Fostering Clinical Research in the Community Hospital: Opportunities and Best Practices

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Abstract

With potential to improve patient outcomes, quality of care and cost-effectiveness, clinical research activity in community hospitals has recently begun to increase. Recognizing that establishing or strengthening a clinical research program in this setting is an important, complex and challenging undertaking, this article introduces many of the resources, best practices and success stories that community hospitals can draw upon to develop and incentivize clinical researchers, operationalize the clinical research enterprise and make clinical research impactful.

Introduction

Historically, clinical research – and clinical trials, in particular – have not been central to the mandate of community hospitals in Canada, but the number of hospitals engaging in clinical research and the volume and complexity of these studies are growing. This trend reflects a greater appreciation of the distinguishing strengths community hospitals bring to clinical research and an understanding of the critical role clinical research can play in preparing hospitals and healthcare systems for the future. Through clinical research, community hospitals can be better positioned to increase the cost-effectiveness and quality of care, test and adopt cutting-edge products and practices and meet the unique healthcare needs of the patients and communities they serve.

Community Hospitals Are Contributing to – and Benefiting from – Clinical Research

Better patient outcomes

Community hospitals recognize the advantages of participating in clinical research. Although measuring the direct impact of clinical research on both individuals and healthcare systems is complex, there is a growing body of evidence suggesting that research-intensive hospitals contribute to better patient outcomes. For example, studies of patients with coronary artery disease, colorectal cancer and ovarian cancer in research-intensive hospitals suggest improved survival for both patients participating in the studies and those (in the same hospital, with the same illness) not participating, compared to similar patients in hospitals who do not participate in clinical trials (Downing et al. 2017; Du Bois et al. 2005; Majumdar et al. 2008; Rochon and du Bois 2011). Data suggest that improved outcomes are not solely driven by early adoption or testing of new therapies/technologies but are also realized through some of the less direct benefits of clinical research, such as the formation of innovative, research-oriented medical teams, enhanced training opportunities for hospital staff, rapid adoption of new clinical guidelines and the attraction and retention of talent (Krzyzanowska et al. 2011).

New revenue streams

Clinical trials also represent a potential revenue stream that can make a positive contribution to increasingly constrained hospital and health system budgets. One study in Alberta estimated that industry sponsor contributions were greater than $120,000 per patient for drugs and clinical services in non-cancer drug clinical trials and over $225,000 for cancer drug clinical trials (Tran et al. 2017). Furthermore, clinical research has the potential to uncover opportunities to enhance cost-effectiveness and efficiency in care delivery (Rahman et al. 2011; Stephen and Berger 2003; UKCRC 2005). Although these financial benefits are very attractive, not all research is funded in the same way, benefits and impacts (e.g., cost-effectiveness, efficiency) are often not immediate and cannot be readily predicted, and establishing and maintaining a functional clinical research environment can be expensive. Revenue expectations must therefore be weighed against potential costs.

Patient engagement

Patient interest in clinical trials and clinical research has been growing. Indeed, Canada*Speaks*!, a 2019 survey co-sponsored by six Canadian organizations, including Research Canada, found that 63% of Canadians are interested in health and medical research and 91% believe that research makes important contributions to the healthcare system (Research Canada 2019). Consistent with these results, a survey conducted by Clinical Trials Ontario (CTO) and Clinical Trials BC in 2015 found that 68% of the respondents were somewhat or very willing to participate in a clinical trial. And among trial participants in a phase 4 cardiovascular study, 91% found the experience to be positive and 87% felt they received better healthcare because they had participated (Willison et al. 2019).

