	5	6	7	8	9
1	Positive contribution for the environment									
2	More engagement of the patient									
3	Cost reduction									
4	Better quality of care									
5	My personal commitment									
6	Reputation of the hospital/institution									

References

1. Massaro M, Dumay J, Garlatti A, Dal Mas F. Practitioners’ views on intellectual capital and sustainability: from a performance-based to a worth-based perspective. *J Intellect Cap.* 2018;19(2):367–86.
2. Hall JK, Daneke GA, Lenox MJ. Sustainable development and entrepreneurship: past contributions and future directions. *J Bus Ventur.* 2010;25(5):439–48. <https://www.sciencedirect.com/science/article/pii/S0883902610000200>.
3. UN. The sustainable development goals: our framework for COVID-19 recovery. 2020 [cited 2020 Oct 17]. <https://www.un.org/sustainabledevelopment/sdgs-framework-for-covid-19-recovery/>.
4. Re B, Magnani G. Value co-creation in circular entrepreneurship: an exploratory study on born circular SMEs. *J Bus Res.* 2022;147:189–207. <https://www.sciencedirect.com/science/article/pii/S0148296322003277>.
5. Re B, Magnani G. Stakeholder engagement mechanisms and value creation in circular entrepreneurship. In: Kujala J, Heikkinen A, Blomberg A, editors. *Stakeholder engagement in a sustainable circular economy.* London: Palgrave Macmillan; 2022.
6. Torain MJ, Maragh-Bass AC, Dankwa-Mullen I, Hisam B, Kodadek LM, Lilley EJ, et al. Surgical disparities: a comprehensive review and new conceptual framework. *J Am Coll Surg.* 2016;223(2):408–18. <https://doi.org/10.1016/j.jamcollsurg.2016.04.047>.
7. Haider AH, Dankwa-Mullan I, Maragh-Bass AC, Torain M, Zogg CK, Lilley EJ, et al. Setting a National Agenda for surgical disparities research recommendations from the National Institutes of Health and American College of Surgeons summit. *JAMA Surg.* 2016;151(6):554–63.

8. Elk R, Felder TM, Cayir E, Samuel CA. Social inequalities in palliative care for cancer patients in the United States: a structured review. *Semin Oncol Nurs*. 2018;34(3):303–15. <https://doi.org/10.1016/j.soncn.2018.06.011>.
9. Barcellini A, Dal Mas F, Paoloni P, Loap P, Cobianchi L, Locati L, et al. Please mind the gap—about equity and access to care in oncology. *ESMO Open*. 2021;6(6):100335.
10. Haider AH, Scott VK, Rehman KA, Velopulos C, Bentley JM, Cornwell EE, et al. Racial disparities in surgical care and outcomes in the United States: a comprehensive review of patient, provider, and systemic factors. *J Am Coll Surg*. 2013;216(3):482–492.e12. <https://doi.org/10.1016/j.jamcollsurg.2012.11.014>.
11. Kronenfeld JP, Graves KD, Penedo FJ, Yanez B. Overcoming disparities in cancer: a need for meaningful reform for Hispanic and Latino cancer survivors. *Oncologist*. 2021;26(6):443–52.
12. Blanford JJ, Kumar S, Luo W, MacEachren AM. It's a long, long walk: accessibility to hospitals, maternity and integrated health centers in Niger. *Int J Health Geogr*. 2012;11(1):24. <https://doi.org/10.1186/1476-072X-11-24>.
13. Alemayehu C, Mitchell G, Nikles J. Barriers for conducting clinical trials in developing countries—a systematic review. *Int J Equity Health*. 2018;17(1):37.
14. Sousa MJ, Dal Mas F, Lopes Da Costa R. Editorial EJKM Volume 18 Issue 3. *Advances in health knowledge management: new perspectives*. *Electron J Knowl Manag*. 2021;18(3):407–11.
15. Tennison I, Roschnik S, Ashby B, Boyd R, Hamilton I, Oreszczyk T, et al. Health care's response to climate change: a carbon footprint assessment of the NHS in England. *Lancet Planet Health*. 2021;5(2):e84–92. [https://doi.org/10.1016/S2542-5196\(20\)30271-0](https://doi.org/10.1016/S2542-5196(20)30271-0).
16. NHS. Delivering a net zero NHS. Greener NHS; 2022.
17. The Royal College of Surgeons of England. Sustainability in the operating theatre. *Standards & Research*. 2022 [cited 2023 May 27]. <https://www.rcseng.ac.uk/standards-and-research/standards-and-guidance/good-practice-guides/sustainability-in-operating-theatre/>.
18. The Royal College of Surgeons of Edinburgh; The Royal College of Surgeons of England; Royal College of Physicians and Surgeons of Glasgow. Intercollegiate Green Theatre checklist compendium of evidence. 2022 [cited 2023 May 27]. <https://www.rcseng.ac.uk/-/media/images/rcs/about-rcs/sustainability/greentheatrechecklist.pdf>.
19. National Institute for Health and Care Research Global Health Research Unit on Global Surgery. Reducing the environmental impact of surgery on a global scale: systematic review and co-prioritization with healthcare workers in 132 countries. *Br J Surg*. 2023;1–14.
20. The Royal College of Surgeons of Edinburgh. Green theatre checklist environmental sustainability and surgery. 2022 [cited 2023 May 27]. <https://www.rcsed.ac.uk/professional-support-development-resources/environmental-sustainability-and-surgery/green-theatre-checklist>.
21. Linstone HA, Turoff M. Delphi: a brief look backward and forward. *Technol Forecast Soc Change*. 2010;78(9):1712–9.
22. Cobianchi L, Dal Mas F, Massaro M, Bednarova R, Biancuzzi H, Filisetti C, et al. Hand in hand: a multistakeholder approach for co-production of surgical care. *Am J Surg*. 2022;223(1):214–5.
23. Dal Mas F, Garcia-Perez A, Sousa MJ, Lopes da Costa R, Cobianchi L. Knowledge translation in the healthcare sector. A structured literature review. *Electron J Knowl Manag*. 2020;18(3):198–211.
24. Cobianchi L, Dal Mas F, Massaro M, Fugazzola P, Coccolini F, Kluger Y, et al. Team dynamics in emergency surgery teams: results from a first international survey. *World J Emerg Surg*. 2021;16:47.
25. Previtali P, Dal Mas F, Denicolai S, Venturi A, Camprostrini S, Cogliati PG, et al. A multidisciplinary approach to care. A Delphi consensus on the case of Pancreas Units. In: Martellucci J, Dal Mas F, editors. *Towards the future of surgery*. Cham: Springer; 2023.
26. Keeney S, Hasson F, McKenna H. *The Delphi technique in nursing and health research*. London: Wiley-Blackwell; 2011. p. 1–208.
27. Bidoli C, Pegoraro V, Dal Mas F, Bagnoli C, Bert F, Bonin M, et al. Virtual hospitals: the future of the healthcare system? An expert consensus. *J Telemed Telecare*. 2023;1–13.

28. Bergmo TS. How to measure costs and benefits of ehealth interventions: an overview of methods and frameworks. *J Med Internet Res*. 2015;17(11):e254.
29. Dal Mas F, Massaro M, Rippa P, Secundo G. The challenges of digital transformation in healthcare: an interdisciplinary literature review, framework, and future research agenda. *Technovation*. 2023;123:102716. <https://www.sciencedirect.com/science/article/pii/S0166497223000275>.
30. Limb M. World will lack 18 million health workers by 2030 without adequate investment, warns UN. *Br Med J*. 2016;354:i5169.
31. Cobianchi L, Pugliese L, Peloso A, Dal Mas F, Angelos P. To a new normal: surgery and COVID-19 during the transition phase. *Ann Surg*. 2020;272:e49–51.
32. Dal Mas F, Biancuzzi H, Massaro M, Miceli L. Adopting a knowledge translation approach in healthcare co-production. A case study. *Manag Decis*. 2020;58(9):1841–62.
33. Pietrabissa A, Pugliese L, Filardo M, Marconi S, Muzzi A, Peri A. My OR goes green: surgery and sustainability. *Cir Esp (Engl Ed)*. 2022;100:317–9.

Chapter 16

Towards a Green Surgery: The Problem of Costs and Sustainability in Surgical Practice



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Introduction

Climate change is one the biggest threats to human health in the twenty-first century. It refers to long-term shifts in temperatures and weather patterns. These shifts may be natural but since the 1800s, human activities have been the main driver of climate change. In fact, since the Industrial Revolution, human activities have released large amounts of carbon dioxide and other greenhouse gases (GHGs) into the atmosphere, which has changed the earth's climate. Natural processes, such as changes in the sun's energy and volcanic eruptions, also affect the earth's climate, however, they do not explain the warming that we have observed over the last century [1]. Carbon dioxide (CO₂) emissions are mainly caused by the combustion of fossil fuels (coal, natural gas, and oil) for energy production and transportation. Globally, 50–65% of total methane emissions come from industrial and agriculture production, land use, and waste management activities [2, 3].

Nitrous oxide (N₂O) molecules, vented by human activities, stay in the atmosphere for an average of 114 years before being removed or destroyed through chemical reactions. The impact of 500 g of N₂O on warming the atmosphere is almost 300 times that of the same amount of carbon dioxide [4].

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The impact on the environment is measured by the carbon footprint which is the total amount of greenhouse gases (including carbon dioxide and methane) that are generated as a result of the activities of a particular individual, organization, or community.

Man-made climate change is one of the biggest threats to Planet Earth and one of the biggest threat to human health in the twenty-first century. It causes extreme weather events leading to injuries and deaths, spread of infectious diseases vectors, temperature related diseases, increase in waterborne illnesses, mass migration of climate refugees, and catastrophic impacts from air pollution. On December 12th 2015, at COP 21, 196 parties signed the Paris Agreement that entered into force on November 4th 2016. Its goal is to limit global warming to well below 2, preferably to 1.5 °C, compared to pre-industrial levels. To achieve this long-term temperature goal, countries aim to reach global peaking of greenhouse gas emissions as soon as possible to achieve a climate neutral world by mid-century. The UN's Intergovernmental Panel on Climate Change warned, in its 2022, report that we must act "now, or never" to limit global warming to 1.5°.

The healthcare sector is on the frontline when it comes to dealing with these health impacts. However, as a major emitter, the sector itself is contributing to the problem. As a whole, the healthcare sector's climate footprint is equivalent to 4.4% of global net emissions; if it were a country, it would be the fifth largest emitter in the world. It contributes to greenhouse gas emissions through energy consumption, transport, and product manufacture, use and disposal. Emissions emanating directly from health care facilities and health care owned vehicles make up 17% of the sector's worldwide footprint. Indirect emissions from purchased energy sources such as electricity, steam, cooling, and heating comprise another 12%. Nearly three quarters (71%) of emissions originate from indirect sources (e.g., business travel, procurement, waste disposal, and water supply/treatment), and it is likely the majority of these emanate from the supply chain through the production, transport, and disposal of goods and services, such as pharmaceuticals and other chemicals, food and agricultural products, medical devices, hospital equipment, and instruments.

Three-quarters of all health care emissions, including from its supply chain, are generated domestically. This means roughly one-quarter of all health care emissions are generated outside of the country where the health care product is ultimately consumed.

The European Union (EU) is the third largest contributor to global healthcare emissions (behind the USA and China), accounting for 12% of global healthcare emissions [5].

The very organizations that we trust to heal us in our time of need also play a role in harming us. Previous research identifies the operating room (OR) as a major source of spending and waste generation in a medical facility [6–8], accounting for 650–1200 kg of medical waste per day and more than 3 million kilograms of GHG emissions per hospital annually [9].

Operating theaters, in particular, have a disproportionate environmental impact not only because of waste production but because of their energy-intensive processes, consumption of resources and the use of volatile anesthetic agents as well. They are estimated to be 3–6 times more energy intensive than clinical wards and

tend to produce approximately 50–70% of the total hospital waste [10, 11]. ORs are highly energy-intensive due to their unique requirement for stringent temperature and ventilation control for patient safety and microbial control. The most significant contributors are heat, ventilation, and air-conditioning (HVAC) systems, followed by lighting and machinery [8, 9, 12].

In high income countries, energy use has been found to account for between 10% and 80% of total OR emissions [9].

Waste Production

Data show that hospitals in developed countries generate on average 1% of a nation's solid waste, and 2.1% of its greenhouse gas (GHG) emissions annually [13, 14].

The amount of waste produced by health care systems rises up to 15% annually contributing to 85% to the pollution of the ecosystem [15], ORs are responsible for 20–70% of hospital waste production, it is estimated that they generate up to 2300 kg of waste per year [16] and surprisingly 80% is already produced during the set up even before the patient begins the surgery. A significant amount of waste produced in this phase is due to “overage” meaning the regular opening of surgical packs and trays before the procedure and that may not be used and therefore discarded [17].

For comparison, on average a single surgical procedure can produce as much waste as an average family in a week [18]. Interestingly there is no correlation between duration of surgery and quantity of waste generated.

The composition of OR waste includes paper, cardboard, metals, glass, linens, several types of plastic, sharps, anesthetic gases, medications, anatomical and pathological waste. If measured by weight out of the total OR waste, 39% is disposable linens, 7% paper, 26% plastic, and 27% miscellaneous waste [19].

Since the 1980s, because of the spreading awareness of infectious diseases, many surgical devices became single use ending up increasing the waste production. It is demonstrated that the same instruments, if reusable, would reduce the relative waste production up to 65% [20].

Different kinds of waste must be identified, labeled, and treated accordingly. This process starts at the point of generation, directly in the OR where the personnel differentiate the general waste from clinical waste. All clinical waste must be treated before disposed to landfill. Incineration is the preferred treatment option since it is suitable for all types of waste (excluding radioactive waste), and it significantly reduces weight and volume of waste transferred to landfill [21].

This process is from 10 to 25 times more expensive and more energy consuming than regular waste and eventually releases hydrochloric acid, dioxins, furans, and various other chemicals into the atmosphere. The repercussions on human health are enormous, long-term exposure to low doses of dioxins and furans released into the environment can lead to immune system disorders as well as abnormal development of the nervous system, endocrine disruption, and reproductive damage while short-term exposure to high doses can cause skin lesions and impaired liver

function. The segregation process of OR waste is highly operator dependent, it is estimated that 50–90% of the waste is wrongly classified as clinical while it should not exceed 15% [22].

Every OR produces up to 2 ton of liquid waste every month, 25% of which is biological hazardous. Liquid waste is disposed through the sewer system, adding immobilizing material or, the safest and least polluting option, through encapsulation in sealed containers disposed to the landfill. Surgical polypropylene draping material accounts for 19% of the total OR waste, the possibility to switch over to reusable sterile draping material should therefore be considered.

Water Consumption

Hospital water consumption is extremely high, it is estimated to be 300–1000 L per bed. The OR contributes significantly to the total consumption, the preoperative surgical hand wash is estimated to consume approximately 18.5 L per scrub per staff member [23].

Implementation of sensor guided or pedal activated faucets and alcohol based hand scrubs save extraordinary amounts of water annually [24].

Anesthetics

GHGs emissions are internationally regulated by the Kigali Amendment of the Montreal protocol, the Kyoto Protocol and the Paris Agreement. Anesthetic gasses, mostly consisting of halogenated organic compounds and nitrous oxide, are recognized to be GHGs as well but, probably because they are considered a clinical necessity, they are exempt from international regulations [25, 26].

With an estimated 10–15% of the total anthropogenic warming effect both because of radioactive forcing and in some cases because of ozone depletion, they consistently contribute to climate change. It is estimated that during the time of surgical operation only 5–20% of volatile anesthetics are metabolized by the patient while the rest reaches directly the atmosphere where they stay for 1.4–21.4 years with 2000–3000-fold warming potential compared to CO₂ [27, 28].

Volatile anesthetics are not all the same, desflurane has the greatest global warming potential (GWP), more than 2000 times that of carbon dioxide (CO₂), while sevoflurane is only 130 times as potent as CO₂ [29].

Disproportionate use of desflurane has been found to be responsible for up to 80% of GHG emissions in ORs in high income countries [30].

Halothane, an anesthetic gas essentially obsolete in most high income countries, remains widely used in parts of the Western Pacific region. Systematically switching from desflurane to sevoflurane can lead to a tenfold reduction in carbon footprint and significant cost saving [31].

Other ways to reduce waste of anesthetic gasses could be the implementation of low fresh gas flow or closed-circuit delivery that can reduce the volume of volatile gas consumed by 20% and the application of new technologies, such as dynamic gas scavenging.

Systems or silica zeolite, can absorb, destroy, and even recycle anesthetic waste gases [32].

Also, the use of volatile anesthetic agents could be profoundly limited by preferentially using total intravenous anesthesia and regional anesthesia when appropriate [33–35].

Unfortunately, intravenous anesthetics are not to underestimate as well, as for example, propofol produces toxic waste products such as phenols. Therefore propofol represents not only the most expensive, but also the most environmentally dangerous anesthetic drug because it does not degrade, it accumulates in fat, it is toxic to aquatic organisms, and it requires incineration to be fully destroyed [22].

But anesthetic gasses are not the only waste generated by anesthetists, which is approximately 25% of the total OR production. Almost half of it is recyclable, mostly consisting of glass and plastic. Glass, produced by a carbon intensive process, is recyclable and should be treated accordingly. Plastic accounts for circa 50% of the total anesthetic waste production; anesthesiology departments are considered the highest generators of hazardous waste, closely followed by intensive care units [36].

Other Sources of Emission

Different kinds of surgical approaches have different CO₂ emissions, robotic surgery seems to have a greater impact compared to laparoscopic surgery which is more demanding than open surgery, therefore the type of surgery impacts differently on the environment. It is estimated that the total CO₂ production of all laparoscopic procedures in the USA account for 355.924 ton of CO₂ emissions per year, which is equivalent to 645,000 flights from New York to London [37].

A careful understanding of the environmental impact of equivalent therapies for a single clinical issue may help in the guidance to the therapeutic choice, as, for instance, a fundoplication surgery for reflux disease impacts by 30 kg of CO₂ emissions per procedure while medical approach with proton pump inhibitors accounts for ca 100 kg of CO₂ emissions per patient per year [38].

Transportation is another important factor in the health system. Patient and staff travel to and from the hospital contributes up to 18% of the total healthcare carbon emissions. Incentives to use public transportation, car sharing, electric mobility, cycling or even walking should be provided. Patients should be visited and checked, whenever safety criteria are met, by remote technology.

Further Controversies and the 5Rs

The need for a better understanding of climate change and a prompt application of mitigation strategies in the health sector is urgent. Differently from industry, health care has less regulations regarding environment safety therefore, while patient safety and hygienical standards always have maximum priority, the need to reduce carbon footprint was rather suggested by the common sense of the administrators. Carbon footprint studies that evidence the entity of the problem are just a starting point. In recent years, also under the pressure of the literature on the matter, the need to make more environmentally sustainable choices leaked inside the ORs but the task of better decision making around carbon is demanding and needs support. There are several organizations which offer a range of proposals in this regard such as Health Care Without Harm, Greening the Operating Room, Practice Green-health and Operating Green. Health administrators need to evaluate all options in terms of their cost effectiveness, but the shared principles may be resumed in the 5Rs: reduce, reuse, recycle, rethink, and research. On a practical level to reduce means reduction of ORs energy consumption such as reduction of heating/cooling or ventilation when unoccupied, switching to led bulbs; reduction of water consumption by reducing the flow in OR faucets, implementing pedal or sensor activated water flow or even switching to other means of surgical scrubbing. Printed reports may be eliminated preserving paper consumption. Plastic may be decreased by saving up on single use materials and packaging. The reduction of overage saves drugs and materials. Anesthetic gasses should be used wisely, low flow anesthesia on closed circuit should be a rule, future goal should be the scavenging or oxidizing of all inhaled anesthetics before they are vented in the atmosphere. Medical devices can be reprocessed, such as surgical instruments, drapes, and gowns; the use of disposable instruments should be limited. A correct waste identification allows to increase the volume of the recycled material reducing the energy for de novo production. Rethink refers to the removal of unnecessary items and unused tools from surgical kits, the use of telemedicine whenever possible, the reduction of hospital length of stay through fast tracking and eras protocols. Sustainable purchasing should be privileges on the base of life cycle analysis and carbon emissions. Benefits should be reinvested in projects supporting patients and/or professionals as, for instance, providing incentives for the use of public transport or eco-sustainable mobility by also creating suitable spaces. Research is essential for decision making, data on life cycle analysis of medical devices should be provided, carbon footprint of new practice and technologies must be investigated also to push development of sustainable devices. Comparing different health systems is useful to identify strategies on how to improve, based on the experience of others.

