Future of Surgery: Process Transformation is required to quantify Surgical Innovation in the era of Data Intelligence

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Abstract

Novel surgical innovations are being introduced at a rate and volume that surpasses our capacity to quantify them. The current system for assessing innovations is primarily qualitative so that there is confusion in the selection of new surgical devices. As a result, the selection of innovations in surgery is subject to exploitative marketing efforts, which can result in the diffusion of costlier technologies that lack evidence of added value over established practice. With the current global healthcare pressures straining budgets, there is a growing sense of urgency to develop rigorous surgical innovation metrics. Data intelligence, enabling the automated collection, processing and analysis of large, complex datasets to measure innovation remains largely underutilized in healthcare. Metrics will enable quantified benchmarking, comparisons, and rankings of innovations according to their individual value. This is fundamental for informing policy and guiding clinical practice in view of the strategic adoption of innovations of highest value.

Introduction

Innovation has been defined as *"the implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organizational method in business practices, workplace organization, or external relations"*.[1] This definition has relevance to surgical innovation as it emphasizes the two key characteristics of innovation: novelty ("new") and added value ("improvement"). An additional and important point highlighted in this definition is that innovation may not necessarily be a product but can relate to a process, organizational change, or even a new marketing strategy (**Fig. 1**). Thus, as long as novelty and added value are present, the implementation of any change can be regarded as innovation.[1]