Community Hospitals Are Building New Capacity for Clinical Research

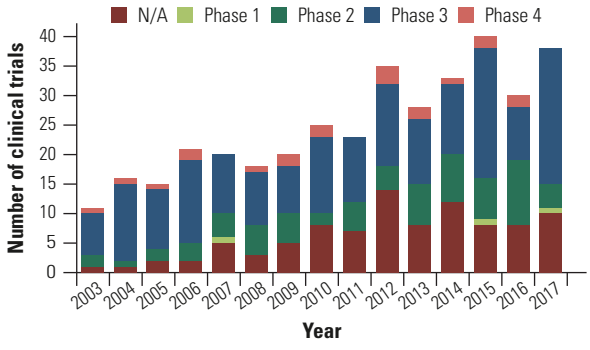
Barriers to clinical research

Although the benefits of clinical research are significant, establishing a productive clinical research program within a community hospital is a challenging process that can be delayed or impeded by several barriers. Recognizing that clinical research has primarily been conducted in large academic hospitals, securing organizational commitment is important for fostering a culture of inquiry and accessing essential financial support, and can represent a meaningful shift in mandate. Although external funding sources can often be identified for clinical research, start-up costs (e.g., research infrastructure, policies and procedures) and operating costs (e.g., research support staff, overhead) are important for the success of research operations and may need to be sourced internally. Access to relevant study populations can also emerge as a barrier to participation in some clinical research. Finally, physicians can encounter barriers when contemplating clinical research: they often have no formal training in research and/or may not have access to protected time or other incentives to enable participation. Resources and best practices that address many of these issues are presented in the third section of this article.

Growing clinical research capacity

Recognizing that building clinical research capabilities is a resource-intensive process, many community hospitals first build research capabilities within established areas of clinical excellence as clinicians seek new and innovative ways to care for their patients. Initial forays into research may involve questions that can be answered by chart reviews, quality/process improvement studies, surveys and interviews. As interest, commitment and expertise grow, the research portfolio may expand to include more complex studies, such as clinical trials. Conducting clinical trials is now well within the capabilities of many community hospitals. Indeed, there has been significant growth in the total number of interventional trials – phase 1 (safety in healthy volunteers), phase 2 (effectiveness in target populations), phase 3 (safety and effectiveness in different populations, of different dosages and/or of the intervention in combination with other drugs) and phase 4 (trials following regulatory approval) – and observational studies (phase N/A; Figure 1) – initiated at Ontario's largest community hospitals between 2003 and 2017. Phase 2, phase 3 and observational studies make up the greatest proportion and drive the greatest growth over time.

FIGURE 1.
Clinical trials initiated at large community hospitals in Ontario: 2003–2017



N/A = not applicable to observational studies.

Note: Clinical trials started at the 10 largest (based on budget) community hospitals in Ontario were identified using clinicaltrials.gov. Trials were categorized by Phase (N/A, phase 1, phase 2, phase 3 and phase 4) and were assigned to a year based on the start date of the trials.

… community hospitals are well positioned to enhance the attraction and retention of study participants…

Making clinical research accessible

With clinical trials facing fierce competition for space, time and capacity and more than 80% of sites failing to reach recruitment goals, community hospitals may provide much-needed site capacity (Huang et al. 2018). Based on patient volume alone, community hospitals provide care to more patients than traditional research-intensive academic hospitals (Tsang and Ross 2017). In Ontario, 55% of hospital beds are in large (>100 beds) community hospitals, and 65% of medical and surgical patients are seen in this setting (DiDiodato et al. 2017). Community hospitals are also geographically closer to the patients they serve (on average less than 16 km), which makes participation in clinical trials more feasible (Lam et al. 2018). One study calculated that, on average, patients travel over 40 km to participate in a trial, often multiple times a week (Borno et al. 2018). By providing research opportunities where patients live, community hospitals are well positioned to enhance the attraction and retention of study participants and contribute to healthcare equity by extending clinical research opportunities to a wider range of individuals (Branson et al. 2007; Unger et al. 2016).

Best Practices and Resources Can Help Foster Clinical Research in Community Hospitals

Although community hospitals have an opportunity to promote a learning health system that enhances patient care and treatment outcomes through research and innovation, establishing a research enterprise in the community hospital setting is a major undertaking. Clinical research requires strategic vision; institutional leadership; a trained, research-ready workforce; financial resources; and specialized infrastructure and processes that may not exist within community hospitals. To foster a thriving clinical research environment, the following questions must be considered:

1. How can community hospitals optimize training and incentives to support and encourage clinical research?
2. How can community hospitals operationalize a clinical research enterprise?
3. How can community hospitals make clinical research impactful?