Greening Surgery Is Greening People

The goal of greening is demanding, concerns about staff attitudes and increased workload, a lack of leadership and a lack of governance engaging in health care, transport policies and technology application, are mostly advocated to be the main

barriers. It is demonstrated that health care personnel attitudes or lack of awareness represent one of the most significant barriers to OR greening [39].

Research showed that staff members sometimes does perceive the engagement in greening initiatives as an inconvenient, time-consuming activity, as, for instance, because of the different plastic composition used in OR it cannot be recycled together and segregating individual plastics would likely interrupt the OR workflow. Usefulness of segregation is, as well, not always perceived because of the “it all goes out as trash anyway” attitude [20].

Interestingly this kind of concerns are often present already outside the workplace as, for instance, global warming is not always believed to be a consequence of human activity and therefore creating a serious psychological barrier for engagement during the working activities [18].

Reluctance to change can also be due to the lack of understanding and education. Sometimes concerns around infection control arise because often early in professional curricula it is tough that cleanliness and sterility depends on the use of disposable products or that liquid medications may be disposed down the sink rather than in general landfills specifically designed to contain and control pharmaceutical waste or even that incinerating OR waste before disposal “is never a mistake.” Furthermore, the exigencies associated with anesthesia, surgery, and medico legal requirements have amplified the apparent need for preparedness, even being over-prepared. This can be a hard habit to break because the alternative of “under-preparedness” can affect patient safety, patient outcome, and medico legal costs.

To overcome this resistance to change strong leadership is essential to create lasting effect and an environmentally mindful culture. The aim of reducing carbon footprint from healthcare facilities must necessarily pass from the implementation of directives aimed at reducing emissions. These should be structured in guidelines and applied by all employees. It is by imposition of guidelines that personnel is induced to pursue the objectives of the eco-sustainable reorganization plan over time. It has been shown that employees are generally enthusiastic to participate and being directly involved in initiatives aimed at protecting the environment, but a constant motivational boost is required. This can be encouraged through ongoing education programs or through mandatory retraining offered by hospital management.

At the operating room level, the surgeons play a prominent role having a strong decision-making role on the choice of instruments and operating equipment. A strong collaboration between surgeons, anesthetists, nurses, room attendants, hospital administrations, and even local administrations is necessary to be able to obtain a concrete change with a shared responsibility.

To facilitate this interaction, and prevent failure due to unclear scope, it is proposed to set up an “OR greening team” with a team leader who maintains motivation on shared objectives, a facilitator who ensures that the group works well and a sponsor who can intervene by mitigating or solving any unforeseen events [40].

From the political-administrative point of view, the challenge is demanding due to the delay between the implementation of adequate policies with the reduction of GHG emissions and the achievement of climate change. If, today, we would achieve the reduction in emissions required to keep global warming below 2 °C, we would

not be able to appreciate a deviation until the year 2050 and such a 30–40 years prevision is difficult for financial systems to cope with.

The analysis of the costs for a more eco-sustainable operating room are, however, interesting and reserve some surprises as the savings are sometimes substantial. Annual healthcare cost in the USA in 2020 was 4.1 trillion USD, in UK 289.6 billion USD, and 118 billion USD in Italy. The percentage of gross domestic product invested on healthcare is progressively increasing internationally. A study on Mediterranean countries has shown a positive correlation between economic growth, health expenditure and sanitation and on life expectancy. In detail it showed that a 1% upsurge in health expenditure contributes to a 0.0184%, 0.0252%, and 0.0574% upsurge in life expectancy. Proper sanitation and waste management were identified as principal factors for preventing health related death [41].

In the USA, the disposal of healthcare waste accounts for about 20% of a hospital's environmental services budget. Regulated waste costs 10–20 times more than general waste due to additional handling and processing. Given the considerable costs, it is reasonable to propose a correct differentiation of waste in the place where it is generated, which represents the single intervention with the greatest economic impact.

At a single institution appropriate segregation saved USD 576,024 in a 24-month period for over 80,000 surgical cases [42].

Operation rooms do not only produce a lot of waste, but they are also highly energy consuming.

Saving energy, reducing emissions and at the same time saving on operating room costs is possible if appropriate initiatives are proposed and implemented. These can be divided into programmatic areas such as waste separation and recycling, reprocessing of surgical instruments, appropriate fluid management, adaptation of operating room lighting, reformulation of operating kits, use of multipurpose containers and reusable instruments, and conscientious use of anesthetic gases. An analysis of environmental stewardship programs in the USA in 2018 showed that utilizing a reusable canister fluid management system for suction canisters that automatically empties to the sanitary sewer could save up to 3.613 USD annually per OR; appropriate energy management by “powering down” ORs when unused, by switching off lights and computers and switching to LED for surgical lighting would save up to almost 8000 USD annually per OR. Medical device reprocessing saves 12,000 USD per year per OR, surgical kit reformulation limiting overage saves 9524 USD per OR annually and switching to reusable medical products and sterilization containers saves almost 23,000 USD per OR year [43]. Recycling single use devices by reprocessing saves almost 100,000 USD annually per 100 bed hospital [44].

The total projected theoretical cost savings per OR are about 56,321 USD and this figure must be multiplied by the number of ORs of every single hospital. A unified and consistent approach to implementing best practices across the health care sector could save U.S. hospitals and ambulatory surgery centers nearly 2.95 billion USD annually and reduce waste to landfill by more than 265,000 ton each year.

Furthermore, it is possible to donate unused or discarded materials by operating theaters to charity. These materials can be sent and used in countries in need in accordance with the directives and regulations in force. It is estimated that in the USA up to 200 million USD worth of unused or discarded OR material could be annually donated to charity [45].

References

1. National Academy of Sciences. Climate change: evidence and causes: update 2020. Washington, DC: The National Academies Press; 2020. p. 5. <https://doi.org/10.17226/25733>.
2. IPCC. Climate change 2013: the physical science basis. Contribution of working group I to the fifth assessment report of the intergovernmental panel on climate change. Cambridge: Cambridge University Press; 2013. 1585 pp.
3. Stavert AR, Saunio M, Canadell JG, Poulter B, Jackson RB, Regnier P, Lauerwald R, Raymond PA, Allen GH, Patra PK, Bergamaschi P, Bousquet P, Chandra N, Ciais P, Gustafson A, Ishizawa M, Ito A, Kleinen T, Maksyutov S, McNorton J, Melton JR, Müller J, Niwa Y, Peng S, Riley WJ, Segers A, Tian H, Tsuruta A, Yin Y, Zhang Z, Zheng B, Zhuang Q. Regional trends and drivers of the global methane budget. *Glob Chang Biol.* 2022;28(1):182–200. <https://doi.org/10.1111/gcb.15901>.
4. IPCC. Climate change 2007: the physical science basis. In: Solomon S, Qin D, Manning M, Chen Z, Marquis M, Averyt KB, Tignor M, Miller HL, editors. Contribution of working group I to the fourth assessment report of the intergovernmental panel on climate change. Cambridge: Cambridge University Press; 2007. 996 pp.
5. Health care's climate footprint: how the health sector contributes to the global climate crisis and opportunities for action, a report by Health Care Without Harm. <https://noharm-global.org>.
6. Zygourakis CC, Yoon S, Valencia V, et al. Operating room waste: disposable supply utilization in neurosurgical procedures. *J Neurosurg.* 2017;126(2):620–5.
7. Stockert EW, Langerman A. Assessing the magnitude and costs of intraoperative inefficiencies attributable to surgical instrument trays. *J Am Coll Surg.* 2014;219(4):646–55.
8. Thiel CL, Eckelman M, Guido R, et al. Environmental impacts of surgical procedures: life cycle assessment of hysterectomy in the United States. *Environ Sci Technol.* 2015;49(3):1779–86.
9. MacNeill AJ, Lillywhite R, Brown CJ. The impact of surgery on global climate: a carbon footprinting study of operating theatres in three health systems. *Lancet Planet Health.* 2017;1(9):e381–8.
10. Guetter CR, Williams BJ, Slama E, et al. Greening the operating room. *Am J Surg.* 2018;216:683–8.
11. Yates EF, Bowder AN, Roa L, et al. Empowering surgeons, anesthesiologists, and obstetricians to incorporate environmental sustainability in the operating room. *Ann Surg.* 2021;273:1108–14.
12. Campion N, Thiel CL, DeBlois J, Woods NC, Landis AE, Bilec MM. Life cycle assessment perspectives on delivering an infant in the US. *Sci Total Environ.* 2012;425:191–8.
13. Lui JT, Rudmik L, Randall D. Reducing the preoperative ecological footprint in otolaryngology. *Otolaryngol Head Neck Surg.* 2014;151:805–10.
14. Stall NM, Kagoma YM, Bondy JN, et al. Surgical waste audit of 5 total knee arthroplasties. *Can J Surg.* 2013;56:97–102.
15. Eckelman MJ, Sherman JD. Environmental impacts of the U.S. Health care system and effects on public health. *PLoS One.* 2016;11(6):157014.
16. Southorn T, Norrish AR, Gardner K, et al. Reducing the carbon footprint of the operating theatre: a multicentre quality improvement report. *J Perioper Pract.* 2013;23:144–6.
17. Laustsen G. Greening in healthcare. *Nurs Manag.* 2010;41:26–31.

18. Kagoma YK, Stall N, Rubinstein E, Naudie D. People, planet and profits: the case for greening operating rooms. *CMAJ*. 2012;184(17):1905–11.
19. Tieszen ME, Gruenberg JC. A quantitative, qualitative, and critical assessment of surgical waste. Surgeons venture through the trash can. *JAMA*. 1992;267:9765–80.
20. Conrardy J, Hillanbrand M, Myers S, Nussbaum GF. Reducing medical waste. *AORN J*. 2010;91(6):711–21.
21. Francis MC, Metoyer LA, Kaye AD, et al. Exclusion of noninfectious medical waste from the contaminated waste stream. *Infect Control Hosp Epidemiol*. 1997;18:656–8.
22. Wyssusek KH, Keys MT, van Zundert AAJ. Operating room greening initiatives—the old, the new, and the way forward: a narrative review. *Waste Manag Res*. 2018;37(1):3–19.
23. World Health Organization. Global guidelines for the prevention of surgical site infection. Geneva: World Health Organization; 2016.
24. Wormer BA, Augenstein VA, Carpenter CL, Burton PV, Yokeley WT, Prabhu AS, et al. The green operating room: simple changes to reduce cost and our carbon footprint. *Am Surg*. 2013;79(7):666–71.
25. Charlesworth M, Swinton F. Anaesthetic gases, climate change, and sustainable practice. *Lancet Planet Health*. 2017;1:e216–7.
26. Sherman JD, Ryan S. Ecological responsibility in anesthesia practice. *Int Anesthesiol Clin*. 2010;48:139–51.
27. Royal Australasian College of Surgeons. Environmental impact of surgical practice (Position Paper). 2018. <https://www.surgeons.org>.
28. Kagoma Y, Stall N, Rubinstein E, et al. People, planet and profits: the case for greening operating rooms. *Can Med Assoc J*. 2012;184:1905–11.
29. Thiel CL, Woods NC, Bilec MM. Strategies to reduce greenhouse gas emissions from laparoscopic surgery. *Am J Public Health*. 2018;108:S158–64.
30. Richter H, Weixler S, Schuster M. The carbon footprint of anaesthesia: how the choice of volatile anaesthetic affects the CO₂ emissions of a department of anaesthesiology. *Anasth Intensivmed*. 2020;61:154–61.
31. Meyer MJ. Desflurane should des-appear: global and financial rationale. *Anesth Analg*. 2020;131:1317–22.
32. Rauchenwald V, Rollins MD, Ryan SM, et al. New method of destroying waste anesthetic gases using gas-phase photochemistry. *Anesth Analg*. 2020;131:288–97.
33. Petre M-A, Malherbe S. Environmentally sustainable perioperative medicine: simple strategies for anesthetic practice. *Can J Anaesth*. 2020;67:1044–63.
34. Bravo D, Gaston RG, Melamed E. Environmentally responsible hand surgery: past, present, and future. *J Hand Surg Am*. 2020;45:444–8.
35. McGain F, Muret J, Lawson C, Sherman JD. Environmental sustainability in anesthesia and critical care. *Br J Anaesth*. 2020;125:680–92.
36. Vaccari M, Tudor T, Perteghella A. Costs associated with the management of waste from healthcare facilities: an analysis at national and site level. *Waste Manag Res*. 2018;36:39–47.
37. Power NE, Silberstein JL, Ghoneim TP, Guillonneau B, Touijer KA. Environmental impact of minimally invasive surgery in the United States: an estimate of the carbon dioxide footprint. *J Endourol*. 2012;26(12):1639–44.
38. Gatenby PAC. Modelling the carbon footprint of reflux control. *Int J Surg*. 2011;9(1):72–4.
39. Delmonico DVG, Santos HH, Pinheiro MAP, et al. Waste management barriers in developing country hospitals: case study and AHP analysis. *Waste Manag Res*. 2018;36:48–58.
40. Simon RW, Canacari EG. A practical guide to applying lean tools and management principles to health care improvement projects. *AORN J*. 2012;95:85–100.
41. Radmehr M, Adebayo TS. Does health expenditure matter for life expectancy in Mediterranean countries? *Environ Sci Pollut Res*. 2022;29:60314–26. <https://doi.org/10.1007/s11356-022-19992-4>.
42. Stonemetz J, Pham JC, Necochea AJ, et al. Reduction of regulated medical waste using lean sigma results in financial gains for hospital. *Anesthesiol Clin*. 2011;29:145–52.

43. [PracticeGreenhealth.org/GOR](https://www.practicegreenhealth.org/GOR).
44. Moduga A. Reduce, reuse, recycle: reprocessing medical devices. www.hospitalmanagement.net/features/feature80981/. Accessed 5 Dec 2022.
45. Rosenblatt WH, Silverman DG. Cost-effective use of operating room supplies based on the REMEDY database of recovered unused materials. *J Clin Anesth.* 1994;6:400–4.

Part VI
Over the Future

Chapter 17

The Bionic Man: From Neuromodulation to Visual Prosthesis



Jacopo Martellucci  and Francesca Dal Mas 

Introduction

Modern medicine and, in particular, surgery can nowadays be considered as an advanced technological activity. Today, thanks to medical technology advancements of recent years, medical and surgical practice and healthcare, in general, cannot be separated from technology and the doctor–patient relationship is usually filtered by technological interface (computer, devices, sensors, etc.).

However, technology is progressively moving from a place between the doctor and the patient to a place inside the patient. From the concept of cyborg that was introduced in the late 1950s, the idea of integrating humans and machines has recurred in science fiction and popular culture.

Even if there is still a lot of confusion between cybernetic, bionic, robotic, artificial intelligence, and many other trendy concepts, one thing is sure: the development of body–machine interfaces that provide a link between the human and an external or implanted machine may be capable not only to replace functions, but also to improve human capabilities.

When talking about bionics, we are considering the design of engineering systems, especially electronic ones, based on biological systems.

Cybernetics is instead the science of communication and control in living things (animals, humans) and machines.

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Robotics involves design, construction, operation, and use of robots. The goal of robotics is to design machines capable of carrying out a complex series of actions automatically and that can help and assist humans.

Current bionic technologies like bionic hands, leg prostheses, exoskeletons for paraplegia, retina-implants for blindness, and cochlear implants for deafness have helped numerous individuals with physical disabilities to recover and sometimes improve their lost function.

According to the World Health Organization, almost 16% of the global population have a disability, and the increasing proliferation of bionic technologies has the potential to change stereotypes toward people with disabilities, usually perceived as good intentioned but lacking in physical abilities [1].

For many of these therapeutic possibilities, surgery is asked to play a decisive role, creating an interface between the nervous system and the machine, enabling it to communicate.

Technology first allowed us to move from the idea of “great incision: great surgeon” to the idea of “less invasive: greater surgeon.” In the near future it will enable us to move from the idea of “resecting surgery” to that of “replacing surgery.”

Bionics, cybernetics, robotics, and biotechnology, in general, are developing many fascinating ways of integrating our biological system with mechanical devices, such as limbs prosthesis, tissue regeneration, neurostimulators, pacemakers, a lot of monitoring and therapy regulation sensors (cardiac function, pressure, glucose level, brain activity, etc.), vascular neuromodulation, artificial kidney, synthetic tissues, cochlear implants, bionic eye, exoskeletons, and many others. The aim of this paper is to briefly describe some of those in which surgery is primarily involved in creating the neural-computer interface and in which the literature recognizes potential or well established indications.

Brain

From the use of electric eels described by Scribonus Largus in 47 AD in his Compositions for the treatment of headache and other diseases (such as arthritis), to Galvani and especially his nephew Aldini, that in the early 1800 carried out numerous studies on the effects of electricity (or galvanism) on the human body, during which he also investigated its therapeutic potential (in 1803 he described the treatment of severe melancholy by head electrical stimulation), until electroconvulsive therapy for neuropsychiatric disorders, a large variety of techniques for controlling, influencing, or modulating brain function have been explored in the history of medicine [2].

The modulation of brain function through the application of weak direct current was first observed directly in the early nineteenth century. Today, techniques for brain stimulation or neuromodulation vary depending on the clinical context, the precise location and size of targeted areas, and the desired effect.

In the last decades, deep brain stimulation and transcranial magnetic stimulation have had growing applications, offering alternatives to pharmacological treatment of neurological and neuropsychiatric disorders.

Deep brain stimulation (DBS) has evolved considerably over the past four decades. Although it has primarily been used to treat movement disorders such as Parkinson's disease, essential tremor, and dystonia, it has further been approved to treat obsessive compulsive disorder and epilepsy. Moreover, novel potential indications in both neurological and psychiatric disorders are undergoing active study [3].

Deep brain stimulation has a more favorable side-effect profile compared to lesioning procedures (such as thalamotomy and pallidotomy), and given the vast array of potential stimulation parameters, is highly adjustable. Moreover, it has also played an invaluable role for research, helping to a better understanding of basal ganglia circuitry and other connected neural networks and leading a renaissance of functional neurosurgery (Table 17.1). In the last years more than 1500 papers per year have been published (Fig. 17.1) and it is estimated that to date more than 200,000 patients have received DBS and the number of new patients treated worldwide is growing by more than 15,000 per year.