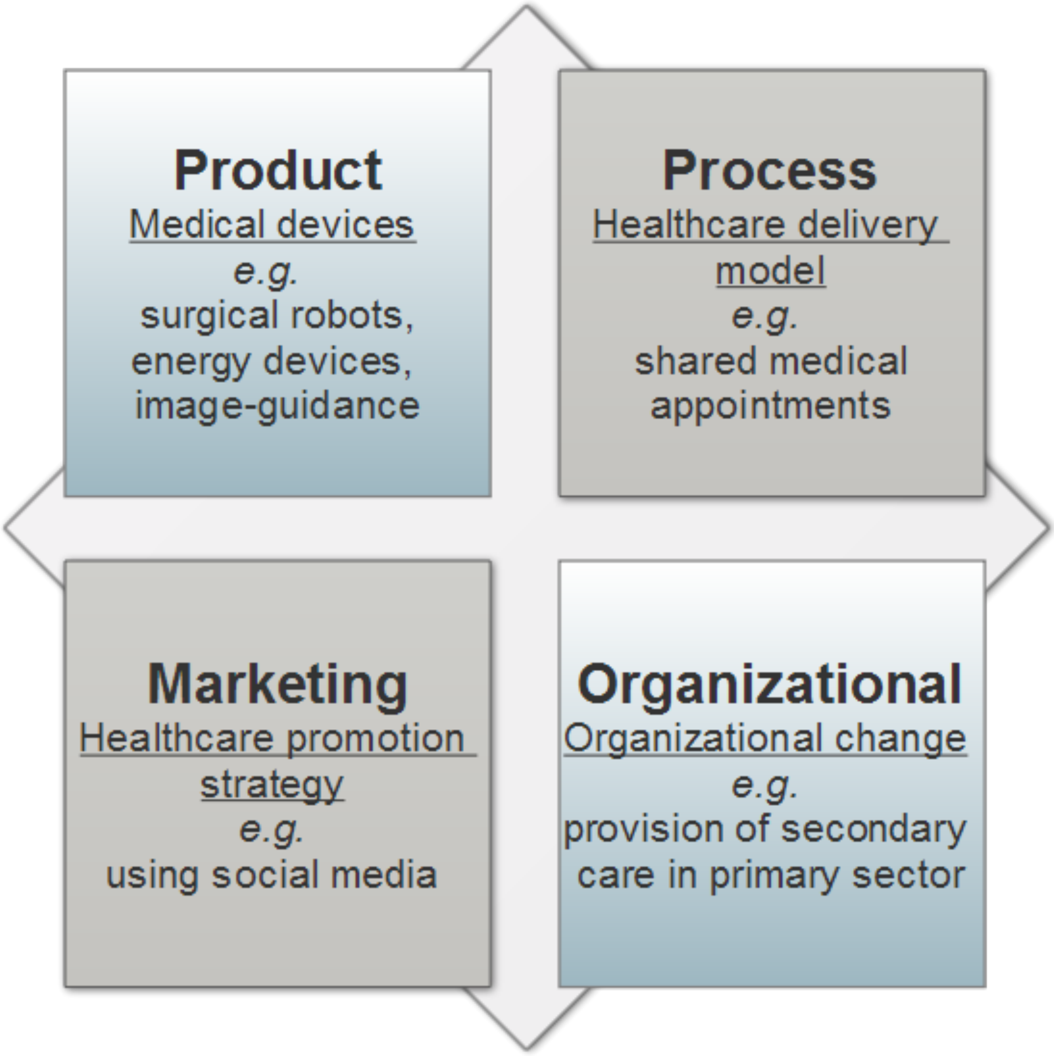

Figure 1. Examples of the four different types of surgical innovation. A 'hybrid' innovation relates to the combination of two (or more) innovation types, e.g., virtual shared medical appointments (process innovation) conducted through Skype® (product innovation).

Novelty may not necessarily refer to 'first ever appearance' of a product, service or process, but can also relate to 'first ever translation' of a product from one sector to another, for example the implementation of an established organizational model from the corporate world to healthcare. Similarly, novelty may relate to the introduction of an established product (e.g., a medical device) to a new anatomic location or patient group (e.g., first application in the pediatric population).[2] One core definition of value can derive from the quantifiable factor of financial potential so that in the healthcare sector, value has been defined as a *"meaningful outcomes achieved for a patient relative to the money spent on his or her care"*[3] (see **Fig. 2**).

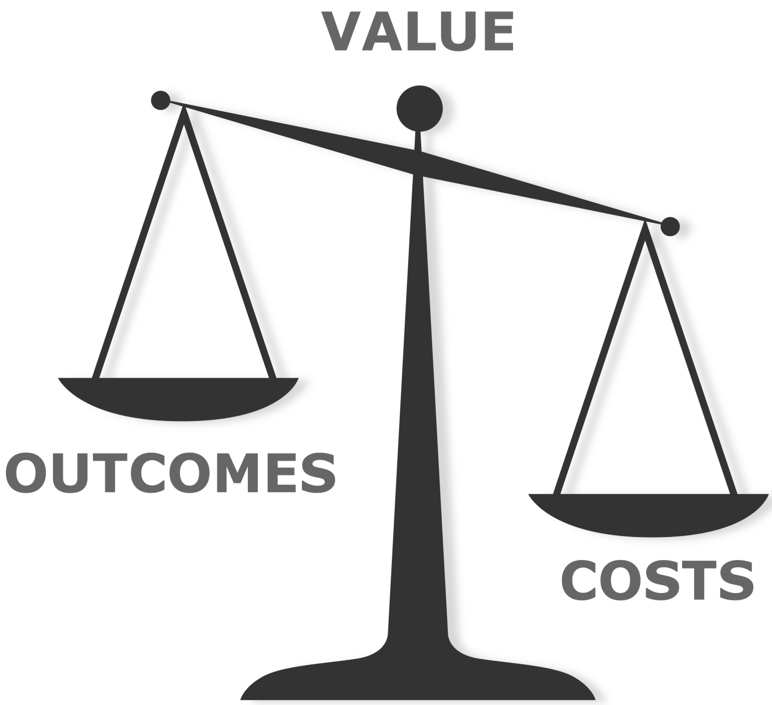

Figure 2. Value in healthcare relates to balance between improved patient outcomes and reduction in associated costs.

Value

The definition of value in healthcare may at first appear simple (essentially represented by the ratio between outcomes and costs),[4] however measuring value - and thus innovation can be challenging. This is evident by the absence of innovation metrics in many medical fields, which lies in direct contrast to many other industries (such as financial technologies and commercial online sales platforms) where the strengths and weaknesses of new innovations are formally characterised through specific innovation metrics. [5, 6]

Surgery is one such field where innovation metrics are lacking and here smart metrics are urgently needed if innovation is to flourish.[7] SMART, relates to an acronym commonly used in management for optimal performance indicators and stands for Specific, Measurable, Achievable, Results-based, and Time-bound.[8] After all, *"we can only be sure to improve what we can actually measure"*.[9, 10] In the era of big data, artificial intelligence (AI), and an unceasing technological revolution, the lack of surgical innovation metrics can no longer be considered sustainable. Beyond the obvious implications to patients and the wider society, there are real financial risks that are becoming increasingly apparent even in G7 country-members, the world's seven largest and most advanced economies.[11, 12]

These include ageing populations and Western sedentary lifestyles that are powerful strains on country-level healthcare budgets.[13] This is further compounded by an increasing pressure to adopt expensive medical devices; many of which are promoted and often perceived as superior despite no clear evidence to support this.[14, 15] Without properly measuring innovation, there is a real risk that marketing and financial factors as well as intuition rather than actual value will increasingly drive the way demand is met.