Below, we share examples of best practices and valuable resources that can help strengthen clinical research within community hospitals. Additional information on the clinical research resources for community hospitals that are mentioned in the text below can be found in Appendix Table A1 (available at: https://www.longwoods.com/content/26277).

How can community hospitals optimize training and incentives to support and encourage clinical research?

Training programs and courses

The emergence of clinical research at community hospitals has exposed a critical need to ensure that individuals are trained to conduct research to the highest ethical and safety standards and in compliance with national/global clinical research and ethics standards, such as the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Good Clinical Practice and the *Personal Health Information Protection Act* (Government of Ontario 2004). Community hospitals can access a number of external resources to build this capability. In partnership with Network of Networks (N2), the Collaborative Institutional Training Initiative (CITI) Program offers a comprehensive suite of courses tailored to meet the educational needs of Canadian researchers. CTO has also created programs to support clinical trials in Ontario, including *Research Ready* – a community-driven initiative to connect research personnel and interested investigators to training and mentorship opportunities and facilitate knowledge sharing among distinct teams. Individual hospitals may also offer small-scale training courses to embed general research knowledge and build core skills among staff. For example, the research office at Niagara Health helps clinicians and research teams navigate the research process – from project initiation to dissemination of results – by providing hands-on guidance and mentorship. Lakeridge Health enables knowledge transfer and capacity building through a monthly educational speaker series on research, innovation and patient care that is open to all staff.

Institutional commitment to clinical research

Initiatives – often led or approved by senior management – that signal a community hospital's commitment to clinical research have also been shown to be highly effective in stimulating activity and instilling a research mindset among clinical staff. This may include making research a key priority in a hospital's strategic plan, increasing investment in research operations and recruiting research support staff. In 2014, William Osler Health System committed to making clinical/applied research a strategic priority and developed a formal research plan. Likewise, Trillium Health Partners (THP) formed the Institute for Better Health in 2014 to provide oversight and help manage clinical research/clinical trials across its three sites. These efforts contributed to a significant jump in the number of clinical trials initiated at both hospitals. In addition to prioritizing applied research, North York General Hospital (NYGH), in partnership with the hospital's foundation and donors, established an exploration fund to provide clinicians with seed funding for research. Through these and other efforts, NYGH has seen an increase in clinical research and industry-sponsored trials in key research areas and has established new research chair positions.

How can community hospitals operationalize a clinical research enterprise?

Managing a clinical research enterprise is a complex undertaking for any organization. Hospitals must identify the unique operating conditions that will optimize their research program and answer critical questions: What is the most appropriate structure to support research operations? What types of research support services should the hospital provide? What systems, policies and processes must be in place to uphold the highest standards of ethical conduct? What financial mechanisms are required to provide adequate oversight and minimize risk? In contemplating these and other questions, hospitals must not only consider what is needed to support existing research activities, but also ensure that the foundation is built to meet the future demands of its clinical research enterprise and environmental trends (e.g., big data, pragmatic trials).

Research operating model

Community hospitals and academic health systems use a variety of models – ranging from highly centralized to highly decentralized – to support clinical research operations. A more centralized operating model is typically reflective of a higher degree of institutional prioritization of clinical research and offers a mechanism through which an institution can influence research activities and foster alignment with corporate priorities. Centralized operating models may also be more common in organizations whose programs span the continuum of clinical research – focusing on population health and/or discovery research in addition to clinical trials (e.g., William Osler, THP, NYGH). A more decentralized or hybrid model is more common in hospitals that focus on clinical trials, which require a different level of investment and may be more program specific. For example, Southlake Regional Health Centre (Southlake) engages primarily in phases 2, 3 and 4 clinical trials and has a greater affinity for program-led clinical trial initiatives (e.g., medical oncology, cardiac) with some centralized support (e.g., research ethics). While every model offers distinct benefits and limitations, an increasingly centralized research operating model can reduce risk, increase efficiency and minimize the administrative burden on researchers (WCG Insights 2019). Recognizing that community hospitals, research programs and operating models are diverse, it is important to consider a wide range of factors, including institutional support, research activity/intensity, staffing and resources, when determining the most appropriate structure for a new or evolving research enterprise.