Table 17.1 Main indication for DBS with stimulation areas and levels of evidence according to Oxford classification (LoE: level of evidence)

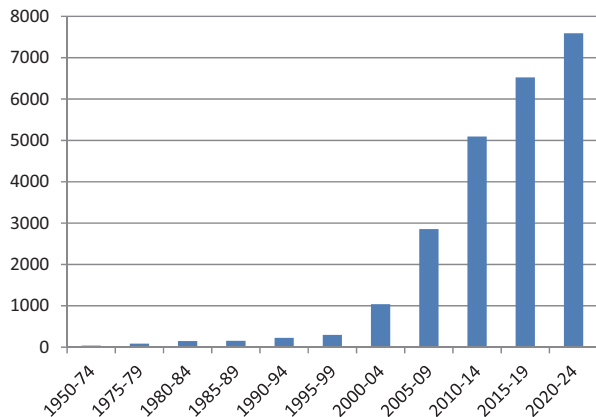
Indication	Main stimulation area	Other stimulation areas	LoE
Essential tremor	Ventrointermedius thalamic nucleus	– Caudal zona incerta/posterior subthalamic area – Ventrolateral thalamus – Ventral oral posterior nucleus	I
Parkinson's disease	Superior-lateral subthalamic nucleus	Globus pallidus internus	I
Dystonia	Posteroventral globus pallidus internus	Subthalamic nucleus	I
Obsessive compulsive disorder	Ventral capsule/ventral striatum	– Nucleus accumbens – Bed nucleus of the stria terminalis – Anteromedial subthalamic nucleus – Anterior limb of the internal capsule – Inferior thalamic peduncle	III
Epilepsy	Anterior nucleus of the thalamus	– Cerebellum-hippocampus – Centromedian-parafascicular complex	II
Chronic pain	– Periaqueductal periventricular gray – Sensory thalamus (ventral posterolateral nucleus/ventral posterior medial nucleus)	– Ventral capsule/ventral striatum – Anterior cingulate cortex – Centromedian-parafascicular complex – Anterior limb of the internal capsule – Posterior hypothalamus	III
Alzheimer's disease	Fornix	– Nucleus basalis of Meynert – Ventral capsule/ventral striatum	III
Depression	Subcallosal cingulate gyrus	– Habenula – Medial forebrain bundle – Inferior thalamic peduncle – Ventral capsule/ventral striatum – Nucleus accumbens – Anterior limb of the internal capsule	III

(continued)

Table 17.1 (continued)

Indication	Main stimulation area	Other stimulation areas	LoE
Tourette syndrome	– Centromedian/ parafascicular complex – Dorsomedial thalamus	– Globus pallidus internus – Anterior limb of the internal capsule	IV
Obesity	Lateral hypothalamus	– Nucleus accumbens – Medial/lateral orbitofrontal cortex – Medial prefrontal cortex – Ventral pallidum – Caudate-insula – Anterior cingulate cortex-amygdala – Putamen-hippocampus	IV
Anorexia nervosa	Subgenual cingulate gyrus	– Nucleus accumbens – Bed nucleus of the stria terminalis – Ventral capsule/ventral striatum	IV
Tinnitus	Transverse temporal gyri (Heschl’s gyrus)	– Subthalamic nucleus – Ventral intermediate thalamic nucleus – Locus of the caudate neurons – Amygdala-hippocampus	IV
Post traumatic stress disorder	Basolateral amygdala	Subgenual cingulate gyrus	V
Anxiety	Anterior limb of the internal capsule	Nucleus accumbens	V
Substance abuse	Nucleus accumbens	– Subthalamic nucleus – Anterior limb of the internal capsule	IV
Refractory chronic cluster headache	Red nucleus	– Substantia nigra-subthalamic nucleus – Centromedian nucleus – Parafascicular/subparafascicular nucleus – Mammillothalamic tract – Habenulo-interpeduncular tract	III
Vegetative state	Centromedian- parafascicularis nucleus complex	Mesencephalic reticular formation	IV

Fig. 17.1 Number of publications per year. (Pubmed search: Deep Brain Stimulation)



The basic components of DBS include the internal system, consisting of the lead and electrodes, the extension cables, and the implantable pulse generator (IPG), as well as the external system, consisting of the clinician programmer, the patient programmer, and a recharger for rechargeable devices [4].

A variety of DBS lead designs with different electrode configurations are available and the electric stimulation parameters vary according to the disorders and symptoms to treat. Emerging technology applied to DBS systems is enabling programming choice to be shifted from a clinician's empirical assessment to an automatic device response to intrinsic neuronal changes, through recording of local field potentials (LFP). The use of LFP opens to an adaptive stimulation, representing a tailored closed loop control to the patient's therapy management [5].

Despite the large amount of studies published about DBS, the exact mechanism of action still has to be completely clarified. One of the hypothesis is that electrical stimulation modulates abnormal circuits toward a more physiological state, through an inhibition/excitation activity. Moreover, neuroplasticity and remodeling effects have been reported, moving from a symptom control function to a disease cure activity [6].

Further development of novel neuromodulation techniques employing ultrasound, micro-scale magnetic fields, and optogenetics is emerging thanks to the rapid improvement and understanding of the clinical and experimental applications of artificial modulation of brain activity in human health and disease, suggesting a future yet to be written.

Senses

Another well established example of brain-machine interaction is represented by the sensory prostheses. The cochlear implant, also known as the bionic ear, is one of the earliest forms of brain-machine interaction, with over 30 years of studies and more than 320,000 deaf patients treated [7, 8].

The cochlear implant is currently the only medical treatment available to partially restore some form of hearing in patients with profound-to-severe hearing loss. Current literature suggests positive benefits of cochlear implantation regarding sound localization, QoL, tinnitus, and speech perception in noise and quiet. It is surgically placed under the skin behind the ear where it can bypass the normal sound-conducting mechanism converting sounds into electrical impulses which directly stimulate the residual auditory nerves.

In this field, remote implants programming, totally implanted devices, intraneural electrode placement, hybrid implants with electroacoustic stimulation could be promising evolutions of the actual technology.

However, even more fascinating are the various research lines that are currently ongoing to develop an artificial retina or "bionic eye" to enable blind people to see again.

Since the 1950s, vision researchers have been working toward the ambitious goal of restoring a functional level of vision to blindness via electrical stimulation of the visual pathways.

The target of such stimulation is to evoke neuronal activity at a site where the visual pathway maintains his functional activity, irrespective of the underlying cause of blindness, then propagating to the visual cortex, resulting in some form of visual perception (usually spatially localized flashes of light, called phosphenes).

Considering this, patients with blindness resulting from retinal disease, such as age-related macular degeneration or inherited dystrophies such as retinitis pigmentosa that often leaves the inner retina and optic nerve relatively intact, could be good candidates for a retinal vision prosthesis.

Conversely, damage to the inner retina or optic nerve requires a prosthesis that stimulates more distal sites along the visual pathway.

Regardless of whether the implant is cortical or retinal, there are common features in the visual prostheses systems that include image acquisition, simplification/processing, and transmission [9, 10].

Image acquisition is usually obtained through a camera, typically built into a pair of glasses. However, compared to normal vision, the percept that can be restored with visual prostheses is still rudimentary and the resolution remains relatively limited, even with relatively high numbers of electrodes.

Therefore, an important role in the optimization of prosthetic vision can be fulfilled by image processing techniques, aiming to maximize the usefulness and interpretability of phosphene representations, that involve from basic edge-filtering to more sophisticated algorithms, such as segmentation models for object recognition or facial landmark detection for emotion recognition.

Then, the image elaboration process generates electrical impulses for transmission to the electrode arrays that can take place across a wired or wireless connection.

Despite the appeal of the possibility of recovering sight, there is still few data on the results of the application of these devices in humans. Moreover, carefully designed training and rehabilitation programs will therefore be necessary to achieving successful outcomes, as will the development of appropriate tools for evaluating outcomes.

For sure, potential benefits in the evolution of these devices will be obtained through the advances of computer vision, deep learning models, artificial intelligence, and neural interfaces, that will help in the near future to improve those factors that are still limiting the potential of these projects.

Limbs

At least as fascinating as the bionic eye, and at an even earlier stage of development, is the form of brain-machine interaction in which the brain directly controls a computerized prosthesis.

Every year, more than one million of patients' limbs are amputated in the world, mainly due to diabetes, trauma, peripheral arterial disease and cancer. Thanks to diseases and wars, amputations and consequently prostheses as their most immediate solution, have a long history, starting with hooks and other prosthetic replacements of the Middle Ages up to modern bionic limbs.

However, there is a big difference in the function (and consequently construction) of bionic limbs for the upper (including hand) and the lower extremity.

In fact, while the lower limbs are used for balance, stability, standing, and walking, the situation in hand or forearm amputation, is the most complex, since the hand represents the highest level of evolution with sophisticated and unique functions.

The main problem of this kind of device is to connect and make the machine interact with the human body and his nervous system with a bidirectional communication between the electronic signals and the ionic currents of the living organism.

A standard myoelectric prosthesis usually consists of a shaft with a socket (when osseointegration is not preferred), the connection between the device and the patient, called the man-machine interface, and a robotic hand.

These prostheses receive their control motor signals from electromyographic electrodes placed in the prostheses' shaft on the remnant stump muscles and skin. Novel surgical techniques have improved the efficacy of these surface technologies with direct muscular electrodes, direct nerve connection or neuromuscular rerouting. In this last option, the remaining nerves of the brachial plexus, which have lost their distal target, are connected to new muscles (such as stump muscles or pectoral muscle). Those signals are then registered by the electrodes and transferred to the prosthesis to control motor function. In order to complete a bidirectional connection between the prosthesis and the nervous system, aiming to restore also the sensory function, some approaches have been proposed. These include non-invasive methods such as vibro or electrotactile direct stimulations, or invasive methods, by implanting electrodes to directly stimulate the peripheral nerves. Moreover, a targeted sensory reinnervation has been proposed [11–14].

Despite several promising aspects offered by innovative bionic solutions, there are still several limitations, which must be faced prior to the widespread use of similar devices. Moreover, patients may still have issues that limit the acceptability of these devices. These include the need for extensive training and components maintenance, noise during the movements, weight of the prosthesis, aesthetic limitations, and prosthetic coverings.

However, the rapid technological advancements, the development of specialized centers and surgeons, and the need to improve these patients' lives make us think that within a few years these devices will become an important reality.

Heart

The forerunner of all neuromodulation systems and the first that comes to mind in the mass imagination is surely the cardiac pacemaker. After more than 60 years from the first implanted device, huge improvements have been made to leads, devices, batteries, and indications.

The first pacemakers were little more than a battery and a timer, without any sensing capability. Moreover, a thoracotomy was required for the surgical implant.

Actual pacemakers allow wide programmability, wireless communication, modulated pacing rate, and automatic responses can be remotely monitored by physicians and are provided with long life or rechargeable batteries [15].

However, modern bionic cardiology is not only pacemakers and involves several bioengineered devices for many diseases such as blood pressure control, heart rate control, angina pectoris, and heart failure (Table 17.2) [16]. In fact, bionic cardiology can be defined as medical science in the field of cardiovascular medicine, which explores the electronic control of the heart and consequently of the entire human body.

Considering that, according to WHO, cardiovascular disease is responsible for up to 30% of mortality worldwide, the evolution of bionic cardiology may have a highly significant impact on global health and cardiac surgery.

For example, considering heart failure, there are over a million heart attacks or clinically significant angina episodes per year in the USA. Even if near to 90% of these patients survive, about one third may expect a recurrence in the future and of the 26 million heart failure patients worldwide, around 50% will die within 5 years from diagnosis.

Heart failure is not (yet) a curable condition, but its progress can be slowed considerably thanks to drugs and other medications. The impact of cardiac implantable electronic devices on the incidence and progression of heart failure depends upon the type of device and device programming. While right ventricular pacing may exacerbate or worsen heart failure, cardiac resynchronization therapy or implantable cardioverter defibrillator can improve clinical outcomes.

Table 17.2 Cardiovascular diseases and potential electrical modulation treatments

Disease	Potential treatment
Angina pectoris	Carotid sinus nerve modulation
Arrhythmias	Pacemaker Carotid sinus nerve modulation Vagal nerve stimulation
Hypertension	Carotid sinus nerve modulation Electroacupuncture
Hypotension	Closed loop spinal cord stimulation Transcutaneous electrical stimulation
Heart failure	Implantable cardiac defibrillator Implantable chronic vagal neurostimulator Cardiac resynchronization treatment device

Moreover, heart transplantation has become one of the standard therapeutic modalities to treat patients with severe heart failure; however, the availability of donor hearts is limited and another possible option is the artificial heart. Although greatly improved over the years, the artificial heart still remains a temporary solution, usually as a bridge to transplantation. The main problem is that the host body is not able to directly control the artificial heart and the prosthesis does not always work in concert with the host body. To solve this, an artificial heart must exchange various forms of information with its host body and the aim of the bionic medicine is to achieve such artificial organs, involving nerve activity and connections, micro-processors and neuromodulation systems, blood pressure control, and cardiovascular brain interface.

Moreover, besides neural interface evolution, artificial heart technology continues to advance, with many innovative prototypes based on 3D printing, magnetic systems and new materials.

It is, therefore, to be expected that due to technological developments, cardiology and cardiac surgery will change dramatically in the near future, affecting our current medical knowledge and the course of our patients' lives.

Visceral Activity

As happens for the other systems in our body, electrical stimulation of the enteric nervous system is an attractive approach to modify gastrointestinal activity. This is because the gastrointestinal tract, like the heart, has its own natural pacemakers, and the electric signals they generate can be influenced by externally delivered stimulations.

Various studies on animal models and humans have been performed, aiming to explore the potential effects on a large variety of diseases, including gastroparesis, slow transit constipation, obesity and dumping, short bowel, and other post-surgical or neurological syndromes [17, 18].

Moreover, as for brain or heart stimulation, pulse generators, pacemakers, batteries, and electrodes evolution have made these types of devices increasingly accessible, tolerable, and effective.

However, the results of the stimulation of the gastrointestinal tract are strongly influenced by the complexity of the brain gut (microbiota) axis, that involves intrinsic and extrinsic neural connections, metabolic/hormonal activity, immunological system interactions, and microbiota direct and indirect influence on gastrointestinal function. Without considering the combined effect of all these factors, the results of this type of therapies are difficult to predict and evaluate.

The majority of GI electrical stimulation treatments are performed through electrodes placed in the serosal musculature or near the target nerves, connected to an implantable pulse generator (pacemaker) (Table 17.3).

Unfortunately, an easy and safe placement of the electrodes is not always possible, and endoscopic or transcatheter approaches have been proposed.

Table 17.3 Neuromodulation treatments of gastrointestinal disorders

Organ	Disease	Treatment
Esophagus	– Dysphagia – Achalasia – GE reflux disease	Transcutaneous stimulation LES stimulation
Stomach	– Gastroparesis – Obesity – Diabetes – Dumping syndrome – Roux stasis syndrome	Gastric electrical stimulation Vagus nerve stimulation
Small intestine	– Regulation of digestion and metabolism – Pseudo-obstruction syndrome – Postoperative ileus – Short bowel syndrome	Small intestine stimulation Transcutaneous stimulation
Colon	Slow transit constipation Hirschsprung's disease	Colonic stimulation Transcutaneous stimulation

In fact, while the surgical placement of electrodes is (quite) easy for the stomach and the colon, it becomes prohibitive for the esophagus (accessibility) and small intestine (motility and risk of complications).

This could be one of the reasons why, with the exception of the Enterra® therapy (gastric stimulation for gastroparesis), other GI neuromodulation methods have still not received regulatory approval for clinical use.

The gastric pacemaker has shown varying effects on nausea, vomiting, abdominal bloating, weight loss, and quality of life in patients with gastroparesis, as well as reduction in inflammatory markers and increased insulin levels [19].

The colonic pacemaker has shown potential benefits on colonic transit, even if further studies and a better understanding of the pathophysiological mechanisms of slow transit constipation are needed before it can be introduced into routine clinical practice [20].

Although much has yet to be proven, the use of electrical stimulation, rather than chemical/pharmacological treatment, may allow a better organ-specific control, an earlier temporal effect (seconds/minutes) and a more modulable therapeutic coverage (on/off), suggesting that its role will increase in the near future. Minimally invasive surgical or interventional approaches for implantation or organ/nerve specific connection, beside technological evolution, will make these treatment options increasingly accessible and affordable.

Pelvic Floor

Pelvic floor disorders were reported in 25–30% of women [21] and represent a major social problem, also due to an increase in the average age and life expectancy.

There are many conditions that may affect pelvic anatomy and function and include pelvic organs prolapse, bladder, and bowel dysfunction (incontinence, urinary retention, constipation, etc.), pelvic muscles and connective tissues weakening, pelvic pain, sexual dysfunction, neurogenic alterations.

Many treatments have been reported for pelvic floor disorders, that include pharmacological, rehabilitative, surgical and behavioral options, giving the idea of the complexity of this integrated anatomic-functional system.

Sacral neuromodulation (SNM) uses electrical modulation to affect the physiological response of the bladder, the rectum, and other pelvic viscera. Initially applied for bladder dysfunction, its concomitant previously unevaluated positive effect on intestinal function has prompted an extension of the potential indications also in the bowel function area.

There are currently well established indications for SNM (Table 17.4), and it is included in guidelines and clinical practice, although costs and expertise still limit its widespread use [22–25]. For other diseases it is still being studied, in some cases with promising results.

Aiming to obtain the same effects of neural modulation, the percutaneous tibial nerve stimulation (PTNS) has been proposed. However, compared to SNM, PTNS appears less effective and with less evidence supporting its use.

The surgical procedure of SNM includes implanting the electrode through one of the sacral foramina (usually S3), after testing the various sensitive and motor responses bilaterally and then connecting it to a subcutaneous or external pulse generator [26].

Even if a definitive understanding of the sacral neuromodulation mechanism of action is yet to be determined, multiple potential effects have been described that involve brain, spinal, peripheral pathways and reflexes.

However, with more than 300,000 patients treated with sacral neuromodulation worldwide, this kind of treatment will represent a solid reality also in the future, being part of the increasingly numerous therapeutic solutions based on a neural-computer interface.

Table 17.4 SNM indications

Overactive bladder	Well established
Urinary retention (nonobstructive)	Well established
Fecal incontinence	Well established
Neurogenic disorders of pelvic floor	Selected patients
Pelvic pain	Selected patients
Constipation	Selected patients
Inflammatory bowel disorders	Experimental
Inflammatory bowel syndrome	Experimental
Sexual dysfunction	Experimental
Spinal cord injury	Experimental

Conclusions

The therapeutic possibilities described in this chapter certainly represent fascinating options, in some cases already well established, in others only potential. However, many issues still need to be addressed, not only technological or clinical, but also social and cultural. Patients' acceptance of implantable devices, the social prejudices about disabled people having such devices, the indications for these treatments also in pediatric age, the relevant costs, the fast technological obsolescence of long life devices, the management and disposal of batteries and other electronic components are just some of the problems that will have to be addressed in the coming years.

Surely, the improvement of knowledge needed for the evolution of these devices will also answer many unsolved questions on the complex physiological and pathophysiological connection of our body.