Robotic surgery is a prominent example that is characterized by marked diffusion across a number of surgical specialties in the absence of demonstrable value beyond minimally invasive prostatectomy.[16] Recent studies have shown that despite over 30 years of incremental advances, robotic surgery remains a surgical intervention of *"low value"*, representing *"a potential candidate for disinvestment"* and an *"unfulfilled promise"*.[11, 17, 18] Yet, despite no clear demonstration of improved outcomes over conventional laparoscopic surgery and substantially increased costs (estimated at around 13% across a range of surgical specialties), the market share of robotic surgery has continuously been expanding for over a decade now.[19] This can only be explained by non-clinical factors driving diffusion, such as the industry's intense marketing strategy targeting not only surgeons and other healthcare providers (*business-to-business model*) but also to patients directly (*business-to-consumer model*) that it turn sustains interest and demand. [20, 21]

It thus becomes apparent that, to ensure progress in healthcare, the ability to measure innovation (through value created or added) is crucial. It is only through innovation metrics that benchmarking, comparisons, and rankings can become possible, all critical for informing healthcare policy and ensuring the selective adoption of those innovations of highest value.[22] To do so, both components of value – outcomes and costs – must be incorporated in those metrics.

What is also important to appreciate is that outcomes should be *"meaningful"* and, as *"value should always be defined around the customer"*,[22] what should actually be measured is what patients deem important (rather than what healthcare providers and/or policy-makers choose to measure - their perspectives and priorities often differ substantially from those of patients).[3]

A variety of measures for patient outcomes have been developed and validated for different diseases and patient populations. Examples include overall and disease-specific survival rates primarily used in oncology, Quality of Life (QoL) scores and Patient Reported Outcome Measures (PROMs) used in a range of diseases to measure the impact of treatments on patients' wellbeing.[23] More recently, with an increasing trend towards value-based purchasing, composite quality measures of surgical performance have been developed and validated for certain surgical operations.[24]

Similarly, costs too should be defined around the patient, and should thus take into consideration the 'full cycle of care'.[22] This is paramount as healthcare delivery often takes place across several organizational units (e.g., primary and secondary care) that therefore need to be properly coordinated.[22] It is this fragmented nature of healthcare with costs often dispersed across a variety of healthcare providers and organizational units that substantially adds to the challenges of measuring the 'true' value of healthcare innovations.[25]

Unless a systematic framework is employed that will take into account all of the above, the likelihood is that any measurement risks being inaccurate and misleading with potentially detrimental consequences on healthcare delivery. It is also crucial that any evidence utilised in an innovation benchmarking process is derived from adequately designed sources that accommodate sound methodological comparison methods (such as demographics, economics, population size, geography, etc).

Conceptualizing surgical innovation

To conceptualize the innovation process in surgery, it is important to look outside healthcare, at sectors where innovation has been extensively studied. The *Innovation Value Chain* (IVC), a concept introduced and applied a decade ago,[26] depicts innovation as a continuous process consisting of three successive phases linked to each other in the following order: 'idea generation', 'conversion' (also referred to as 'translation' or 'materialization'), and 'diffusion' (relating to the uptake of innovation and associated 'market success') (**Fig. 3**).[26]