Research support services

Dedicated research support services (e.g., research management, ethics) are core to most clinical research programs in both community and academic hospital environments. These provide guidance to clinicians on research practices, support day-to-day management of activities (e.g., operations, cost recovery), develop policies and standards to support research/ethics compliance, conduct impact analyses and provide Research Ethics Board (REB) services. Given that research needs and intensity can fluctuate, the right staffing model in a community hospital is often a moving target. Flexible capacity is often achieved by employing staff who can manage several portfolios related to clinical research (e.g., serving as a director of research and a manager of a specific research program) while building capacity incrementally and diversifying responsibilities as clinical research activities mature and grow. Partnership is another option for community hospitals looking to enter the clinical research space. Through its collaboration with Princess Margaret Hospital in 2010 to establish a regional cancer centre to advance world-class care, education and research, Southlake was able to benefit from the expertise of experienced researchers and trialists while learning to independently navigate the complex ethical, regulatory and operational requirements associated with clinical research.

Resources that can help offset the immediate need for a large research team, partnership and/or specific skill sets to support clinical research also exist. For example, the Canadian Clinical Trials Coordinating Centre (CCTCC) provides a standardized framework for model clinical trial agreements (mCTA); although contract/budget negotiations must still take place on a trial-by-trial basis, the mCTA has helped streamline the contracting process and expedite clinical trial start-up times across Canada.

Institutional research policies and standard operating procedures

Hospitals often have a set of core policies and standard operating procedures (SOPs) to guide involvement in clinical research that can be developed de novo or modified using standardized research frameworks. Membership in N2 affords organizations access to national SOPs that can be adopted or tailored to meet the specific needs of each institution's clinical research enterprise. Examples of N2 SOP templates include clinical trial-related SOPs, biorepository SOPs, REB SOPs and other general SOPs.

Research ethics

Most research-intensive hospitals rely on their own internal REBs to review and approve research involving humans. In certain cases, hospitals may leverage external resources to support the REB review process, including leveraging REBs from other hospitals to review proposals (e.g., Southlake provides REB reviews for Mackenzie Health, Stevenson Memorial Hospital and SE Health) or partnering with clinical trial support organizations to participate in streamlined

and integrated ethics review processes (e.g., CTO Stream, a streamlined research ethics review platform). Other national organizations, such as N2 and the Canadian Association of Research Ethics Boards (CAREB-ACCER), work to create, uphold and advocate for national research ethics standards. N2 and CAREB-ACCER have collaborated to develop standardized REB SOPs to guide clinical research activities and ensure compliance with established research ethics standards.

Performance management

Optimizing operations and management of clinical research benefits from accurate tracking of clinical research performance and outcomes. At the research enterprise level, accurate and consistent tracking empowers senior leaders to make evidence-informed decisions on research priorities and operational requirements, as well as identify barriers to research success (e.g., enrolment and patient participation). At the individual trial level, these data can inform the feasibility of a research study, allow investigators to track progress during the course of a study and measure outcomes once a study is complete. Organizations such as CCTCC and the Canadian Cancer Clinical Trials Network have a standard set of operational and quality-focused metrics that can be used by community hospitals to guide their performance management systems.

Financial management

Community hospitals must create tracking tools and cost recovery systems to optimize clinical research. Adapting legacy systems to integrate and streamline clinical and research financial management is one best practice that helps enhance monitoring, transparency and accountability. Many hospitals also embed individuals with specialized research finance expertise to manage the intricacies of clinical research. Through these mechanisms, hospitals are able to optimize tracking and recovery of direct costs associated with shared research resources/services, program-specific operations and other research-related costs. In addition to direct costs, it is important for hospitals to set policies around indirect cost recovery and determine how these are reallocated across the research enterprise. Standards for indirect costs (e.g., facilities, administrative costs) are typically 30%–40% for industry-sponsored trials and lower (and more highly variable) for publicly funded clinical research.