References

1. Meyer B, Asbrock F. Disabled or cyborg? How bionics affect stereotypes toward people with physical disabilities. *Front Psychol.* 2018;9:2251.
2. Lewis PM, Thomson RH, Rosenfeld JV, Fitzgerald PB. Brain neuromodulation techniques: a review. *Neuroscientist.* 2016;22:406–21. <https://doi.org/10.1177/1073858416646707>.
3. Lee DJ, Lozano CS, Dallapiazza RF, Lozano AM. Current and future directions of deep brain stimulation for neurological and psychiatric disorders. *J Neurosurg.* 2019;131:333–42. <https://doi.org/10.3171/2019.4.JNS181761>.
4. Frey J, Cagle J, Johnson KA, Wong JK, Hilliard JD, Butson CR, Okun MS, de Hemptinne C. Past, present, and future of deep brain stimulation: hardware, software, imaging, physiology and novel approaches. *Front Neurol.* 2022;13:825178. <https://doi.org/10.3389/fneur.2022.825178>.
5. Wårdell K, Nordin T, Vogel D, Zsigmond P, Westin CF, Hariz M, Hemm S. Deep brain stimulation: emerging tools for simulation, data analysis, and visualization. *Front Neurosci.* 2022;16:834026. <https://doi.org/10.3389/fnins.2022.834026>.
6. Aum DJ, Tierney TS. Deep brain stimulation: foundations and future trends. *Front Biosci (Landmark Ed).* 2018;23:162–82. <https://doi.org/10.2741/4586>.
7. Blume S. Histories of cochlear implantation. *Soc Sci Med.* 1999;49:1257–68.
8. Chen F, Ni W, Li W, Li H. Cochlear implantation and rehabilitation. *Adv Exp Med Biol.* 2019;1130:129–44. https://doi.org/10.1007/978-981-13-6123-4_8.
9. Lewis PM, Ackland HM, Lowery AJ, Rosenfeld JV. Restoration of vision in blind individuals using bionic devices: a review with a focus on cortical visual prostheses. *Brain Res.* 2015;1595:51–73. <https://doi.org/10.1016/j.brainres.2014.11.020>.
10. Lewis PM, Ayton LN, Guymer RH, Lowery AJ, Blamey PJ, Allen PJ, Luu CD, Rosenfeld JV. Advances in implantable bionic devices for blindness: a review. *ANZ J Surg.* 2016;86:654–9. <https://doi.org/10.1111/ans.13616>.
11. Marasco PD, Hebert JS, Sensinger JW, Beckler DT, Thumser ZC, Shehata AW, Williams HE, Wilson KR. Neurorobotic fusion of prosthetic touch, kinesthesia, and movement in bionic upper limbs promotes intrinsic brain behaviors. *Sci Robot.* 2021;6:eabf3368. <https://doi.org/10.1126/scirobotics.abf3368>.

12. Bumbaširević M, Lesic A, Palibrk T, Milovanovic D, Zoka M, Kravić-Stevović T, Raspopovic S. The current state of bionic limbs from the surgeon's viewpoint. *EFORT Open Rev.* 2020;5:65–72. <https://doi.org/10.1302/2058-5241.5.180038>.
13. Clement RG, Bugler KE, Oliver CW. Bionic prosthetic hands: a review of present technology and future aspirations. *Surgeon.* 2011;9:336–40. <https://doi.org/10.1016/j.surge.2011.06.001>.
14. Aman M, Sporer ME, Gstoettner C, Prahm C, Hofer C, Mayr W, Farina D, Aszmann OC. Bionic hand as artificial organ: current status and future perspectives. *Artif Organs.* 2019;43:109–18. <https://doi.org/10.1111/aor.13422>.
15. DeForge WF. Cardiac pacemakers: a basic review of the history and current technology. *J Vet Cardiol.* 2019;22:40–50. <https://doi.org/10.1016/j.jvc.2019.01.001>.
16. Sugimachi M, Sunagawa K. Bionic cardiology: exploration into a wealth of controllable body parts in the cardiovascular system. *IEEE Rev Biomed Eng.* 2009;2:172–86. <https://doi.org/10.1109/RBME.2009.2034623>.
17. Ramadi KB, Srinivasan SS, Traverso G. Electroceuticals in the gastrointestinal tract. *Trends Pharmacol Sci.* 2020;41:960–76. <https://doi.org/10.1016/j.tips.2020.09.014>.
18. Lin Z, Chen JDZ. Developments in gastrointestinal electrical stimulation. *Crit Rev Biomed Eng.* 2017;45(1–6):263–301. <https://doi.org/10.1615/CritRevBiomedEng.v45.i1-6.120>.
19. Rajamanuri M, Mannava SM, Chhabra J, Karwarker GV, Chahal M, Maligireddy AR, Dai E, Alfonso M. A systematic review of the therapeutic role of gastric pacemakers in adults with gastroparesis. *Cureus.* 2021;13:e18152. <https://doi.org/10.7759/cureus.18152>.
20. Martellucci J, Valeri A. Colonic electrical stimulation for the treatment of slow-transit constipation: a preliminary pilot study. *Surg Endosc.* 2014;28:691–7. <https://doi.org/10.1007/s00464-013-3192-0>.
21. Wu JM, Vaughan CP, Goode PS, Redden DT, Burgio KL, Richter HE, Markland AD. Prevalence and trends of symptomatic pelvic floor disorders in U.S. women. *Obstet Gynecol.* 2014;123:141–8. <https://doi.org/10.1097/AOG.0000000000000057>.
22. Tahseen S. Role of sacral neuromodulation in modern urogynaecology practice: a review of recent literature. *Int Urogynecol J.* 2018;29:1081–91. <https://doi.org/10.1007/s00192-017-3546-6>.
23. van Ophoven A, Engelberg S, Lilley H, Sievert KD. Systematic literature review and meta-analysis of sacral neuromodulation (SNM) in patients with neurogenic lower urinary tract dysfunction (nLUTD): over 20 years' experience and future directions. *Adv Ther.* 2021;38:1987–2006. <https://doi.org/10.1007/s12325-021-01650-9>.
24. Maeda Y, O'Connell PR, Lehur PA, Matzel KE, Laurberg S, European SNS Bowel Study Group. Sacral nerve stimulation for faecal incontinence and constipation: a European consensus statement. *Color Dis.* 2015;17(4):O74–87. <https://doi.org/10.1111/codi.12905>.
25. Thaha MA, Abukar AA, Thin NN, Ramsanahie A, Knowles CH. Sacral nerve stimulation for faecal incontinence and constipation in adults. *Cochrane Database Syst Rev.* 2015;2015(8):CD004464. <https://doi.org/10.1002/14651858.CD004464.pub3>.
26. Martellucci J. The technique of sacral nerve modulation. *Color Dis.* 2015;17:O88–94. <https://doi.org/10.1111/codi.12900>.

Chapter 18

Regenerative Surgery: Tissue Engineering in General Surgical Practice



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Biomaterial Science, Regenerative Medicine and Tissue/Organ Bioengineering

Regenerative medicine aims to replace and repair organ non-function through two fields: biomaterial science and tissue engineering. Biomaterial science wants to synthesize biologically inert grafts to replace or repair impaired organ function. It combines disciplines such as medicine, chemistry, chemical engineering, and mechanical

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engineering. Joint replacements and osteosynthetic materials for the treatment of complex fractures, or the use of stents and mechanical heart valves, vascular grafts, cochlear, and dental implants are such examples. A wide range of biocompatible materials are already clinically used, including metals, ceramics, carbon, polymers, and alloys.

Biocompatibility, a crucial concept in the field of bioengineering, refers to the capacity of a biomaterial to execute a specific function while eliciting an appropriate response from the host organism. Inadequate biocompatibility can drive to a host immune response causing a “foreign body” reaction, finally resulting in the destruction of the implanted material. One of the most biocompatible materials is titanium, which is widely used in orthopedic surgery. The assessment of a material’s biocompatibility requires *in vivo* and *in vitro* testing, with factors ranging from the variability of the host’s own immune system to the physical and chemical capabilities of the material.

In the literature, regenerative medicine is a term that encompasses various definitions. It can be defined as a multidisciplinary science that allows the repair of a specific organ function through the combination of procedures such as cellular manipulation and material scaffolding [1–3]. It can be achieved through tissue engineering, a subdiscipline of regenerative medicine, enabling tissue material to be created from bioactive molecules, cells, and cellular scaffolds. Tissue engineering (TE) aims to address the ongoing problem of donor organ shortage in transplantation and eliminate the need for anti-rejection medication [4, 5]. TE has led to bioengineered bladders, vessels, heart valves, and even solid organs such as kidneys, hearts, livers, and lungs. TE principally relies on seeding cells into a synthetic/biological scaffold. A wide variety of cells can be used, from pluripotent cells to specialized adult cells [6]. Although very disposable and easy to obtain, adult specialized cells have the disadvantage of a short lifespan and very limited differentiation [7]. Stem cells derived from the blastocyst stage, known as embryonic stem cells, possess the highest potential for differentiation. Adult stem cells are found within specific tissues of the body: skin, fat lung, heart, kidney, and urethra. These cells play a crucial role in tissue repair and possess the capacity to differentiate into different cell lineages.

Adult stem cell transplantation with *ex vivo* seeding is a powerful TE tool; they are accessible and possess minimal risk of rejection. They can be divided into three groups according to their origin: autologous, allogeneic, and heterologous [8]. Employing autologous cells acquired through host biopsy, presents the challenge of achieving adequate proliferation levels, as the presence of a supportive scaffold is necessary to facilitate both functionality and proliferation [9].

This scaffold, which mimics the extracellular matrix *in vivo*, often comprises biomaterials that offer three-dimensional structural support and cellular signals [10] (Fig. 18.1).

There are three categories of biomaterial: synthetic polymers (polyglycolic acid), natural (collagen and hyaluronic acid), and decellularized tissue matrix (obtained with enzymatic breakdown). A high-quality scaffold ought to have a degradation profile compatible with tissue regeneration with minimal immunogenicity [11].

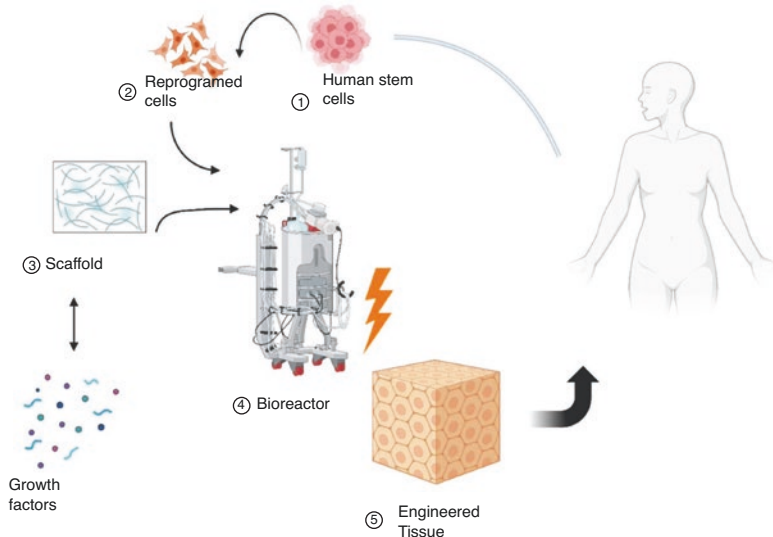


Fig. 18.1 *Tissue engineering: cultivating human stem cells into engineered tissue*; this illustration showcases the process of tissue engineering using human stem cells (1), starting with the procurement of stem cells from humans, which are then reprogrammed to a pluripotent state (2). The reprogrammed cells are placed in a bioreactor with a scaffold (3 and 4), where they interact with growth factor promoting the development of engineered tissue that can be transplanted onto the human body (5)

An adequate vascular supply is essential to maintain the viability of all tissues [12], similarly true in bioengineering. Decellularized scaffolds allow the maintenance of an internal vascular framework that may be reconnected to host vessels, or promote de novo vasculature in vivo with proangiogenic growth factors [13, 14].

Tissue Engineering Applications in General Surgery

Abdominal Wall Reconstruction with Tissue-Engineered Solutions

Abdominal wall defects and tissue loss due to trauma, surgical resection, failed abdominal closure or hernias are common and abdominal wall surgery is one of the most commonly performed surgical act worldwide. The reconstructive challenge for surgeons is the repair of these tissue defects. The goal of abdominal wall reconstruction is to restore and maintain a functional abdominal wall. Repairing may be by direct secondary closure of the aponeurosis or with the aid of a biological or inert (prosthetic) mesh. The use of mesh in abdominal wall reconstruction has been shown to reduce the risk of recurrence and is now the treatment of choice.

Complex hernias require a component separation technique, which consists of dividing the multiple layers of the abdominal wall to create an advancement flap used to cover a large defect. However, poor quality tissue at the defect site usually does not allow for direct reconstruction. In these cases, a mesh could be often required to bridge or reinforce the defect. Although the technique of choice, the use of a prosthesis carries a higher risk of infection, particularly in incarcerated or perforated hernia. Prostheses can be subdivided into synthetic or biological, and absorbable or non-absorbable. Synthetic meshes are disposable and cheaper, the most commonly used material is polypropylene. Biological prostheses are made from composite non-cellular collagen scaffolds derived from cadaveric human dermis (allograft) or porcine dermis (xenograft), both of which have shown similar results in terms of strength and vascularization [8]. With no standard treatment for large abdominal defects and a high risk of recurrence, foreign body reaction and infection, a tissue engineering approach offers promising solutions.

Several studies have shown encouraging results. The use of stem cells in abdominal wall defects has been successfully demonstrated using autologous skeletal muscle satellite stem cells seeded on collagen scaffolds with adequate integration and cellularization into the tissue host in rats [9]. Abdominal wall defects were repaired with tissue-engineered sheets in rats using a hybrid scaffold containing bone marrow fluid. Results after 16 weeks showed vascularization and regeneration of muscle tissue without recurrence. Adipose tissue-derived stem cells injected into a dermal acellular matrix were shown to improve bioprosthetic mesh repair of ventral hernias in rats with increased vascularization [10].

Biomaterials currently available for abdominal wall reconstruction include:

- *Synthetic Meshes.* After the introduction of high-density polyethylene fiber (Marlex[®]) as the initial synthetic mesh [11], polypropylene (PP) started being used because of its flexible, heat-resistant properties which enabled it to be sterilized through autoclaving [12]. PP remains the most widely used material in abdominal applications [13], despite the advent of other materials like polyester (PS) [14]. These materials typically exhibit a net-like arrangement of filaments, frequently leading to damage to the peritoneum and a high incidence of adhesion formation. Infections are also a major complication when synthetic materials are used [15]. Furthermore, PP exhibits a shrinkage rate between 30% and 50% within 4 weeks, potentially resulting in subsequent folding after implantation, especially in situations involving limited elasticity and small pores [16]. Therefore, the employment of net-like meshes is not recommended for intraperitoneal placement.
- *Biological meshes,* often termed as grafts or biomeshes, are usually made from animal (xenograft) tissues like Surgisis[®] [17], Permacol[™] [18, 19], CollaMend[™] [20], Tutomesh[®], and Strattice[®] [21], or human (allograft). The first implant based on tissue, porcine constructed intestine submucosa for abdominal wall reconstruction (Surgisis[®]), received approval in 1998. These decellularized matrices permit soft tissue to penetrate the mesh, ultimately remodeling with integration into the body. However, this process tends to result in a swift decrease

in mechanical strength, causing recurrence, particularly with allografts [22]. Chemically cross-linked meshes, like Permacol™ (an acellular dermal sheet derived from pigs), have enhanced the stability and longevity of grafts, reduced hernia recurrence rates while still achieving successful integration. Nevertheless, some studies [22] argue that cross-linking doesn't substantially affect the tensile strength of the graft composites. Cross-linking these materials can prolong the absorption of the material [23] and enhance mesh stability, yet it may trigger a foreign body reaction similar to that seen with permanent synthetic meshes [24]. Consequently, the intended benefits of the so-called biocompatibility may be undermined. Traditionally, the use of enduring synthetic materials in clean, uncontaminated fields, opposing biological material within infected fields. However, some lightweight, macroporous permanent synthetic meshes have demonstrated positive results in contaminated environments [25], arguing for superiority in biological meshes.

- *Cell-Coated Meshes.* The synergy between surgical mesh and the peritoneal membrane is pivotal in graft success, minimizing adhesions. Studies reveal that autologous cell-coated meshes, such as Parietex™, TIGR® or Strattice™, increase tissue integration, reduce inflammation, and postoperative complications. Nonetheless, the widespread use of surgical meshes in abdominal hernia repair is limited due to technical challenges, the potential for premature cell detachment, and regulatory constraints [26, 27]. A recent study by Cheng and colleagues [28] highlighted that a PP mesh layered with adipose-derived stem cells decreased tissue adhesion, fibrosis, and mesh-related complication rates. While cell-coated meshes show promise in abdominal hernia repair, there are significant hurdles. These include the workload of attaching autologous stem cells to the scaffold material before implantation, potential early detachment, and approval regulations. As a result, these challenges restrict the widespread application and reduce the frequency of using cell-coated meshes in abdominal hernia repairs [29].

Innovations in Skin Engineering and Regenerative Medicine for Skin Replacement

Skin engineering and regenerative medicine have fast emerged as revolutionary fields in modern healthcare, promising new hope for individuals suffering from severe skin damage or loss [30]. These techniques cover various methods to produce bioengineered skin substitutes for effective wound management, skin grafts, and total skin replacement. Currently, primary skin therapy includes autologous and allogenic treatments using healthy tissue grafts, which limits the possibility of adequate coverage for large wounds. The main challenge for chronic wounds is to restore an adequate environment promoting vascularization and control of inflammation. Moreover, in the face of severe burns, chronic ulcers, traditional treatments

often fall short, leading to considerable morbidity and mortality [31]. Given the limitations of conventional autografts and allografts, such as restricted availability of donor sites, risk of rejection, and potential disease transmission, regenerative medicine emerges as a promising alternative for skin replacement [32]. One of the most promising developments in this field is the use of stem cells in skin engineering. Stem cells, notably mesenchymal stem cells and induced pluripotent stem cells (iPSCs), are capable of differentiating into keratinocytes and fibroblasts required for dermis regeneration [33]. Through the process of seeding these stem cells onto biomaterial scaffolds, bioengineered skin is generated, which not only replicates the structural characteristics of native skin but also exhibits functional properties [34]. Biomaterial scaffolds are another integral part of skin engineering. They provide a three-dimensional framework for cell attachment and growth, leading to tissue formation. The selection of materials plays a critical role, with a growing preference for biodegradable and biocompatible substances such as collagen, hyaluronic acid, and polylactic acid. These scaffolds are designed to mimic the extracellular matrix of skin, supporting cellular interaction and growth while also degrading at a rate that allows for the regeneration of tissue [35]. A further innovative approach involves the use of bioprinting in skin engineering. Bioprinting is a technique that allows for the precise placement of cells, biomaterials, and growth factors layer by layer, mirroring the complex structure of human skin [36]. Despite the significant advances in skin engineering, several challenges remain. One of the main issues is the vascularization of bioengineered skin, crucial for nutrient supply and waste removal [37]. Another challenge is achieving full functionality, including sweat glands and hair follicles, which are typically missing in currently available skin substitutes [38]. Furthermore, ensuring that bioengineered skin replacements are safe, effective, and affordable enough for widespread clinical use is a significant hurdle, particularly in light of stringent regulatory requirements [39]. In conclusion, skin engineering and regenerative medicine have the potential to revolutionize skin replacement therapies and promise treatment options for patients with severe skin injuries, reduce the reliance on traditional grafts and accelerate recovery [40].

Tissue Engineering and Regenerative Medicine Applied to Gastrointestinal Tract

The advent of organ bioengineering has heralded a new era in the treatment of gastrointestinal diseases, offering a transformative approach toward organ replacement and regeneration [41]. Gastrointestinal diseases, ranging from inflammatory bowel disease to gastroesophageal reflux disease, have long caused significant morbidity and mortality [42, 43]. Traditional treatment approaches, although efficacious, are often marred by long-term complications and the burden of lifelong medication [44, 45]. This groundbreaking technology leverages the regenerative capabilities of stem cells and the architectural support of biocompatible scaffolds, giving rise to

functional tissues and organs for transplantation [46]. If successfully implemented, it could provide a sustainable solution to the perennial challenge of organ shortage, presenting an unprecedented opportunity to fundamentally transform the management of gastrointestinal diseases [47].

