

Changing the Paradigm of Surgical Research During a Pandemic

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The traditional model for surgical research typically involves generating incremental improvements in clinical outcomes either through the optimization of existing approaches, or through the introduction of novel techniques. This process is often painstakingly slow¹ with a significant time lag from the initial development of an idea, through to the delivery of a highly controlled trial and subsequent clinical translation.^{2–4} In many instances, this resource consuming process may not produce an agreed conclusion nor be widely adopted within routine practice. Surgical research is absolutely necessary during a pandemic to guide surgical treatment during the pandemic, to prepare surgical services for what is to come after the pandemic, and the next stages of healthcare recovery.

The current COVID-19 pandemic^{5,6} has demonstrated that the existing paradigm of surgical research, predominantly reliant upon incremental innovation, is not fit for this purpose. As such, to prevent avoidable harm, we must now urgently adapt from a rigid system of highly controlled prospective trials, towards an adaptive and pragmatic approach, which is focused upon delivering agile evidence-based changes in practice at pace and scale. To achieve this, we must be cognizant of the specific challenges that lie ahead and the strategies that we must champion so that we may overcome them.

RESEARCH CHALLENGES DURING A PANDEMIC

Global crisis such as COVID-19, exert intolerable stress on the delivery of clinical research, which is typically compromised as clinical scientists are redirected to the front line. This represents a significant threat to the process of clinical research; safe and effective care is only possible if critical learning systems are maintained and trials can be deployed to demonstrate efficacy of emerging therapies for novel threats. Modern research is multidisciplinary, and surgeons are often critical players that not only provide samples, but important insights into experimental design, analysis, execution, and leadership.

Research in a time of crisis must also address system wide challenges. First, like any other service it requires effective leadership with a command and control structure. This has been strikingly absent, and it is now critical that global funding bodies and our professional associations pick up the ball and take the initiative.⁷ We urgently require clear priorities and networks around which clinical research can be coordinated.

Time remains a significant limiting factor in this pandemic, particularly because of the speed of transmission which has caught many governments and healthcare providers off guard.⁸ As a result, critical functions of research, such as ethical approvals, must be acquired under immense pressure. This process is further compounded by limited capacity within research infrastructures to adapt to staff becoming unwell or the loss of administrative staff. Similarly, clinical academics will face increasing demands in service provision leaving limited bandwidth to dedicate to research. Some of these challenges are predictable, but many are not, and a global crisis of this magnitude means that both research networks and systems may be unreliable, and patient responses to both established and new surgical interventions may vary dramatically. Therefore, confounders may strongly influence outcomes seen during a pandemic.

However, during a crisis many barriers to research also come down, facilitating widespread collaboration within and between units on an international scale. During the COVID-19 pandemic, there is evidence of trials in medical therapies,⁹ prevention strategies,¹⁰ and vaccines.¹¹ Surgeons now urgently require the same approach if we are to optimize the treatment of surgical pathology and protect our staff. But, even during times of crisis balance between rapid dissemination and robust scientific methodology is required if robust work of impact is to be produced. Moreover, it must be communicated and synthesized at pace. Many journals, including *Annals of Surgery*, have changed their publication process to facilitate learning and create new models of content distribution. Teams are finding new ways of working through digital platforms and social networks, and there has never been more data and computing power available to clinicians who have to solve some of our biggest problems.

ETHOS OF SURGICAL RESEARCH

During a pandemic, the ethos of surgical research must change. The traditional model of scientific investigation and peer-reviewed publication must swiftly adapt to the fast moving pace of the disease, aiming to achieve greater understanding with quality improvement measures, rapid dissemination, and clinical implementation to maximize the quality of care we deliver to our patients. Not doing so risks the propagation of falsehoods and nonevidence based practice.

STRATEGIES FOR SURGICAL RESEARCH DURING A PANDEMIC

A new tailored approach to surgical research that aims to address the pandemic crisis should include four key principles.

First, collaborative learning is essential to the success of any surgical project. New digital technologies with a national, and more importantly, a global reach can serve as incredibly useful forums for discussion and shared learning across countries and health systems as they enter different stages in their pandemic response. These are important to support the widespread dissemination of new

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knowledge and allow learned experiences to be shared amongst healthcare professionals. The PanSurg collaborative,¹² an international collaboration of clinical academics who are coordinating targeted COVID-19 studies, have sought to address this knowledge gap by hosting webinars with subject matter experts from a variety of backgrounds. The most common question that panelists in these webinars are asked is, “if you knew what you know now four weeks ago, what would you do differently?” The answers to this question are vitally important to health systems in which the pandemic has started later, allowing them to implement change early, avoid making the same mistakes and reduce unnecessary morbidity by interrupting the vicious spiraling cycle of disease sooner. These lessons must be centrally collated and communicated.

Second, novel sources of reliable information and opportunities for rapid dissemination of findings need to be sought. The traditional process of peer-review just takes too long, and is not dynamic enough to keep up with the rapidly changing context of a pandemic. Conversely, social media platforms, utilization of preprints, and other online resources allow for faster dissemination, with the potential for more timely clinical adoption and subsequent impact. When adopted in conjunction with open and transparent online discussion and critique, they also provide a degree of “real-time” peer-review and debate. This model caters for the delivery of robust evidence to inform effective decision-making.

Third, it is vital to remember that data is key to surgical research during a pandemic. Data capture must be focused to limit collection and entry fatigue, but also robust enough to permit meaningful analysis. Focused analytics during pandemics may include the generation of novel dynamic risk prediction models¹³; these can serve to guide clinical decision making and the allocation of limited resources such as choice of intervention and intensive care unit bed utilization. The modeling of risk during a pandemic is challenging for two important reasons; (i) the disease itself may change the risk associated with surgical intervention (often increasing risk), and (ii) healthcare resources will be stretched beyond any previous situation and thus cannot be modeled from historical data. Importantly, processes for the review and approval of such data collection and analysis must also adapt to ensure that vital data and time is not lost.

The fourth principle involves engagement with industry; this is one of the major strengths of technology-focused surgical research and may provide a common model upon which to base new relationships. During a pandemic the traditional funding model is not fit for purpose; the process of applying for a research grant, gaining funding, and implementing a project is far too time consuming. Transparent engagement with industry will allow shared learning and pooling of resource, the introduction of new expertise, and the rapid

delivery of additional funding to support surgical research and new initiatives in a dynamic way.

CONCLUSIONS

The rapidly evolving and progressing nature of the present COVID-19 pandemic has highlighted several critical limitations in the traditional model of surgical research; namely, the inability to provide timely evidence to rapidly inform and change clinical practice, thus ultimately defeating its main purpose of improving patient outcomes. The key question remains the same; “how do we deliver the best possible care for our patients?” What has changed; however, is that the novel context of a rapidly evolving pandemic which necessitates speed in dissemination and clinical implementation. The traditional approach to surgical research must evolve to cater for (1) iterative learning, (2) novel dissemination methods, (3) rapid data generation, and (4) industry collaboration to meet the current pandemic challenge.

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