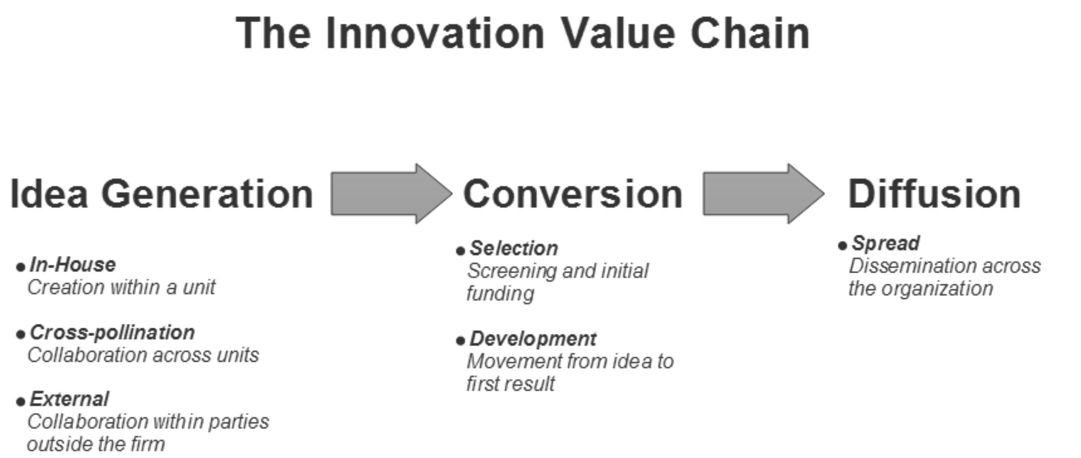

Figure 3. The three phases of the innovation process according to the innovation value chain.

All links between those three phases must be present and strong if innovation is to occur. If any link is deficient or even weak, it does not matter how strong the others are, the 'chain' will break and innovation will be compromised. Hence, it is the weakest link that dictates innovative ability.[26]

For innovation to transpire, a flow of novel ideas is vital but insufficient. Mechanisms are needed to capture and filter those ideas worthy of further evaluation. The ability to convert (translate) those ideas into actual products, processes (or other novel changes), and subsequently diffuse these across the market is paramount. Diffusion (dissemination) does not usually happen passively nor does it happen by chance. On the contrary, it is an active process that requires carefully planned and executed strategies for boosting the visibility of novel products, services or processes, and thus optimizing their chances of uptake and becoming a success.[26]

The generation, development and dissemination of innovations are subject to a natural-selection type process ('survival of the fittest').[27, 28] This natural selection becomes even more prominent in the context of surgical innovation as a result of the strict monitoring and regulatory frameworks in place to safeguard patient safety and address ethical concerns.[29] This is particularly true when it comes to 'first-in-human' applications or when proposing the expansion of small studies to larger ones or to a new patient cohort (e.g., from an adult to a pediatric population).

To exemplify this natural selection process, the *Surgical Innovation Funnel* (SIF) concept has been recently introduced.[30] This consists of the different stages of implementation of surgical innovation including the description of ideas, and the pre-clinical (i.e., laboratory, animal, and cadaveric studies) as well as clinical (based on the levels of evidence) phases. Innovations progressively and selectively flow along these stages, with only the fittest ones ending up at the final stage (**Fig. 4**).[30]

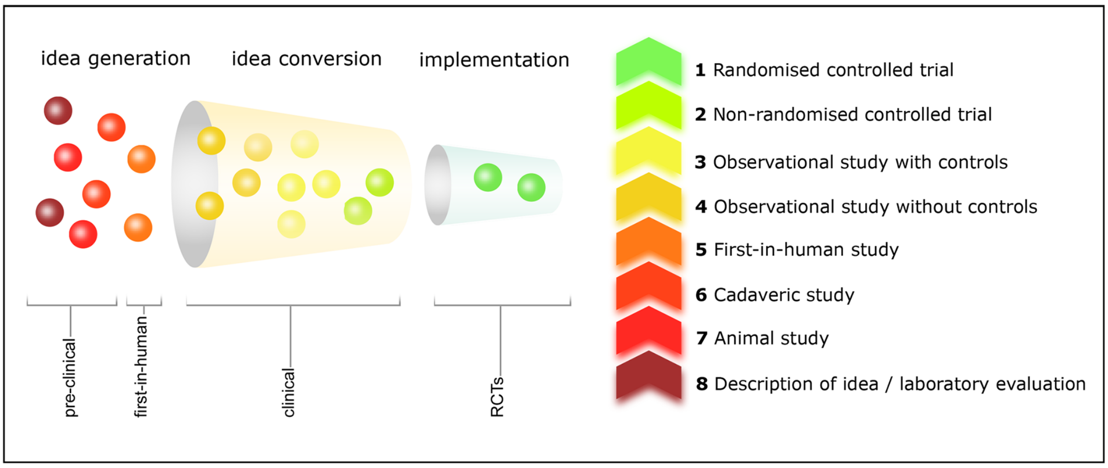

Figure 4. The surgical innovation funnel.