Tissue Engineering Applied to Esophageal Replacement

Tissue engineering may substitute traditional esophageal replacement methods. Reconstructive procedures after esophagectomy for benign conditions or cancer, typically involve gastric or colonic translocations or, less frequently, free or pedicled jejunal grafts, also used in the treatment of long-segment esophageal atresia. Whether addressing a relatively short diseased segment of the esophagus or strictures recalcitrant to dilatation, complete esophageal replacement is typically necessary. Despite the significant morbidity, mortality, and imperfect functional outcomes related to esophageal reconstruction, including reflux, delayed emptying, dumping syndrome, and long-term strictures or distensions, it remains the primary treatment options [48, 49]. In the past, the clinical use of synthetic materials like Teflon and Dacron has been reduced due to inconsistent success rates, primarily attributable to the high frequency of foreign body rejection, anastomotic fistula, and stricture formation. Even in cases where rejection doesn't occur, these materials' lack of biocompatibility often results in persistent infection accompanied by severe fibrosis, hindering future attempts at esophageal tissue remodeling techniques [50]. Allogeneic esophageal graft has also been explored as clinical alternatives however, these approaches were quickly abandoned due to the difficulty associated with revascularization [51]. A more modern approach involves a hybrid technique that incorporates a cell-free matrix and autologous epithelial and muscle cells, which are showing a considerable success. In the realm of esophageal tissue engineering, advancements have predominantly focused on natural matrices, primarily extracellular matrix (ECM) and collagen. These matrices, well-regarded for their role in reducing inflammation, fibrosis and promoting tissue remodeling, are generated through enzymatic treatment of native organs or tissues, each providing a unique three-dimensional environment for the residing cells [52]. The process of creating ECMs involves a careful balance by fully removing cellular components while preserving the intricate protein structures. Alongside structural and adherence proteins, these matrices harbor polysaccharides that assist cell adhesion. Furthermore, ECMs are known to release specific proteins that can stimulate cell growth and migration, playing a crucial role in tissue repair [52]. However, collagen matrices, typically constructed from type I bovine collagen due to its similarity to human collagen, can be molded into two or three-dimensional shapes. Their composition of only one ECM constituent is thought to limit their effectiveness compared to natural ECMs [53, 54]. Current studies are harnessing the potential of mesenchymal stem cells, which are well-known for their differentiation potential, pro-angiogenesis, immunomodulation, and anti-inflammation. Interactions between cells and these matrices, *in vitro*, allows the assessment of cell adhesion, proliferation, and the formation

of a structured tissue. A variety of studies have demonstrated the potential of these matrices to cultivate multilayered epithelial structures [55, 56]. Additionally, studies have revealed that seeding myoblasts, the precursors of striated muscle cells, on a small intestinal submucosa-derived matrix can promote the formation of multinucleated muscle fibers [57]. The future may see the creation of esophageal replacements from acellular “smart matrices” that encapsulate molecules necessary for tissue regeneration, bypassing the implantation stage yet eliciting standardized biological responses *in vivo*. Currently, tissue engineering applications for esophageal replacements are confined to enlargement procedures using absorbable, non-cellular matrices.

Tissue Engineering Applied to Stomach

TE principles have also been applied in the field of gastric oncology, as the use of benign strictures has become limited with the advancements in medical ulcer treatments. Gastrectomy is often an important strategy in the treatment of gastric cancer [58]. A common postoperative complication is the post-gastrectomy syndrome, which is characterized by diminished food intake capacity and abdominal discomfort caused by the rapid emptying of the stomach. The diminished functionality of the endocrine, exocrine and paracrine systems primarily contributes to these symptoms. Gastric replacement with Roux-en-Y jejunal transposition is a common approach to address this issue. However, this technique does not significantly improve food intake. Another viable option is to create a jejunal pouch [59].

Minimally invasive procedures such as endoscopic submucosal dissection, laparoscopic wedge resection, and intramucosal resection represent a significant advancement in the treatment of early-stage gastric tumors [60, 61]. TE involves the primary culture of different types of gastric epithelial cells, such as the chief cells that produce pepsinogen, the parietal cells responsible for acid secretion, and the cervical and pit cells that produce mucus [62, 63]. When cells are cultured outside their natural environment, they often experience a loss of their specialized properties, which hampers their functionality and practical application. Furthermore, the lack of selectivity poses a significant challenge. The stomach consists of a diverse range of cell types, making it difficult to culture a purified sample of a single cell type [64]. This highlights the need for refined techniques that can accurately isolate specific cells to obtain a pure culture. The cell-free approach introduces a promising strategy that employs biomaterials solely for the purpose of promoting cellular growth. For instance, research conducted by Chandra et al. demonstrated the successful utilization of porcine collagen dermal graft derived in conjunction with a PGA scaffold repair the anterior wall defect of a canine lower stomach body [65]. The outcomes highlighted successful repair without the occurrence of anastomotic leakage or infection, but did not exhibit smooth muscle layer regeneration. The use of epithelial organoid units offers another novel approach. This innovative method facilitates interactions between epithelial and mesenchymal cells, which are crucial for processes such as morphogenesis, proliferation, and differentiation [66]. In a

related study, tissue-engineered stomachs were created from epithelial organoid units. These were implanted onto biodegradable polymer tube scaffolds from neonatal rats and then grafted into the omentum to stimulate growth [67]. Within a span of just 3 weeks, the implanted tissue reached its maximum size. The presence of parietal and gastric cells was confirmed, along with neovascularization, demonstrating the success of this technique. Nevertheless, no submucosal layers were detected, and the size of the villi, considerably smaller than expected. In 2021, Wells et al., succeeded in creating a mini-stomach that has complex features such as nerve-mediated muscle contractions and acid production [68]. These “organoids” may well be able to repair the gastrointestinal tract. A stomach organoid with mixture of three embryonal cell types—epithelial, enteric neural crest, and mesenchymal cells. After the initial developmental phase in the incubator, the organoids were transplanted into mice.

Organ Engineering Applications in Transplantation Surgery

Bioengineering Liver Transplantation

The use of animal-derived ECM as a scaffold in the bioengineering of liver tissue has been studied with success. Porcine liver ECM was used for human hepatocyte repopulation, which resulted in improved liver function by increased albumin secretion and cytochrome P450 activity [69] (Fig. 18.2). Likewise, rat liver ECM has been used to repopulate human liver cells, demonstrating functional bile production and secretion [70]. Nevertheless, concerns regarding immunogenicity and potential transmission of infectious agents have been raised with the use of animal-derived ECM. As a result, there is a growing interest in the use of human-derived ECM for liver bioengineering. Human liver ECM has been shown to effectively facilitate liver regeneration in animal models [71]. Furthermore, decellularized human liver tissue has been successfully used as a scaffold to repopulate human hepatocytes, demonstrating improved hepatic function including albumin and urea synthesis [72]. Research has also focused on using modified ECM to bioengineer the liver. Techniques such as cross-linking have been used to improve the mechanical properties of ECM scaffolds [73].

In addition, the creation of a liver scaffold starting from discarded human graft, has been also explored. In 2015, Mazza et al. have proposed a detergent-based protocol to produce acellular, whole human liver-lobe scaffold. This protocol involves the use of a freeze/thaw series followed by perfusion with two distinct detergents (Sodium Dodecyl Sulphate SDS (1%); Triton X-100 (3%)). After histological confirmation of successful decellularization, the different scaffold components were analyzed quantitatively and finally the scaffold was recellularized in order to verify its biocompatibility. Collagen and elastin quantification have shown a complete preservation compared to non-treated liver. Also, the ultrastructural characterization

Bioengineering liver with human hepatocytes and porcine derived ECM:

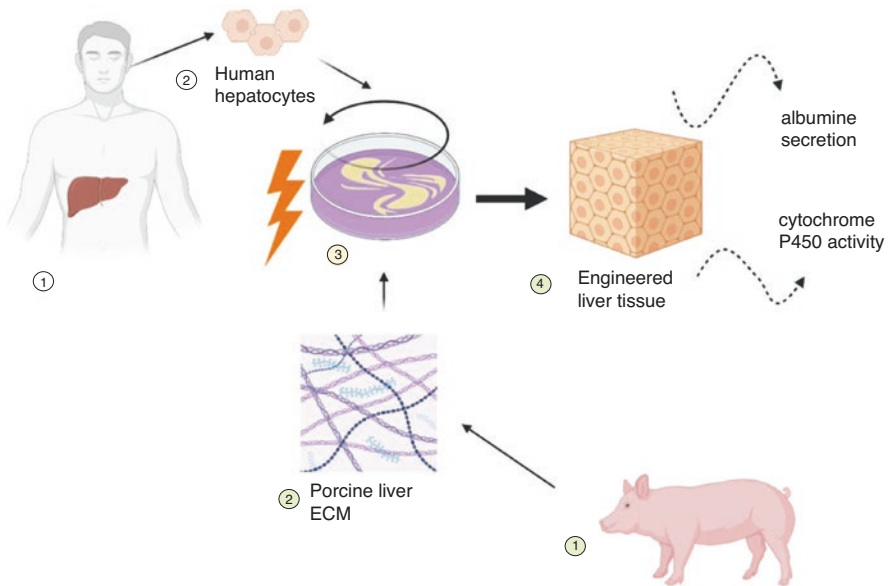


Fig. 18.2 Organ reengineering through development of a transplantable recellularized liver graft using decellularized liver matrix; porcine derived liver is decellularized obtaining a patient-size liver scaffold. The scaffold is then recellularized with human hepatocyte finally resulting in a engineered, metabolic active, liver tissue able to secrete albumin

confirmed how the decellularization process does not affect the original geometrical morphology. Finally, the authors have tested human liver scaffold biocompatibility through two important essays. Firstly, they have weathered interspecies biocompatibility of decellularized human liver ECM scaffolds by implanting ECM acellular scaffold into immunocompetent mice. Samples have been then evaluated 7 and 21 days after the implantation. Lymphocytes and PMN cells were detected at 7d post-implantation whereas modest signs of inflammation were identified after 21 days. These results were therefore able to show that, 3 weeks after implantation, no immune reaction can be detected. Moreover, observation of host-derived endothelial and other mesenchymal cells repopulating a biological scaffold highlights the need for further research to understand this aspect and to better comprehend the process following the implantation of the scaffold. Secondly, the authors explored cell behavior once seeded on this scaffold. LX2 (a human hepatic stellate cell line), HepG2 (epithelial cells derived from hepatocellular carcinoma) or Sk-Hep-1 (endothelial cells, derived from highly invasive human adenocarcinoma) human cell types were used to repopulate liver cubic scaffold. At different time points, cellular lines have shown progressive engraftment into the matrix. HepG2 successful repopulation was also proven by marked Ki67 positivity. This paper has paved the way toward the use of a human-derived ECM-based scaffold for liver bioengineering.

Moreover, introducing growth factors and other bioactive molecules into the ECM scaffold has been shown to promote cell differentiation and tissue growth [74]. Beyond liver bioengineering, ECM-based scaffolds have been investigated for potential treatment of liver diseases. For example, a decellularized ECM hydrogel derived from rat liver was used to stimulate liver regeneration in a rat model of liver fibrosis, resulting in a reduction in liver fibrosis and improvement in liver function [75]. Furthermore, building on the knowledge gathered on the creation of a transplant purposes, the importance of the liver matrix also for *in vitro* studies is becoming increasingly significant. However, despite the significant potential of ECM-based scaffolds in liver bioengineering for the generation of transplantable liver tissue and the treatment of liver disease, numerous challenges remain. These include optimizing ECM composition and structure to support cell growth and function, ensuring appropriate cell sourcing, obtaining regulatory approval, and facilitating clinical translation.

Bioengineering Pancreas Transplantation

The emerging field of pancreatic bioengineering, particularly using techniques based on ECM, holds great potential to revolutionize regenerative medicine and pancreatic transplantation. This advancement is particularly significant for the management of diabetes [76]. In the field of beta-cell replacement, ECM-centered bioengineering has the potential to overcome a number of obstacles currently facing medical practitioners and researchers. A primary concern is the shortage of available donor organs, resulting in long waiting lists for patients requiring pancreas or islet transplantation [77]. Utilizing ECM-based bioengineering offers a promising foundation for creating functional pancreatic tissue from alternative sources like induced pluripotent stem cells (iPSCs) [78]. Moreover, the recognized critical role of the ECM in supporting the survival, proliferation, and differentiation of pancreatic progenitors and beta cells has garnered significant interest [79]. Ongoing research is focused on the development of ECM-based hydrogels and scaffolds specifically designed for the encapsulation of pancreatic islets and beta cells. The aim of these efforts is to enhance cell viability and functionality after transplantation [80]. These methods could provide treatments for type 1 diabetes patients, who currently rely on external insulin delivery and are at significant risk of complications [81]. A notable example of pancreatic ECM-based bioengineering revolves around the process of decellularization. This involves the extraction of cellular components from donor organs while leaving the native ECM structure intact. This results in acellular ECM scaffolds that retain their biochemical and biomechanical properties. These scaffolds can then be repopulated with isolated islet cells, theoretically circumventing issues of immune rejection and organ scarcity [82–84]. Research by Goh et al. (Fig. 18.3) demonstrated the feasibility of using decellularized porcine pancreatic ECM as a scaffold for the differentiation of human iPSCs into insulin-producing beta cells [77]. The team found that the pancreatic ECM promoted the

Bioengineering B-cells with porcine ECM scaffold and iPSC human cells

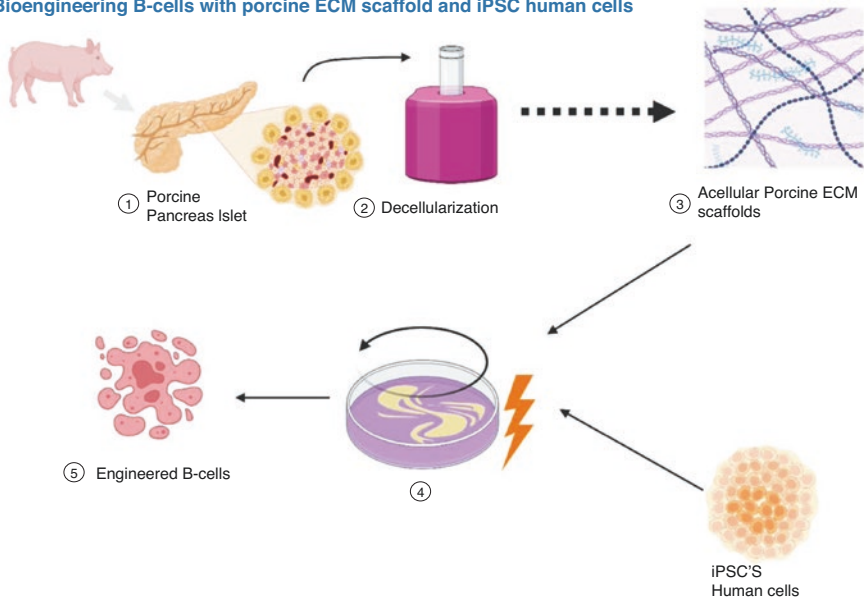


Fig. 18.3 Porcine pancreas extracellular matrix as a platform for endocrine pancreas bioengineering; porcine pancreas is decellularized, resulting in an acellular extracellular matrix (ECM) which is then combined with induced pluripotent stem cells (iPSCs) derived from human cells, leading to the development of engineered β -cells

formation of three-dimensional islet-like structures that exhibited glucose-responsive insulin secretion and improved survival compared to cells grown under traditional two-dimensional conditions. This work highlights the potential of ECM-based bioengineering techniques to generate functional, transplantable pancreatic tissue from iPSCs. Beyond decellularization, the exploration of synthetic ECM analogs for pancreatic bioengineering is also underway [85]. These materials can be fine-tuned to mimic the physical and biochemical properties of the native ECM, allowing precise control of cell behavior and tissue formation [86]. For example, hydrogels composed of polyethylene glycol (PEG) and heparin have been used as scaffolds to encapsulate pancreatic islets, demonstrating the potential to protect cells from immune attack while preserving their functionality *in vivo* [87]. However, despite the significant progress made in pancreatic ECM-based bioengineering, several hurdles remain. A key issue is the need to improve techniques for its isolation, purification and characterization of pancreatic tissue-derived ECM components. The extraction process is challenging due to the limited presence of ECM in the pancreas and its complex composition. Improving techniques to isolate, purify, and fully characterize ECM components is a critical concern. However, this improvement is essential for the development of well-defined, reproducible, and efficient biomaterials [88]. In 2016 we have proposed the use of human discarded pancreas to bioengineer pancreas-like ECM. This study successfully produced acellular

extracellular matrix scaffolds from the human pancreas (hpaECMs), an important step toward creating a fully human-derived bioartificial endocrine pancreas with potential patient-specific cell compatibility. Not only did the human-derived ECM retain vital growth factors, innate molecular and spatial framework, and stiffness, but they also inhibited naïve CD4 T-cell expansion while promoting their conversion into regulatory T cells, which play a crucial role in maintaining immune balance by inducing and sustaining tolerance in organ transplantation. This demonstrates significant potential as a promising platform for future advancements in regenerative medicine, specifically for the development of bioartificial pancreas [89]. More recently different cellular sources have been explored for recellularization. In particular, Lebreton et al. have made a significant breakthrough in organoid research, creating functional insulin-secreting organoids (ISOs) from dissociated islet cells and human amniotic epithelial cells (hAECs), generating organoids with predictable shapes and sizes similar to pancreatic islets, thus highlighting the necessity of an accessory cell component for organoid stability. Notably, hAECs were found to promote the insulin-producing cells viability, enhance organoid resilience under pre-implantation conditions, promote angiogenesis, and improve long-term survival and graft function in a mouse model of type 1 diabetes, all of which underpin their promise for future diabetes research and organoid engineering [90]. Recent findings by the team headed by Citro Antonio have highlighted the remarkable potential of combining ECM scaffolds with iPSCs to generate transplantable pancreatic tissue. In their study, they showed that ECM scaffolds could support the differentiation of iPSCs into beta cells and improve their function [91]. These findings represent a significant step forward in the field of pancreatic bioengineering. Informations deriving from all the above-described experiments are crucial to correctly select cell population for repopulate pancreatic ECM scaffold. It suggests that with continued research and development, ECM-based bioengineering may become a viable approach to pancreas transplantation in the near future.

Bioengineering Kidney Transplantation

While kidney transplantation is considered the only cure for end-stage renal disease (ESRD), the lengthy average waiting period of 3–5 years highlights the pressing need for alternative solutions. One promising approach is the bioengineering of kidney extracellular matrix (ECM) as a scaffold to create functional kidney substitutes, potentially revolutionizing transplantation methods [92]. The concept behind ECM-based kidney bioengineering involves the process of decellularizing kidney tissues, which carefully extracts cells while leaving the ECM intact. This decellularized ECM scaffold is then populated with kidney cells or stem cells, capable of maturing into functional renal tissue [93]. ECM-based scaffolds provide a natural environment conducive for cell growth and differentiation, promoting tissue regeneration [94]. A significant advantage of this approach is the potential to create functional kidneys using patient-derived cells, minimizing the risk of organ rejection

and reducing the need for immunosuppressive treatments [95]. Moreover, scaffolds sourced from animal ECMs provide a viable alternative to those derived from humans, demonstrating efficacy in supporting cell growth and differentiation [96].

Promising results have been achieved in kidney bioengineering studies. For instance, Song et al. created a bioengineered kidney using decellularized rat kidneys as a scaffold and neonatal kidney cells from rats as seed cells, as documented in *Nature Medicine* [97]. This engineered kidney was capable of urine production both *in vitro* and *in vivo* post-transplantation into rats. A similar study employed porcine kidneys as a scaffold coupled with human kidney cells, yielding a functional kidney [98].