Developing surgical innovation metrics: The time is now

Having defined, classified, and described the stages of innovation, an important question ensues: how can such a complex, multi-faceted, and dynamic process be measured? Answering this question is critical for (i) informing healthcare policy and (ii) guiding clinical practice towards the strategic adoption of innovations with the highest value. At the same time, innovation metrics can also enable (iii) the early dismissal of low value pseudo-innovations before substantial financial, human, and social capital resources are further consumed. This strategic and timely disinvestment will likely reduce waste in healthcare thus optimizing efficiency in terms of resource utilization.[11, 31]

In addition to optimizing patient care, patient safety, and resource utilization, innovation metrics can be valuable in (iv) strategically directing research funding through comparative analysis and rankings to uncover superiority and enable prioritization. This is fundamental as innovation in surgery is entirely dependent on research. Surgical research whether involving basic science, engineering, clinical trials, or big data analytics is typically associated with high costs.[32] In the presence of finite resources and competing national interests for investment, the need for innovation metrics is evident.[33, 34] Furthermore, as surgical research represents such a diverse range of themes and complex data types (that can be multi-dimensional and multi-relational), the introduction of innovation metrics would (v) offer a common platform to appraise and compare new surgical developments irrespective of their nature.

By looking outside healthcare, it becomes apparent that innovation metrics are extensively used. International corporations including innovation leaders such as Apple Inc. and Amazon.com, Inc. have been using smart innovation metrics for years, and heavily rely on these to systematically evaluate their innovation efforts.[6] It is through innovation metrics that strategy is devised towards enhancing innovation and driving performance.[5] Whilst most metrics used in these industries cannot be directly translated to healthcare (as the outcomes of interest differ), they nonetheless offer important lessons[6] that can be adopted to enhance medical and surgical practice.

There are two main categories of innovation metrics - those measuring ‘activity’ (input) and those measuring ‘impact’ (output).[5, 35] For innovation to take place, the output must be shown to offer added or new value (**Fig. 5**). Common metrics used for measuring input in corporate innovation include expenditure towards Research &

Development (R&D) and marketing, whilst for output, sales and profits are often used.[5] Another metric is Return On Investment (ROI), the ratio between output and input.[5]