Kidney bioengineering has made significant strides since its early small animal studies. Meticulous experimentation and advancements in tissue engineering techniques have proven the feasibility of generating functional kidney tissue in small animal models. These studies have provided vital knowledge on cell sourcing, scaffold design, and organ maturation. Building on this foundation, researchers are now focused on translating these findings into clinical applications. The field of kidney bioengineering holds great promise in addressing the increasing need for organ transplantation. It brings hope to patients awaiting life-saving treatments and paves the way for future breakthroughs in regenerative medicine [99].

Extracellular Matrix and Tumor Bioengineering

The extracellular matrix (ECM) plays also a critical role in tissue homeostasis and cellular behavior. In the context of tumor bioengineering, ECM is a dynamic microenvironment that influences tumor initiation, progression and response to therapy [100]. In tumor bioengineering, alterations in ECM composition and remodeling processes can create a pro-tumorigenic microenvironment exemplified, for example, by deposition of collagen type I and fibronectin which promote tumor growth and invasion or by metalloproteinases (MMPs) which facilitates tumor cell migration and metastasis [101, 102]. Mechanical properties of the ECM, including stiffness and topography, contribute to tumor progression, supporting tumor cell survival, proliferation and resistance to apoptosis [103, 104]. Mechanotransduction also influences tumor cell phenotype and gene expression [105] whereas ECM topography can guide tumor cell migration and invasion, with aligned fibers promoting directional movement [106]. Furthermore, it has been demonstrated that ECM proteins, particularly those belonging to the laminin family, play a role in drug resistance and the induction of tumor cell dormancy [107]. Advances in bioengineering techniques have enabled the development of tumor models that mimic the complex ECM architecture and tumor-stromal interactions. Three-dimensional (3D) cell culture systems incorporating biomimetic ECM scaffolds have provided insights into tumor behavior and drug response [108]. Microfluidic platforms have facilitated the study of tumor invasion and metastasis in a controlled

microenvironment [109]. Moreover, bioengineered tumor models incorporating patient-derived ECM components have the potential to personalize cancer therapy [110–112]. In conclusion, the interplay between the ECM and tumor bioengineering is a complex and multifaceted process: alterations in ECM composition, mechanics and signaling contribute to tumor initiation, progression and resistance to therapy. By understanding the intricate relationship between the ECM and tumor biology, researchers can develop innovative bioengineering strategies to better mimic the tumor microenvironment and improve cancer treatment outcomes.

Conclusions: Future Directions and Challenges

While stem cells hold great potential to revolutionize clinical medicine, it is important to acknowledge that many stem cell-based treatments have not shown long-lasting improvements. Most of the observed benefits appear to be temporary, and the ability of stem cells to integrate and differentiate effectively over the long term has not been convincingly established [113]. Previous initiatives in regenerative medicine have relied on stem cell administration via injection or topical application, often yielding marginal benefits. Hence, contemporary research increasingly turns to scaffolds and biomolecules to boost cell survival and potentially enhance clinical outcomes following stem cell therapies [114, 115]. This concept refers to the biochemical and biophysical conditions found in tissue-specific environments that support stem cell functionality. Current regenerative medicine strategies strive to emulate these homeostatic cues in order to preserve the effectiveness of administered stem cells within an unfamiliar environment. Almost all known stem cells' functional niches have been described, underlining the intricacy of adjacent cells, the surrounding matrix, biochemical gradients, and physical forces in supporting cell “stemness.”

Vascularization poses a significant challenge in the clinical application of tissue-engineered structures. While *in vitro* constructs can be sustained via nutrient/waste diffusion alone, bioengineered tissues and organs for *in vivo* use must develop and maintain a vigorous vascular system to safeguard graft viability. The “*de novo*” creation of a microvasculature is exceptionally complex, and the underlying mechanisms remain unclear. The capacity to integrate these constructs with the host vascular system could also be a challenge, as functioning arterial, capillary, and venous components must be in place. An innovative approach that could potentially overcome both of these obstacles involves the use of autologous expendable microcirculatory beds based on microsurgical ‘free’ flaps, such as those used in reconstructive surgery. Our team has developed a rat model where composite tissue flaps (based on the superficial inferior epigastric vessels) can be harvested and maintained on an *ex vivo* bioreactor system. These constructs can either be transfected to produce therapeutic peptides or seeded with stem cells before subsequent reimplantation [93, 116, 117]. These expendable tissue flaps contain preexisting functional

microvascular systems that can be surgically connected to the host vasculature, symbolizing a novel approach to fabricate highly vascularized neo-organs. Another strategy for solid organ engineering involves the use of decellularized whole-organ scaffolds that are subsequently reseeded with adult cells. The decellularization process conserves the matrix architecture, providing a structural framework for delivering exogenous cells.

References

1. Haseltine WA. The emergence of regenerative medicine: a new field and a new society. *J Regen Med.* 2001;2(4):17.
2. Mironov V, Visconti RP, Markwald RR. What is regenerative medicine? The emergence of applied stem cell and developmental biology. *Expert Opin Biol Ther.* 2004;4(6):773–81.
3. Greenwood HL, Thorsteinsdottir H, Perry G, Renihan J, Singer PA, Daar AS. Regenerative medicine: new opportunities for developing countries. *Int J Biotechnol.* 2006;8(1–2):60–77.
4. Orlando G, Wood KJ, Stratta RJ, et al. Regenerative medicine and organ transplantation: past, present, and future. *Transplantation.* 2011;91(12):1310–7.
5. Orlando G, Baptista P, Birchall M, et al. Regenerative medicine as applied to solid organ transplantation: current status and future challenges. *Transpl Int.* 2011;24(3):223–32.
6. Siemionow M. Vascularized composite allotransplantation: a new concept in musculoskeletal regeneration. *J Mater Sci Mater Med.* 2015;26:266. <https://doi.org/10.1007/s10856-015-5601-5>.
7. Suzuhigashi M, Kaji T, Nakame K, Mukai M, Yamada W, Onishi S, Yamada K, Kawano T, Takamatsu H, Ieiri S. Abdominal wall regenerative medicine for a large defect using tissue engineering: an experimental study. *Pediatr Surg Int.* 2016;32(10):959–65. <https://doi.org/10.1007/s00383-016-3949-3>. Epub 2016 Jul 30. PMID: 27476152.
8. Stanwix MG, Nam AJ, Hui-Chou HG, et al. Abdominal ventral hernia repair with current biological prostheses: an experimental large animal model. *Ann Plast Surg.* 2011;66:403–9.
9. Fann SA, Terracio L, Yan W, et al. A model of tissue-engineered ventral hernia repair. *J Investig Surg.* 2006;19:193–205.
10. Altman AM, Abdul Khalek FJ, Alt EU, et al. Adipose tissue-derived stem cells enhance bio-prosthetic mesh repair of ventral hernias. *Plast Reconstr Surg.* 2010;126:845–54.
11. Baylón K, Rodríguez-Camarillo P, Elías-Zúñiga A, Díaz-Elizondo JA, Gilkerson R, Lozano K. Past, present and future of surgical meshes: a review. *Membranes.* 2017;7:47.
12. Usher F, Fries J, Ochsner J, Tuttle LD. Marlex mesh, a new plastic mesh for replacing tissue defects: II. Clinical studies. *AMA Arch Surg.* 1959;78:138–45.
13. Usher FC. Hernia repair with knitted polypropylene mesh. *Surg Gynecol Obstet.* 1963;117:239–40.
14. Stoppa R, Petit J, Henry X. Unsutured Dacron prosthesis in groin hernias. *Int Surg.* 1975;60:411–2.
15. Brown RH, Subramanian A, Hwang CS, Chang S, Awad SS. Comparison of infectious complications with synthetic mesh in ventral hernia repair. *Am J Surg.* 2013;205:182–7.
16. Bauer JJ, Salky BA, Gelernt IM, KreeI I. Repair of large abdominal wall defects with expanded polytetrafluoroethylene (PTFE). *Ann Surg.* 1987;206:765–9.
17. Franklin M, Gonzalez J, Michaelson R, Glass J, Chock D. Preliminary experience with new bioactive prosthetic material for repair of hernias in infected fields. *Hernia.* 2002;6:171–4.
18. Chand B, Indeck M, Needleman B, Finnegan M, Van Sickle KR, Ystgaard B, Gossetti F, Pullan RD, Giordano P, McKinley A. A retrospective study evaluating the use of Permacol™ surgical implant in incisional and ventral hernia repair. *Int J Surg.* 2014;12:296–303.

19. Pavan PG, Pachera P, Todros S. Mechanical characterization of animal derived grafts for surgical implantation. *J Mech Med Biol*. 2016;16(3):1650023.
20. Chavarriaga LF, Lin E, Losken A, Cook MW, Jeansonne LO, White BC, Sweeney JF, Gallo-way JR, Davis SS Jr. Management of complex abdominal wall defects using acellular porcine dermal collagen. *Am Surg*. 2010;76:96–100.
21. Pascual G, Pérez-Köhler B, Rodríguez M, Sotomayor S, Bellón JM. Postimplantation host tissue response and biodegradation of biologic versus polymer meshes implanted in an intra-peritoneal position. *Surg Endosc*. 2014;28:559–69.
22. Beale EW, Hoxworth RE, Livingston EH, Trussler AP. The role of biologic mesh in abdominal wall reconstruction: a systematic review of the current literature. *Am J Surg*. 2012;204:510–7.
23. Dunn RM. Cross-linking in biomaterials. *Plast Reconstr Surg*. 2012;130:18S–26S.
24. Novitsky Y. Biology of biological meshes used in hernia repair. *Surg Clin N Am*. 2013;93:1211–5.
25. Rosen MJ, DeNoto G, Itani KMF, Butler C, Vargo D, Smiell J, Rutan R. Evaluation of surgi-cal outcomes of retro-rectus versus intraperitoneal reinforcement with bio-prosthetic mesh in the repair of contaminated ventral hernias. *Hernia*. 2013;17:31–5.
26. Majumder A, Gao Y, Sadava EE, Anderson JM, Novitsky YW. Cell-coating affects tissue integration of synthetic and biologic meshes: comparative analysis of the onlay and underlay mesh positioning in rats. *Surg Endosc*. 2016;30:4445–53.
27. Gao Y, Krpata DM, Criss CN, Liu L, Posielski N, Rosen MJ, Novitsky YW. Effects of mes-enchymal stem cell and fibroblast coating on immunogenic potential of prosthetic meshes in vitro. *Surg Endosc*. 2014;28:2357–67.
28. Cheng H, Zhang Y, Zhang B, Cheng J, Wang W, Tang X, Teng P, Li Y. Biocompatibility of poly-propylene mesh scaffold with adipose-derived stem cells. *Exp Ther Med*. 2017;13:2922–6.
29. Petter-Puchner AH, Fortelny RH, Gruber-Blum S, Redl H, Dietz U. The future of stem cell therapy in hernia and abdominal wall repair. *Hernia*. 2015;19:25–31.
30. Sen CK. Human wounds and its burden: an updated compendium of estimates. *Adv Wound Care*. 2009;2(2):39–48.
31. Metcalfe AD, Ferguson MWJ. Tissue engineering of replacement skin: the crossroads of biomaterials, wound healing, embryonic development, stem cells, and regeneration. *J R Soc Interface*. 2007;4(14):413–37.
32. MacNeil S. Progress and opportunities for tissue-engineered skin. *Nature*. 2007;445(7130):874–80. <https://doi.org/10.1038/nature05664>. PMID: 17314974.
33. Sen CK. Human wound and its burden: updated 2020 compendium of estimates. *Adv Wound Care (New Rochelle)*. 2021;10(5):281–92. <https://doi.org/10.1089/wound.2021.0026>. PMID: 33733885; PMCID: PMC8024242.
34. Metcalfe AD, Ferguson MW. Tissue engineering of replacement skin: the crossroads of biomaterials, wound healing, embryonic development, stem cells and regeneration. *J R Soc Interface*. 2007;4(14):413–37. <https://doi.org/10.1098/rsif.2006.0179>. PMID: 17251138; PMCID: PMC2373411.
35. Francis E, Kearney L, Clover J. The effects of stem cells on burn wounds: a review. *Int J Burns Trauma*. 2019;9(1):1–12. PMID: 30911430; PMCID: PMC6420705.
36. Shevchenko RV, James SL, James SE. A review of tissue-engineered skin bioconstructs avail-able for skin reconstruction. *J R Soc Interface*. 2010;7(43):229–58. <https://doi.org/10.1098/rsif.2009.0403>. Epub 2009 Oct 28. PMID: 19864266; PMCID: PMC2842616.
37. Murphy SV, Atala A. 3D bioprinting of tissues and organs. *Nat Biotechnol*. 2014;32(8):773–85. <https://doi.org/10.1038/nbt.2958>.
38. Laschke MW, Menger MD. Vascularization in tissue engineering: angiogenesis versus inosulation. *Eur Surg Res*. 2012;48(2):85–92. <https://doi.org/10.1159/000336876>. Epub 2012 Mar 28.
39. Hirsch T, Rothoef T, Teig N, Bauer JW, Pellegrini G, De Rosa L, Scaglione D, Reichelt J, Klausegger A, Kneisz D, Romano O, Secone Seconetti A, Contin R, Enzo E, Jurman I, Carulli S, Jacobsen F, Luecke T, Lehnhardt M, Fischer M, Kueckelhaus M, Quagliano D, Morgante

- M, Bicciato S, Bondanza S, De Luca M. Regeneration of the entire human epidermis using transgenic stem cells. *Nature*. 2017;551(7680):327–32. <https://doi.org/10.1038/nature24487>. Epub 2017 Nov 8. PMID: 29144448; PMCID: PMC6283270.
40. Supp DM, Boyce ST. Engineered skin substitutes: practices and potentials. *Clin Dermatol*. 2005;23(4):403–12. <https://doi.org/10.1016/j.clindermatol.2004.07.023>. PMID: 16023936.
 41. Atala A, Lanza R. Organ bioengineering and regenerative medicine. In: *Principles of regenerative medicine* (second edition). Amsterdam: Elsevier; 2012.
 42. Loftus EV Jr. Clinical epidemiology of inflammatory bowel disease: incidence, prevalence, and environmental influences. *Gastroenterology*. 2004;126(6):1504–17.
 43. El-Serag HB, Sweet S, Winchester CC, Dent J. Update on the epidemiology of gastroesophageal reflux disease: a systematic review. *Gut*. 2014;63(6):871–80.
 44. Colombel JF, Narula N, Peyrin-Biroulet L. Management strategies to improve outcomes of patients with inflammatory bowel diseases. *Gastroenterology*. 2017;152(2):351–361.e5.
 45. Guyette JP, Gilpin SE, Charest JM, Tapias LF, Ren X, Ott HC. Perfusion decellularization of whole organs. *Nat Protoc*. 2016;9(6):1451–68.
 46. Orive G, Santos E, Pedraz JL, Hernandez RM. Application of cell encapsulation for controlled delivery of biological therapeutics. *Adv Drug Deliv Rev*. 2015;67–68:3–14.
 47. Orlando G, Soker S, Stratta RJ. Organ bioengineering and regeneration as the new holy grail for organ transplantation. *Ann Surg*. 2013;258(2):221–32.
 48. Poghosyan T, Gaujoux S, Chirica M, Munoz-Bongrand N, Sarfati E, Cattan P. Functional disorders and quality of life after esophagectomy and gastric tube reconstruction for cancer. *J Visc Surg*. 2011;1485:e327–35.
 49. Chirica M, Veyrie N, Munoz-Bongrand N, et al. Late morbidity after colon interposition for corrosive esophageal injury: risk factors, management, and outcome. A 20-year experience. *Ann Surg*. 2010;2522:271–80.
 50. Freud E, Efrati I, Kidron D, Finally R, Mares AJ. Comparative experimental study of esophageal wall regeneration after prosthetic replacement. *J Biomed Mater Res*. 1999;452:84–91.
 51. Macchiarini P, Mazmanian GM, de Montpreville V, et al. Experimental tracheal and tracheoesophageal allotransplantation. *J Thorac Cardiovasc Surg*. 1995;1104(Pt 1):1037–46.
 52. Tottey S, Corselli M, Jeffries EM, Londono R, Peault B, Badyalok SF. Extracellular matrix degradation products and low-oxygen conditions enhance the regenerative potential of perivascular stem cells. *Tissue Eng Part A*. 2011;17(1–2):37–44.
 53. Bhrany AD, Beckstead BL, Lang TC, Farwell DG, Giachell CM, Ratner BD. Development of an esophagus acellular matrix tissue scaffold. *Tissue Eng*. 2006;122:319–30.
 54. Ozeki M, Narita Y, Kagami H, et al. Evaluation of decellularized esophagus as a scaffold for cultured esophageal epithelial cells. *J Biomed Mater Res A*. 2006;794:771–8.
 55. Wei RQ, Tan B, Tan MY, et al. Grafts of porcine small intestinal submucosa with cultured autologous oral mucosal epithelial cells for esophageal repair in a canine model. *Exp Biol Med* (Maywood). 2009;2344:453–61.
 56. Saxena AK, Ainoedhofer H, Hollwarth ME. Esophagus tissue engineering: *in vitro* generation of esophageal epithelial cell sheets and viability on scaffold. *J Pediatr Surg*. 2009;445:896–901.
 57. Green N, Huang Q, Khan L, et al. The development and characterization of an organotypic tissue-engineered human esophageal mucosal model. *Tissue Eng Part A*. 2010;163:1053–64.
 58. Santoro R, Etorre GM, Santoro E. Subtotal gastrectomy for gastric cancer. *World J Gastroenterol*. 2014;20(38):13667–80. <https://doi.org/10.3748/wjg.v20.i38.13667>.
 59. Li GZ, Doherty GM, Wang J. Surgical management of gastric cancer: a review. *JAMA Surg*. 2022;157(5):446–54. <https://doi.org/10.1001/jamasurg.2022.0182>. PMID: 35319717.
 60. Miyahara K, Iwakiri R, Shimoda R, Sakata Y, Fujise T, Shiraishi R, et al. Peroral endoscopic myotomy and endoscopic submucosal dissection for esophageal achalasia with early-stage cancer. *J Gastroenterol*. 2019;54(2):168–74.

61. Kim HI, Han SU, Yang HK, Kim YW, Lee HJ, Ryu KW, et al. Multicenter prospective comparative study of robotic versus laparoscopic gastrectomy for gastric adenocarcinoma. *Ann Surg.* 2020;271(1):103–10.
62. Schumacher MA, Aihara E, Feng R, Engevik A, Shroyer NF, Ottemann KM, et al. The use of murine-derived fundic organoids in studies of gastric physiology. *J Physiol.* 2015;593(8):1809–27.
63. Nozaki K, Ogawa M, Williams JA, Laffleur BJ, Ng V, Drapkin RI, et al. A molecular signature of gastric metaplasia arising in response to acute parietal cell loss. *Gastroenterology.* 2008;134(2):511–22.
64. Barker N, Huch M, Kujala P, van de Wetering M, Snippert HJ, van Es JH, et al. Lgr5+ve stem cells drive self-renewal in the stomach and build long-lived gastric units in vitro. *Cell Stem Cell.* 2010;6(1):25–36.
65. Chandra L, Borchering DC, Kingsbury D, Atherly T, Ambrosini YM, Bourgois-Mochel A, Yuan W, Kimber M, Qi Y, Wang Q, Wannemuehler M, Ellinwood NM, Snella E, Martin M, Skala M, Meyerholz D, Estes M, Fernandez-Zapico ME, Jergens AE, Mochel JP, Allenspach K. Derivation of adult canine intestinal organoids for translational research in gastroenterology. *BMC Biol.* 2019;17(1):33. <https://doi.org/10.1186/s12915-019-0652-6>. PMID: 30975131; PMCID: PMC6460554.
66. Sato T, Vries RG, Snippert HJ, van de Wetering M, Barker N, Stange DE, et al. Single Lgr5 stem cells build crypt-villus structures in vitro without a mesenchymal niche. *Nature.* 2009;459(7244):262–5.
67. Levin DE, Grikscheit TC, Sala FG. Engineering of neovascularized stomach tissue in vivo. *Regen Med.* 2013;8(5):609–19.
68. Eicher AK, Kechele DO, Sundaram N, Berns HM, Poling HM, Haines LE, Sanchez JG, Kishimoto K, Krishnamurthy M, Han L, Zorn AM, Helmrich MA, Wells JM. Functional human gastrointestinal organoids can be engineered from three primary germ layers derived separately from pluripotent stem cells. *Cell Stem Cell.* 2022;29(1):36–51.e6. <https://doi.org/10.1016/j.stem.2021.10.010>. Epub 2021 Dec 1. PMID: 34856121; PMCID: PMC8741755.
69. Uygun BE, Soto-Gutierrez A, Yagi H, Izamis ML, Guzzardi MA, Shulman C, et al. Organ reengineering through development of a transplantable recellularized liver graft using decellularized liver matrix. *Nat Med.* 2010;16(7):814–20.
70. Soto-Gutierrez A, Wertheim JA, Ott HC, Gilbert TW, Yagi H. Tissue engineering and organ regeneration in the liver. *Curr Opin Biotechnol.* 2011;22(5):724–9.
71. Nagamoto Y, Mizuta H. Decellularized liver matrix as a carrier for the transplantation of human fetal and primary hepatocytes. *J Tissue Eng Regen Med.* 2016;10(11):945–54.
72. Mazza G, Rombouts K, Rennie Hall A, Urbani L, Vinh Luong T, Al-Akkad W, et al. Decellularized human liver as a natural 3D-scaffold for liver bioengineering and transplantation. *Sci Rep.* 2015;5:13079.
73. Wang Y, Cui CB, Yamauchi M, Miguez P, Roach M, Malavarca R, et al. Lineage restriction of human hepatic stem cells to mature fates is made efficient by tissue-specific biomatrix scaffolds. *Hepatology.* 2017;66(2):625–38.
74. Mazza G, Rombouts K, Rennie Hall A, Urbani L, Vinh Luong T, Al-Akkad W, Longato L, Brown D, Maghsoudlou P, Dhillion AP, Fuller B, Davidson B, Moore K, Dhar D, De Coppi P, Malago M, Pinzani M. Decellularized human liver as a natural 3D-scaffold for liver bioengineering and transplantation. *Sci Rep.* 2015;5:13079. <https://doi.org/10.1038/srep13079>. PMID: 26248878; PMCID: PMC4528226.
75. Dias ML, Paranhos BA, Goldenberg RCDS. Liver scaffolds obtained by decellularization: a transplant perspective in liver bioengineering. *J Tissue Eng.* 2022;13:20417314221105305. <https://doi.org/10.1177/20417314221105305>.
76. Peloso A. Editorial: alternative regenerative medicine for diabetes: beyond the stem cell approach. *Front Endocrinol (Lausanne).* 2021;12:648763.

77. Mirmalek-Sani SH, Orlando G, McQuilling JP, Pareta R, Mack DL, Salvatori M, Farney AC, Stratta RJ, Atala A, Opara EC, Soker S. Porcine pancreas extracellular matrix as a platform for endocrine pancreas bioengineering. *Biomaterials*. 2013;34(22):5488–95. <https://doi.org/10.1016/j.biomaterials.2013.03.054>. Epub 2013 Apr 10.
78. Abazari MF, Soleimanifar F, Nouri Aleagha M, Torabinejad S, Nasiri N, Khamisipour G, Amini Mahabadi J, Mahboudi H, Enderami SE, Saburi E, Hashemi J, Kehtari M. PCL/PVA nanofibrous scaffold improve insulin-producing cells generation from human induced pluripotent stem cells. *Gene*. 2018;671:50–7. <https://doi.org/10.1016/j.gene.2018.05.115>. Epub 2018 May 31. PMID: 29860065.
79. Pignatelli C, Campo F, Neroni A, Piemonti L, Citro A. Bioengineering the vascularized endocrine pancreas: a fine-tuned interplay between vascularization, extracellular-matrix-based scaffold architecture, and insulin-producing cells. *Transpl Int*. 2022;35:10555. <https://doi.org/10.3389/ti.2022.10555>. PMID: 36090775; PMCID: PMC9452644.
80. Zhang L, Miao H, Wang D, Qiu H, Zhu Y, Yao X, Guo Y, Wang Z. Pancreatic extracellular matrix and platelet-rich plasma constructing injectable hydrogel for pancreas tissue engineering. *Artif Organs*. 2020;44(12):e532–51. <https://doi.org/10.1111/aor.13775>. Epub 2020 Sep 11. PMID: 32671848.
81. Sackett SD, Tremmel DM, Ma F, Feeney AK, Maguire RM, Brown ME, Zhou Y, Li X, O'Brien C, Li L, Burlingham WJ, Odorico JS. Extracellular matrix scaffold and hydrogel derived from decellularized and delipidized human pancreas. *Sci Rep*. 2018;8(1):10452. <https://doi.org/10.1038/s41598-018-28857-1>. PMID: 29993013; PMCID: PMC6041318.
82. Guruswamy Damodaran R, Vermette P. Decellularized pancreas as a native extracellular matrix scaffold for pancreatic islet seeding and culture. *J Tissue Eng Regen Med*. 2018;12(5):1230–7. <https://doi.org/10.1002/term.2655>. Epub 2018 Apr 10. PMID: 29499099.
83. Xu T, Zhu M, Guo Y, Wu D, Huang Y, Fan X, Zhu S, Lin C, Li X, Lu J, Zhu H, Zhou P, Lu Y, Wang Z. Three-dimensional culture of mouse pancreatic islet on a liver-derived perfusion-decellularized bioscaffold for potential clinical application. *J Biomater Appl*. 2015;30(4):379–87. <https://doi.org/10.1177/0885328215587610>. Epub 2015 May 25. PMID: 26006767.
84. Hashemi J, Barati G, Bibak B. Decellularized matrix bioscaffolds: implementation of native microenvironment in pancreatic tissue engineering. *Pancreas*. 2021;50(7):942–51. <https://doi.org/10.1097/MPA.0000000000001868>. PMID: 34643609.
85. Wang D, Zhu Y, Huang Y, Zhu J, Zhu B, Zhao Y, Lu Y, Wang Z, Guo Y. Pancreatic extracellular matrix/alginate hydrogels provide a supportive microenvironment for insulin-producing cells. *ACS Biomater Sci Eng*. 2021;7(8):3793–805. <https://doi.org/10.1021/acsbomaterials.1c00269>. Epub 2021 Jul 12. PMID: 34251797.
86. Enck K, Tamburrini R, Deborah C, Gazia C, Jost A, Khalil F, Alwan A, Orlando G, Opara EC. Effect of alginate matrix engineered to mimic the pancreatic microenvironment on encapsulated islet function. *Biotechnol Bioeng*. 2021;118(3):1177–85. <https://doi.org/10.1002/bit.27641>. Epub 2020 Dec 25. PMID: 33270214; PMCID: PMC8887826.
87. Kinney SM, Ortaleza K, Vlahos AE, Sefton MV. Degradable methacrylic acid-based synthetic hydrogel for subcutaneous islet transplantation. *Biomaterials*. 2022;281:121342. <https://doi.org/10.1016/j.biomaterials.2021.121342>. Epub 2021 Dec 30. PMID: 34995903.
88. Wagner LE, Melnyk O, Duffett BE, Linnemann AK. Mouse models and human islet transplantation sites for intravital imaging. *Front Endocrinol (Lausanne)*. 2022;13:992540.
89. Peloso A, Urbani L, Cravedi P, Katari R, Maghsoudlou P, Fallas ME, Sordi V, Citro A, Purroy C, Niu G, McQuilling JP, Sittadjody S, Farney AC, Iskandar SS, Zambon JP, Rogers J, Stratta RJ, Opara EC, Piemonti L, Furdulj CM, Soker S, De Coppi P, Orlando G. The human pancreas as a source of protolerogenic extracellular matrix scaffold for a new-generation bioartificial endocrine pancreas. *Ann Surg*. 2016;264(1):169–79.
90. Lebretton F, Lavallard V, Bellofatto K, Bonnet R, Wassmer CH, Perez L, Kalandadze V, Follenzi A, Boulvain M, Kerr-Conte J, Goodman DJ, Bosco D, Berney T, Berishvili E. Insulin-producing organoids engineered from islet and amniotic epithelial cells to treat diabetes. *Nat*

- Commun. 2019;10(1):4491. <https://doi.org/10.1038/s41467-019-12472-3>. Erratum in: Nat Commun. 2020 Oct 9;11(1):5159.
91. Citro A, Neroni A, Pignatelli C, Campo F, Policardi M, Monieri M, Pellegrini S, Dugnani E, Manenti F, Maffia MC, Valla L, Kemter E, Marzinotto I, Olgasi C, Cucci A, Follenzi A, Lampasona V, Wolf E, Piemonti L. Directed self-assembly of a xenogeneic vascularized endocrine pancreas for type 1 diabetes. *Nat Commun.* 2023;14(1):878. <https://doi.org/10.1038/s41467-023-36582>.
 92. Gattazzo F, Urciuolo A, Bonaldo P. Extracellular matrix: a dynamic microenvironment for stem cell niche. *Biochim Biophys Acta Gen Subj.* 2014;1840(8):2506–19.
 93. Ott HC, Matthiesen TS, Goh SK, Black LD, Kren SM, Netoff TI, Taylor DA. Perfusion-decellularized matrix: using nature's platform to engineer a bioartificial heart. *Nat Med.* 2008;14(2):213.
 94. Soto-Gutierrez A, Wertheim JA, Ott HC, Gilbert TW. Perspectives on whole-organ assembly: moving toward transplantation on demand. *J Clin Invest.* 2019;129(12):4998–5009.
 95. Katt ME, Placone AL, Wong AD, Xu ZS, Searson PC. In vitro tumor models: advantages, disadvantages, variables, and selecting the right platform. *Front Bioeng Biotechnol.* 2016;4:12.
 96. Albritton JL, Miller JS. 3D bioprinting: improving in vitro models of metastasis with heterogeneous tumor microenvironments. *Dis Model Mech.* 2017;10(1):3–14.
 97. Pavesi A, Tan AT, Koh S, Chia A, Colombo M, Antonicchia E, Miccolis C, Ceccarello E, Adriani G, Raimondi MT, Bertoletti A. A 3D microfluidic model for preclinical evaluation of TCR-engineered T cells against solid tumors. *J Immunother Cancer.* 2017;5(1):1–14.
 98. Nishida S, Levi DM, Kato T, Nery JR, Mittal N, Berho M, Schiff ER, Tzakis AG. Massive liver resection and portal vein thrombosis in adult polycystic liver disease. *Liver Transpl.* 2002;8(11):1041–3.
 99. Bonandrini B, Figliuzzi M, Papadimou E, Morigi M, Perico N, Casiraghi F, Dipl C, Sangalli F, Conti S, Benigni A, Remuzzi G, Remuzzi A. Recellularization of well-preserved acellular kidney scaffold using embryonic stem cells. *Tissue Eng A.* 2014;20(9–10):1486–98.
 100. Orlando G, Booth C, Wang Z, Totonelli G, Ross CL, Moran E, Salvatori M, Maghsoudlou P, Turmaine M, Delario G, Al-Shraideh Y, Farooq U, Farney AC, Rogers J, Iskandar SS, Burns A, Marini FC, De Coppi P, Stratta RJ, Soker S. Discarded human kidneys as a source of ECM scaffold for kidney regeneration technologies. *Biomaterials.* 2013;34(24):5915–25.
 101. Ross EA, Abrahamson DR, St. John P, Clapp WL, Williams MJ, Terada N, Hamazaki T, Ellison GW, Batich CD. Mouse stem cells seeded into decellularized rat kidney scaffolds endothelialize and remodel basement membranes. *Organogenesis.* 2009;5(2):67.
 102. United Network for Organ Sharing. U.S. organ transplants by organ type. 2022. https://unos.org/data/transplant-trends/#transplants_by_organ.
 103. Johnson BZ, Hogan KD. Extracellular matrix in tumor bioengineering: a paradigm shift. *J Oncol Sci.* 2023.
 104. Orlando G, Baptista P, Birchall M, De Coppi P, Farney A, Guimaraes-Souza NK, et al. Regenerative medicine as applied to solid organ transplantation: current status and future challenges. *Transplantation.* 2019;103(10):1977–89.
 105. Baptista PM, Siddharthan RV, Shah MB, Atala A, Soker S. Tissue-engineered renal proximal tubules for toxicology and drug screening studies. *Int J Artif Organs.* 2011;34(7):557–64.
 106. Zhou J, Li YS, Chien S, Shear JB. Bioengineering kidney tubules. *Curr Opin Chem Eng.* 2014;3:68–75.
 107. Wang Z, Hu J, Liu F, Huang M. Advances in decellularized kidney scaffolds for renal tissue engineering. *Mater Sci Eng C.* 2018;90:323–32.
 108. Wang X, Yang Q, Cheng Y, Liu Y, Fan Z, Chen D, Yin G. Comparison of different decellularization protocols of porcine kidneys for renal tissue engineering. *PLoS One.* 2018;13(8):e0201833.
 109. Song JJ, Guyette JP, Gilpin SE, Gonzalez G, Vacanti JP, Ott HC. Regeneration and experimental orthotopic transplantation of a bioengineered kidney. *Nat Med.* 2013;19(5):646–51.

110. Ko IK, Atala A. Recapitulation of kidney development from pluripotent stem cells to renal tissue engineering. *Wiley Interdiscip Rev Dev Biol.* 2012;1(5):637–51.
111. Bülow RD, Boor P. Extracellular matrix in kidney fibrosis: more than just a scaffold. *J Histochem Cytochem.* 2019;67(9):643–61.
112. Lee AS, Tang C, Rao MS, Weissman IL, Wu JC. Tumorigenicity as a clinical hurdle for pluripotent stem cell therapies. *Nat Med.* 2013;19(8):998–1004.
113. Kim Y, Atala A. Engineering and characterization of functional human microvascular networks in immunodeficient mice. *Lab Chip.* 2012;12(9):1784–91.
114. Morrison SJ, Scadden DT. The bone marrow niche for haematopoietic stem cells. *Nature.* 2014;505(7483):327–34.
115. Watt FM, Hogan BL. Out of Eden: stem cells and their niches. *Science.* 2000;287(5457):1427–30.
116. Nomi M, Atala A, Coppi PD, Soker S. Principals of neovascularization for tissue engineering. *Mol Asp Med.* 2002;23(6):463–83.
117. Atala A, Allickson JG. Clinical translation of stem cell therapies: an overview. In: *Tissue engineering and regeneration in dentistry: current strategies.* Hoboken: Wiley-Blackwell; 2014. p. 3–8.

Part VII

Conclusions

Chapter 19

Translating Knowledge in Surgery



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Introduction

Knowledge is one of the essential resources for every organization [1]. Therefore, knowledge management is regarded as a fundamental business process for institutions in every industry [2]. The purpose of knowledge management is to facilitate the creation of new knowledge, as well as the transfer and dissemination of existing knowledge, both inside and outside the organization. Diverse stakeholders and actors must collaborate within the knowledge cycle for knowledge and meaningful information to be effectively transferred and shared [3].

In the current economic environment, ecosystems are becoming increasingly open and interconnected [3, 4], and a variety of different subjects need to collaborate to reach organizational goals. In healthcare, clinical practices are increasingly based on a multidisciplinary approach, and the clinical course is determined

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collaboratively by professionals from various disciplines [5]. In oncology, multidisciplinary professional groups such as breast units or pancreas units have proven to be more effective than non-specialized centers at providing care [5–9]. In addition, all clinical decisions should be shared with the patient to assess his or her care preferences, values, and goals [10, 11], resulting in shared-decision making [12]. Technology providers and industry partners are required to share information and clinical practices to support medical professionals' decisions with accurate data and facts [13–16].

Knowledge must be communicated and transferred among various stakeholders, whether they are internal or external to an organization [17, 18]. However, the involved parties may have different educational backgrounds, skill sets and competencies, requirements, values, ages, etc. Such differences may represent a formidable barrier that prevents effective knowledge sharing and transmission and, consequently, the creation of new knowledge [19–21].

The Concept of Knowledge Translation and Its Facilitators

The term “knowledge translation” (KT) evokes the concept of a foreign language being translated into a different language in another context. The process describes how knowledge should be transformed to enable individuals with various characteristics to transfer such knowledge effectively [22, 23].

The most famous definition of KT is provided by the Canadian Institutes for Health Research, which defines KT as the process which “includes knowledge dissemination, communication, technology transfer, ethical context, knowledge management, knowledge utilisation, two-way exchange process between researchers and those who apply knowledge, implementation research, and development of consensus guidelines” [24].

The manner in which KT is conceptualized and the eventual instruments that can facilitate the KT process are heavily dependent on the type of actors involved in the translation and sharing of knowledge, as well as the purpose of the transfer.

KT processes may not always appear simple and straightforward. In light of this, the literature has identified a number of tools and techniques that can facilitate the translation process among various stakeholders and contexts. While some of them may appear innovative, such as design artifacts [19, 23, 25] and paradoxes [26], others look more traditional and even linked to an organization's everyday activities, such as management control systems [27]. In general, these tools and facilitators can be categorized into the following groups.

Tools Based on Technology

The translation process can be facilitated by innovative and technologically advanced instruments. New technologies, particularly those associated with the internet and the so-called Industry 4.0 enable people and organizations to interact and share knowledge in novel ways. For instance, electronic health records allow multidisciplinary professionals to share data and information about a single patient (such as test results, CT scans, images, evaluations, etc.) or even to aggregate data from multiple patients with the same pathology [28]. Web portals, social media networks, and online platforms make it possible to collect and share information on virtually any subject, even medical advice. The virtual interaction between users, institutions, and public agencies can result in effective knowledge translation, particularly when information comes from credible sources (such as official websites from national or supranational agencies, countries, or regions), as was the case in the management of the COVID-19 pandemic [29–32].

Tools Based on Technical Skills

The medical profession is characterized by a body of relevant technical knowledge. Tools like clinical guidelines [33] have the vital role of suggesting clinical behaviors to physicians in the event of a particular situation. Checklists [34] are created to ensure that no essential information is overlooked.

Tools Based on Non-technical Skills

Non-technical skills have proved to play a central role in healthcare and surgery [35–38]. Non-technical or soft skills are the personal competencies that can benefit a person's career or success [39]. While technical skills can be readily acquired through formal education or on-the-job training, soft skills appear to be connected to an individual's personality and are, therefore, challenging to obtain from scratch. Examples include leadership and the capacity to work in a team. These non-technical or soft skills have proven to be valuable facilitators in the KT process, such as in multidisciplinary teams [40] or the relationship between physicians and patients [37].

Educational Resources

Education and training, whether in medical schools, during residency, in life-long learning programs, or on the job, are valuable facilitators for aligning competencies to improve the communication process among multidisciplinary professionals. In addition to combining other categories, educational tools may also use web-based platforms, such as webinars or simulators [41] or social media. Education can also refer to non-professional actors, such as citizens, like to promote organ donation [42], or in the case of the COVID-19 pandemic and associated social distancing measures [43].

Creative Instruments

Other tools that rely more on creativity and non-traditional techniques to facilitate the translation of concepts have been identified in the literature. Among these facilitators, design and design artifacts stand out as effective techniques in multiple contexts, such as patient engagement and co-production [19, 21].

Social-Activity-Based Instruments

The final category of tools comprises those that rely on the interaction of multiple parties to facilitate the exchange of knowledge and experience, thereby easing the translation process. Several techniques have been discussed in the literature over the years, ranging from gaming and gamification [44] to dancing and singing [45] and walking [46]. Traditional and more technical social instruments consist of testimonials and multidisciplinary teams and committees [47, 48].