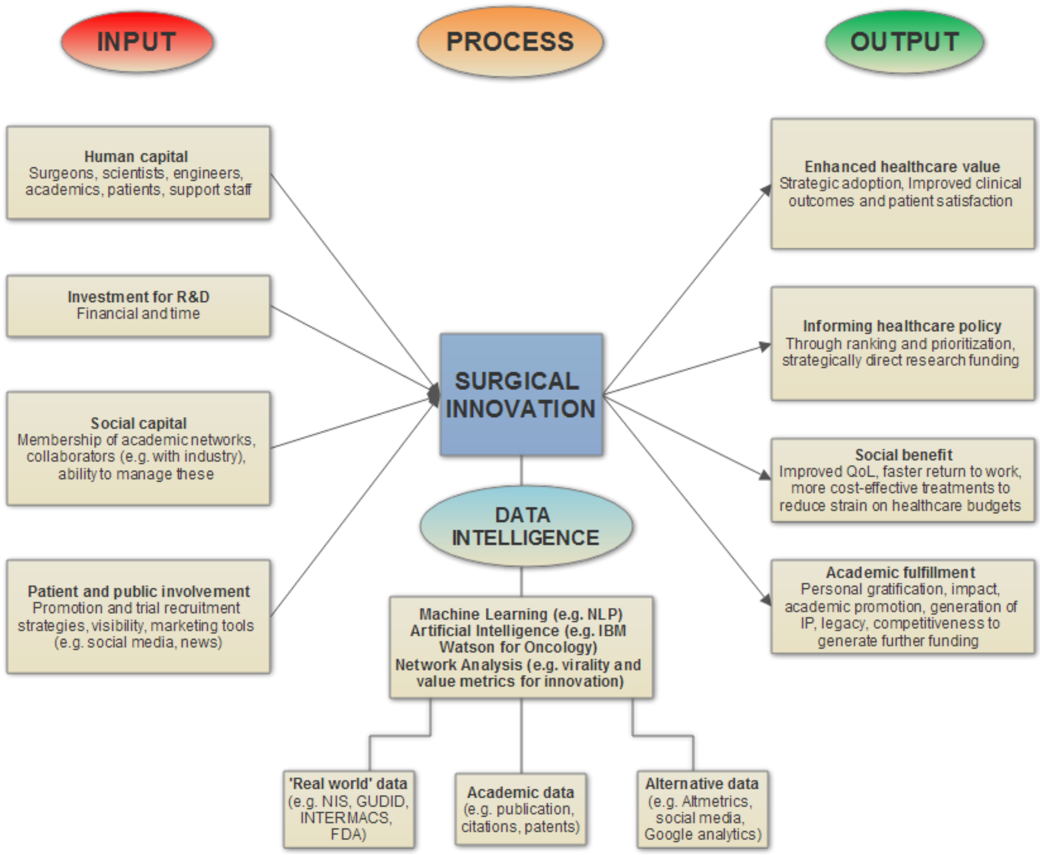

Figure 5. The innovation process in surgery. R&D = Research & Development; NLP = Natural Language Processing; NIS = National (Nationwide) Inpatient Sample database (HCUP); GUDID = Global Unique Device Identification Database (FDA); INTEMACS = Interagency Registry for Mechanically Assisted Circulatory Support; FDA = Food and Drug Administration.

Managing healthcare innovation is complex due to the volume and speed of new evidence generation and the wide variation of clinical practice, so that it is considered "the most complex and fast moving industry".[36] It is the unique Volume, Veracity, Velocity, and Variety of data evidence; collectively referred to as the 'four Vs' that has led to the title of 'big data'.[37, 38] A key challenge relates to its fragmented nature involving a multitude of stakeholders (e.g., patients, surgeons, policy-makers, medical device manufacturers, health insurance companies), each with their own perspective of what represents value.[25]

The need for standardized metrics of global surgical surveillance has been widely emphasized,[39] and a framework for evaluating surgical innovation (the IDEAL framework) developed.[40] However, despite its universal adoption underlining the importance of evaluating innovation in surgery ("no surgical innovation without evaluation"),[41] this framework is primarily qualitative in nature, lacking quantitative components. It is precisely in this area where innovation metrics can offer substantial value in objectively assessing new and current innovations.

In the past, attempts have been made to use patent and publication counts to quantify innovation in surgery.[42] Though this data may be of interest, they both measure activity rather than impact, and more importantly rely on the assumption that the acquisition of Intellectual Property (IP) will eventually translate to new products and revenues.[43] However, this is seldom the case.[44]

The rise of big clinical databases offers a unique opportunity for measuring surgical innovation and conducting comparisons and rankings applicable to the real world.[45] Innovation metrics based on big data can provide a novel insight into surgical innovation and permit meaningful comparisons essential for both clinical practice and policy-making. Conventional statistical techniques (such as regression models) can suffer from some limitations when handling some forms of big data. The 'four Vs' necessitate the use of substantially more powerful analytical tools to capture underlying complex, non-linear relationships.[46] Moreover, data derived from patient registries are often less structured and uncategorized since these are usually set up for different purposes (e.g., billing), thus difficult to analyze unless thoroughly curated. This data processing is not only very expensive (owing to the expertise and time required) but, more importantly, too slow when compared with the rate of production (deposition) of new data. This inevitably makes a curated big dataset likely to be already outdated before it is even ready for analysis.[46, 47] This data complexity therefore requires the application of *Data Intelligence* – the utilisation of advanced analytical process such as machine learning, network approaches and artificial intelligence to manage big data.

Machine Learning (ML) represents a collection of computational tools and techniques with the potential of overcoming these limitations. As an example, Natural Language

Processing (NLP) permits data mining, i.e., the automatic categorization and labeling of previously unstructured data based on content.[48] Another example is Deep Learning (DL), which by implementing algorithms based on a hierarchical multi-level learning approach to recognize patterns (in a fashion similar to the human brain),[49] offers researchers the possibility to extract meaningful abstract representations from heterogeneous, uncategorized big data.[47] Importantly, this can be performed in real time to provide continuously updated results based on the latest evidence and individual patient data.[49]

In addition to the aforementioned techniques falling under the category of 'unsupervised learning' (i.e., discovering structure in unlabeled data), 'supervised learning' (i.e., the training of the DL algorithm to make predictions from novel data based on existing data and outcomes) can prove essential for evaluating surgical innovation.[50] Again, looking outside healthcare, innovation leaders such as Google Inc. and Microsoft Corporation routinely use DL algorithms to analyze big data and facilitate decision-making based on predictive models.[47] By utilizing this approach on individual patient data, the promises of precision medicine can be achieved by selecting the best innovations applied to the populations to which they are most suited.