Table 19.1 KT dynamics and aims in surgery

From	To					
Public sector entities or agencies	Public sector entities or agencies	Universities and research centers	Industrial companies	Medical professionals	Patients	Citizens and communities
Public sector entities or agencies	Sharing and approving new surgical protocols and practices	Setting new research and training goals and directions for surgical science	Assessing results; approving new surgical tools, drugs, and treatment plans; setting new development directions; providing funds	Sharing new surgical protocols and regulations; assessing competencies and skills	Sharing protocols, practices, and data	Sharing and promoting best practices (e.g., in the prevention or healthy habits for risk factors); giving rules (e.g., the COVID social distancing rules)
Universities and research centers	Asking funds. Setting new research avenues and needs. Converting research into new protocols, methods	Sharing multidisciplinary knowledge and data	Experimental trials; converting research into new surgical instruments and techniques	Promoting trials, assessing educational needs, and upskilling	Enrolling patients in trials. Sharing medical knowledge	Sharing medical knowledge
Industrial companies	Asking funds. Setting new protocols and methods. Proposing new tools, techniques, and business models	Sharing practical knowledge and data; proposing alliances for surgical innovation and testing	Sharing knowledge and data	Proposing trials and tests; converting industrial research into new protocols, methods, surgical techniques, and instruments	Enrolling patients in trials. Enrolling new customers (e.g., drug users). Sharing medical knowledge and practices	Sharing medical knowledge and practices. Enrolling new customers (e.g., drug users)

(continued)

Table 19.1 (continued)

From		To					
	Public sector entities or agencies	Universities and research centers	Industrial companies	Medical professionals	Patients	Citizens and communities	
Medical professionals	Sharing medical knowledge and needs	Sharing multidisciplinary knowledge, data, and educational needs	Sharing multidisciplinary knowledge and data, exploring collaboration	Sharing multidisciplinary knowledge and data; engaging in multicentered studies and trials; surgical consultation	Sharing surgical knowledge and co-deciding a treatment path	Sharing medical knowledge in terms of prevention, risk factors, and desired behaviors	
Patients	Asking for better clinical services and reimbursement, safe environments	Sharing clinical data in certain circumstances (e.g., for rare diseases)	Sharing clinical data in certain circumstances (e.g., for rare diseases)	Shared decision-making, narrative medicine, and co-production dynamics	Sharing experiences, best practices, and lessons learned. Seeking support	Sharing experiences, best practices, and lessons learned	
Citizens and communities	Asking for better clinical services	Sharing big data in certain circumstances	Sharing big data in certain circumstances	Seeking support, best practices, and lessons learned	Giving support, sharing information	Giving support, sharing information	

An Overview of Knowledge Flows and Translation Processes in Surgery

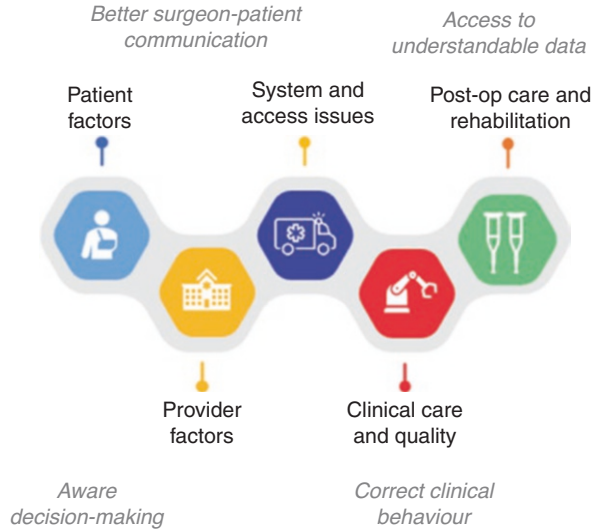
As with all medical specialties, the surgical ecosystem sees the interaction of several actors that need to exchange knowledge to ensure the best possible clinical outcome. Such actors are not limited to the multidisciplinary medical team and the patient, but in some cases, also involve public entities and agencies, for instance, for those pathologies that recommend prevention and early testing. Moreover, surgical science has a strong connection with technology and technological innovation. Therefore, research centers and technology providers belonging to the private industrial sector actively participate in the game, seeking and sharing new knowledge.

Table 19.1 summarizes some of the possible knowledge flows and their aims considering the various stakeholders in the surgical panorama.

Knowledge Translation to Promote Equity and Limit Surgical Disparities

One of the most debated topics in the current surgical organizational literature is related to surgical disparities and equity in access to care [49, 50]. The framework by Torain et al. [51] underlines five crucial steps in the surgical journey in which disparities in care may happen. The first one is related to patient-related factors, as, often, minorities or people with disabilities may experience poorer surgical outcomes, including access to trials [52]. The second one refers to the type of hospitals or institutions. Specialized and high-volume hubs experience better surgical results due to their expertise [8]. However, they may be out of reach. In some geographical areas or contexts, people may not be able to get into such hubs because of the lack of financial means or adequate insurance coverage [51]. And even when patients are, indeed, admitted, they may access different levels of care according to, for instance, the seniority or skills of the surgeon in charge, the level of the available technology, and so on [51]. In developing countries, instruments and advanced training may be lacking, as it happens in oncology [53]. Last but not least, patients

Fig. 19.1 Some of the KT flows in promoting access to care. (Adapted from Torain et al. [51])



who underwent surgery may need extensive follow-up and rehabilitation. Those who cannot access adequate rehabilitation because of a lack of money, time, or the presence of work or family duties may delay their healing process [54].

Although more extensive policies and strategies are needed to treat a complex and challenging issue, KT may contribute to limiting surgical disparities and promoting equity in access to surgical care. Indeed, proper KT strategies and facilitators may enhance surgeon-patient communication, allowing shared-decision making. Understanding medical facts like recommended behaviors, risk factors, and best practices may lead patients to carry on and maintain correct behaviors, boosting satisfaction and outcomes. These may include getting understandable clinical data.

Figure 19.1 summarizes some of the concepts related to KT flows in the various steps when surgical disparities may arise.

Overall, KT stands as an effective and strategic process in surgery and surgical care, facilitating the relationships and knowledge dynamics among the various stakeholders of the surgical scenario. Promoting sound KT practices and aids may contribute to co-production dynamics, patient's engagement, better surgical outcomes, and enhanced communication and dynamics within surgical teams.

References

1. Edvinsson L, Dal Mas F, Ordóñez de Pablos P, Massaro M, Dumay J. From a value-based knowledge economy to a worth economy. New reflections and perspectives on intellectual capital research. *Int J Learn Intellect Cap.* 2022;19(1):83–101. <https://doi.org/10.1504/IJLIC.2022.119282>.

2. Andriani M, Samadhi TMAA, Siswanto J, Suryadi K. Knowledge management strategy: an organisational development approach. *Bus Process Manag J.* 2019;25(7):1474–90.
3. Secundo G, Toma A, Schiuma G, Passiante G. Knowledge transfer in open innovation: a classification framework for healthcare ecosystems. *Bus Process Manag J.* 2019;25(1):144–63.
4. Dal Mas F, Massaro M, Rippa P, Secundo G. The challenges of digital transformation in healthcare: an interdisciplinary literature review, framework, and future research agenda. *Technovation.* 2023;123:102716. <https://www.sciencedirect.com/science/article/pii/S0166497223000275>.
5. Kalager M, Haldorsen T, Bretthauer M, Hoff G, Thoresen SO, Adami HO. Improved breast cancer survival following introduction of an organized mammography screening program among both screened and unscreened women: a population-based cohort study. *Breast Cancer Res.* 2009;11(4):1–9.
6. Taylor C, Munro AJ, Glynne-Jones R, Griffith C, Trevatt P, Richards M, et al. Multidisciplinary team working in cancer: what is the evidence? *Br Med J.* 2010;340(7749):743–5.
7. Wilson ARM, Marotti L, Bianchi S, Biganzoli L, Claassen S, Decker T, et al. The requirements of a specialist breast centre. *Eur J Cancer.* 2013;49(17):3579–87.
8. Balzano G, Guarneri G, Pecorelli N, Reni M, Capurso G, Falconi M. A four-step method to centralize pancreatic surgery, accounting for volume, performance and access to care. *HPB (Oxford).* 2021;23(7):1095–104.
9. Cobiانchi L, Dal Mas F, Denicolai S, Previtali P, Venturi A. Editorial: New frontiers in pancreatic cancer care: multidisciplinary approaches, the role of Pancreas Units, and their organizational impacts. *Front Surg.* 2023;10:1182206. <https://www.frontiersin.org/articles/10.3389/fsurg.2023.1182206>.
10. Brown TT, Hurley VB, Rodriguez HP. Association of patient engagement strategies with utilisation and spending for musculoskeletal problems in the USA: a cross-sectional analysis of medicare patients and physician practices. *BMJ Open.* 2021;11(11):e053121.
11. Mathijssen EGE, Van Den Bemt BJJ, Wielsma S, Van Den Hoogen FHJ, Vriezekolk JE. Exploring healthcare professionals' knowledge, attitudes and experiences of shared decision making in rheumatology. *RMD Open.* 2020;6(1):1–9.
12. Cobiانchi L, Dal Mas F, Agnoletti V, Ansaloni A, Biffi V, Butturini G, et al. Time for a paradigm shift in shared decision making in trauma and emergency surgery? Results from an international survey. *World J Emerg Surg.* 2023;18(1):14. <https://doi.org/10.1186/s13017-022-00464-6>.
13. Loftus TJ, Vlaar APJ, Hung AJ, Bihorac A, Dennis BM, Juillard C, et al. Executive summary of the artificial intelligence in surgery series. *Surgery.* 2022;171(5):1435–9.
14. Loftus TJ, Filiberto AC, Balch J, Ayzengart AL, Tighe PJ, Rashidi P, et al. Intelligent, autonomous machines in surgery. *J Surg Res.* 2020;253:92–9. <https://doi.org/10.1016/j.jss.2020.03.046>.
15. Dal Mas F, Piccolo D, Edvinsson L, Skrap M, D'Auria S. Strategy innovation, intellectual capital management and the future of healthcare. The case of kiron by nucleode. In: Matos F, Vairinhos V, Salavisa I, Edvinsson L, Massaro M, editors. *Knowledge, people, and digital transformation: approaches for a sustainable future.* Cham: Springer; 2020. p. 119–31.
16. Cobiانchi L, Piccolo D, Dal Mas F, Agnoletti V, Ansaloni L, Balch J, et al. Surgeons' perspectives on artificial intelligence to support clinical decision-making in trauma and emergency contexts: results from an international survey. *World J Emerg Surg.* 2023;18:1–17.
17. Savory C. Translating knowledge to build technological competence. *Manag Decis.* 2006;44(8):1052–75.
18. Savory C. Building knowledge translation capability into public-sector innovation processes. *Technol Anal Strateg Manag.* 2009;21(2):149–71.
19. Dal Mas F, Biancuzzi H, Massaro M, Miceli L. Adopting a knowledge translation approach in healthcare co-production. A case study. *Manag Decis.* 2020;58(9):1841–62.
20. Graham ID, Logan J, Harrison MB, Straus SE, Tetroe J, Caswell W, et al. Lost in knowledge translation: time for a map? *J Contin Educ Heal Prof.* 2006;26(1):13–24.

21. Dal Mas F, Biancuzzi H, Massaro M, Barcellini A, Cobianchi L, Miceli L, Knowledge translation in oncology. A case study. *Electron J Knowl Manag.* 2020;18(3):212–23.
22. Lemire N, Souffez K, Laurendeau MC. Facilitating a knowledge translation process. Knowledge review and facilitation tool. Quebec: Institut Publique de Santé du Quebec; 2013.
23. Simeone L, Secundo G, Schiuma G. Adopting a design approach to translate needs and interests of stakeholders in academic entrepreneurship: the MIT Senseable City Lab case. *Technovation.* 2017;64:58–67.
24. CIHR. Knowledge Translation. Canadian Institutes of Health Research. 2016 [cited 2020 Apr 16]. <https://cihr-irsc.gc.ca/e/29418.html#2>.
25. Simeone L, Secundo G, Schiuma G. Arts and design as translational mechanisms for academic entrepreneurship: the metaLAB at Harvard case study. *J Bus Res.* 2018;85:434–43.
26. Bagnoli C, Dal Mas F, Lombardi R, Nucciarelli A. Translating knowledge through business model tensions. A case study. *Int J Manag Decis Mak.* 2021;20(2):182–97.
27. Moilanen S. Knowledge translation in management accounting and control: a case study of a multinational firm in transitional economies. *Eur Account Rev.* 2007;16(4):757–89.
28. Stephanie L, Sharma RS. Digital health eco-systems: an epochal review of practice-oriented research. *Int J Inf Manage.* 2020;53:102032. <https://doi.org/10.1016/j.ijinfomgt.2019.10.017>.
29. Romani G, Dal Mas F, Massaro M, Cobianchi L, Modenese M, Barcellini A, et al. Population health strategies to support hospital and intensive care unit resiliency during the COVID-19 pandemic: the Italian experience. *Popul Health Manag.* 2021;24(2):174–81.
30. Grasselli G, Pesenti A, Cecconi M. Critical care utilization for the COVID-19 outbreak in Lombardy, Italy. *JAMA.* 2020;323(16):1545–6.
31. Wang WT, Wu SY. Knowledge management based on information technology in response to COVID-19 crisis. *Knowl Manag Res Pract.* 2021;19(4):468–74. <https://doi.org/10.1080/014778238.2020.1860665>.
32. Wang CJ, Ng CY, Brook RH. Response to COVID-19 in Taiwan: big data analytics, new technology, and proactive testing. *JAMA.* 2020;323(14):1341–2.
33. World Society of Emergency Surgery. WSES Guidelines. 2022 [cited 2022 Oct 4]. <https://www.wses.org.uk/guidelines>.
34. Kitto SC, Sargeant J, Reeves S, Silver I. Towards a sociology of knowledge translation: the importance of being dis-interested in knowledge translation. *Adv Health Sci Educ.* 2012;17(2):289–99.
35. Yule S, Paterson-Brown S. Surgeons' non-technical skills. *Surg Clin North Am.* 2012;92(1):37–50.
36. Pradarelli JC, Gupta A, Lipsitz S, Blair PG, Sachdeva AK, Smink DS, et al. Assessment of the Non-Technical Skills for Surgeons (NOTSS) framework in the USA. *Br J Surg.* 2020;107(9):1137–44.
37. Stahel PF, Cobianchi L, Dal Mas F, Paterson-Brown S, Sakakushev BE, Nguyen C, et al. The role of teamwork and non-technical skills for improving emergency surgical outcomes: an international perspective. *Patient Saf Surg.* 2022;16(1):1–10. <https://doi.org/10.1186/s13037-022-00317-w>.
38. Yule S, Flin R, Maran N, Rowley D, Youngson G, Paterson-Brown S. Surgeons' non-technical skills in the operating room: reliability testing of the NOTSS behavior rating system. *World J Surg.* 2008;32(4):548–56.
39. Dal Mas F, Biancuzzi H, Miceli L. The importance of soft skills in the co-production of health-care services in the public sector: the oncology in motion experience. In: Lepeley MT, Beutell N, Abarca N, Majluf N, editors. *Soft skills for human centered management and global sustainability.* New York: Routledge; 2021.
40. Cobianchi L, Dal Mas F, Massaro M, Fugazzola P, Coccolini F, Kluger Y, et al. Team dynamics in emergency surgery teams: results from a first international survey. *World J Emerg Surg.* 2021;16:47.

41. Garcia Vazquez A, Verde JM, Dal Mas F, Palermo M, Cobianchi L, Marescaux J, et al. Image-guided surgical e-learning in the post-COVID-19 pandemic era: what is next? *J Laparoendosc Adv Surg Tech.* 2020;30(9):993–7.
42. Ruta F, Gallo G, Ferrara P, Terzoni S, Della Monica A, Dal Mas F, et al. Translating knowledge about organs and tissues donation using webinars. An exploratory study in Italy. *Transplant Proc.* 2021;53(6):1792–7.
43. Massaro M, Tamburro P, La Torre M, Dal Mas F, Thomas R, Cobianchi L, et al. Non-pharmaceutical interventions and the Infodemic on Twitter: lessons learned from Italy during the Covid-19 pandemic. *J Med Syst.* 2021;45(4):50.
44. Balch JA, Efron PA, Bihorac A, Loftus TJ. Gamification for machine learning in surgical patient engagement. *Front Surg.* 2022;9:896351.
45. Charoenboon N, Haenssger MJ, Warapikuptanun P, Xayavong T, Khine ZY. Translating antimicrobial resistance: a case study of context and consequences of antibiotic-related communication in three northern Thai villages. *Palgrave Commun.* 2019;5(1):23. <https://doi.org/10.1057/s41599-019-0226-9>.
46. Irwin ML, Smith AW, McTiernan A, Ballard-Barbash R, Cronin K, Gilliland FD, et al. Influence of pre- and postdiagnosis physical activity on mortality in breast cancer survivors: the health, eating, activity, and lifestyle study. *J Clin Oncol.* 2008;26:3958.
47. Cobianchi L, Dal Mas F, Piccolo D, Peloso A, Secundo G, Massaro M, et al. Digital transformation in healthcare. The challenges of translating knowledge in a primary research, educational and clinical centre. In: Soliman KS, editor. *International Business Information Management Conference (35th IBIMA)*. Seville: IBIMA; 2020. p. 6877–88.
48. Cobianchi L, Dal Mas F, Barcellini A, Vitolo V, Facoetti A, Peloso A, et al. Knowledge translation in challenging healthcare environments: the PLOPPO experience at the National Centre of Oncological Hadrontherapy (CNAO Foundation). In: Garcia-Perez A, Simkin L, editors. *Proceedings of the 21st European conference on knowledge management—ECKM2020*. Coventry, UK, 2–4 Dec 2020: Academic Conferences & Publishing International Ltd.; 2020. p. 124–32.
49. Hisam B, Zogg CK, Chaudhary MA, Ahmed A, Khan H, Selvarajah S, et al. From understanding to action: interventions for surgical disparities. *J Surg Res.* 2016;200(2):560–78. <https://doi.org/10.1016/j.jss.2015.09.016>.
50. Haider AH, Dankwa-Mullan I, Maragh-Bass AC, Torain M, Zogg CK, Lilley EJ, et al. Setting a National Agenda for surgical disparities research recommendations from the National Institutes of Health and American College of Surgeons summit. *JAMA Surg.* 2016;151(6):554–63.
51. Torain MJ, Maragh-Bass AC, Dankwa-Mullen I, Hisam B, Kodadek LM, Lilley EJ, et al. Surgical disparities: a comprehensive review and new conceptual framework. *J Am Coll Surg.* 2016;223(2):408–18. <https://doi.org/10.1016/j.jamcollsurg.2016.04.047>.
52. Awad E, Paladugu R, Jones N, Pierce JY, Scalici J, Hamilton CA, et al. Minority participation in phase I gynecologic oncology clinical trials: three decades of inequity. *Gynecol Oncol.* 2020;157(3):729–32. <https://doi.org/10.1016/j.ygyno.2020.03.002>.
53. Barcellini A, Dal Mas F, Paoloni P, Loap P, Cobianchi L, Locati L, et al. Please mind the gap—about equity and access to care in oncology. *ESMO Open.* 2021;6(6):100335.
54. Cobianchi L, Dal Mas F, Massaro M, Bednarova R, Biancuzzi H, Filisetti C, et al. Hand in hand: a multistakeholder approach for co-production of surgical care. *Am J Surg.* 2022;223(1):214–5.