In healthcare, IBM has recently implemented AI to create IBM Watson for Oncology a DL predictive algorithm trained by Memorial Sloan Kettering Cancer Center (MSKCC) physicians to assist in the decision-making of the tumor board.[51] IBM Watson for Oncology ranks treatment options and offers evidence-based, personalized advice by integrating and analyzing data from a variety of sources including not only the literature, but also the individual patients' laboratory results and physicians' notes.[52] This can be achieved within seconds and shown to correlate by 90% with the actual recommendations of the tumor board.[53] This exceptional ability of real-time, multi-dimensional analytics is likely to be of special salience when it comes to measuring surgical innovation.

To measure surgical innovation, modeling the underlying process is required. As the global spread of ideas, knowledge and innovation is a complex, network-driven dynamic process,[54] an effective way to model the footprints of innovation is through the use of network analysis.[55] Networks (e.g., citation and collaboration networks) enable the precise tracing of how all stakeholders (i.e., the nodes of the networks) involved in the innovation process forge, maintain, and sever connections (i.e., links between nodes) over time, and thus discover, exchange and apply new information.

A promising first step in this direction was recently made with the development of the first two network-based, surgical innovation-specific metrics, namely the *structural virality* and *innovation index* aimed at measuring the diffusion of surgical innovation and evidence-based innovation value, respectively.[30] These indices were also validated against real world data (from the National Inpatient Sample-NIS database) showing a strong, statistically significant correlation.[30] Of note, no correlation was found when traditional metrics (including number of publications and citations) were studied alongside the same real world data. This further supports the need for the introduction and adoption of novel innovation-specific metrics rather than traditional metrics (that were not developed for directly to assess innovation in this way).[30]

Novel innovation metrics can be applied to all relevant data available and should not be confined to Randomized Controlled Trials (RCTs). This is especially relevant to surgery where the conduction (and even analysis on certain occasions) of RCTs remains problematic, as is their practicality when it comes to assessing harm.[34, 56] The latter is of particular importance as surgical innovation inherently involves risk.[2] Surgical innovation metrics should complement the traditional evidence-base with real-world evidence incorporating multiple additional sources including those derived from administrative healthcare databases.[57]

In addition to more traditional publication and patent data as well as financial data, recently emerging alternative metrics (altmetrics) are required for the evaluation of surgical innovation in an ‘all-rounded’ perspective.[58] In the modern digital world, these represent “indicators of different types of visibility” and offer the ability to measure both input/activity (in terms of online presence, social media promotion and digital marketing) and output/impact (in terms of references in news media, Internet citations, search engine hits, downloads, and other metrics of impact relating to Patient and Public Involvement, PPI).[58]

It becomes apparent that SMART surgical innovation metrics are essential and can only be developed through data intelligence where big data from a number of diverse sources are collected, linked and analyzed in real time using an array of advanced computational tools, including ML, neural networks and AI. It is important to appreciate that with these immense opportunities, new challenges emerge. Examples relate to data governance; in particular issues concerned with privacy, access, storage, database linkage, and online safety. Patient confidentiality and the application of cybersecurity principles are paramount and cannot be compromised. Technology to address these challenges is being developed in parallel. Examples include high security cloud storage (e.g. Iron Mountain®)[59] and distributed ledger technologies such as Blockchain, a digital network originally designed to ensure safety in online transactions and more recently introduced to healthcare by IBM to manage clinical trial data and electronic medical records while maintaining regulatory compliance.[60]

Conclusion

Data intelligence, enabling the automated collection, processing and analysis of large, complex (multi-dimensional and multi-relational) datasets to measure innovation remains largely underutilized in healthcare. Surgical innovation metrics will enable quantified benchmarking, comparisons, and rankings of innovations according to their individual value. This is fundamental for informing policy and guiding clinical practice in view of the strategic adoption of innovations of highest value. The future in this field is to engage with healthcare leaders and policy makers to highlight the strengths and powerful advantages of introducing quantifiable innovation indices and to setup both national and international strategies with which to implement them.

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