How can community hospitals make clinical research impactful?

Maximizing the impact of clinical research outputs requires approaches that support innovation and rapid dissemination and uptake of research evidence. One common approach involves the creation of innovation hubs that bring together inventors/clinicians, private sector partners and others to advance solutions with the potential to improve healthcare delivery. Southlake established a healthcare-focused innovation centre called CreateIT Now that offers innovators access to community and regional hospitals and the patients, clinicians and researchers who work there; drives partnership between industry and academic institutions; and unlocks hospital resources for clinical research to develop, test and validate new technologies and services. Through this collaborative, interdisciplinary centre, Southlake has helped overcome barriers to clinical research and bring cutting-edge innovations to the clinic (Box 1).

BOX 1.
Success story: piloting an app to support patient care after discharge

Background: Identifying a gap in managing care upon hospital discharge, CoHealth was launched to provide patients with real-time access to tailored treatment plans and general care management resources, as well as a platform to interact with care providers and provide feedback on recovery.
Challenge: With a pilot version of the app in place, CoHealth found it difficult to establish relationships with Canadian hospitals to conduct research in a clinical, real-world setting to test and validate the app.
Approach: Leveraging support from FedDev Ontario, Markham Stouffville Hospital and Southlake offered a clinical research environment to test the app in emergency rooms and cardiac units and hone the process of implementing this solution in a clinical setting. CreateIT Now at Southlake was also instrumental in connecting CoHealth with Medtronic, a global leader in medical technology, services and solutions, which facilitated further research and development into optimizing the app and integrating it with clinical care.
Outcomes and Impact: Pilot testing at Markham Stouffville Hospital and Southlake demonstrated significant reductions in administrative costs and improvements in patient experiences. Through these early adopters, CoHealth has been able to expand clinical testing to 30 health systems across Ontario and British Columbia and has shown a multi-day reduction in length of stay for orthopedic surgery patients. In 2019 alone, 65,000+ patients have used this platform across several different units

Other examples of health innovation networks across Ontario and Canada exist. The Joint Centres for Transformative Healthcare Innovation – a partnership among seven community hospitals, including Southlake and Markham Stouffville Hospital – serves as a "living laboratory" to test, validate and disseminate innovations. Recently, a $20-million federal project was launched in Canada – with preliminary piloting in Ontario and western Canada – to create a CAN Health Network to help promising companies connect with healthcare organizations and early adopters to understand their needs and work collaboratively to research, develop and refine medical technologies (Canadian Healthcare Technology 2019).

Another best practice in knowledge translation involves early integration of patients and communities in research activities – an approach that reflects current knowledge from the

field of implementation science and the principles underpinning leading health research strategies, such as the Canadian Institutes of Health Research's Strategy for Patient-Oriented Research (Canadian Institutes of Health Research 2019). By building relationships with patient partners to help define research questions, shape methodologies, envision solutions and support dissemination, research becomes increasingly relevant to its primary beneficiaries.

There are also examples of community hospitals embedding mechanisms to translate evidence-based practices into patient care more efficiently within their research strategies. For example, Waypoint Centre for Mental Health Care (Waypoint) has taken a holistic approach to managing its research portfolio and prioritizing institutional investment/support into activities with the potential to generate outcomes that reinforce the hospital's strategic and clinical plans. To support these research projects, Waypoint mobilizes specialized teams (including content experts, support staff and clinicians) and provides access to knowledge translation, program evaluation, research and analytics to accelerate and integrate evidence-based practices within routine clinical care.

Conclusions

Community hospitals are uniquely positioned to lead clinical research programs that can better serve the specific health needs of their patient population; fill gaps in clinical research that large academic hospitals cannot address; provide more equitable access to clinical research for under-represented patient groups; and address imperatives central to all hospitals and healthcare systems – improving the quality, cost-effectiveness and clinical outcomes of healthcare. Despite these attractive opportunities, many community hospitals encounter barriers to expanding the hospital mandate to include research, sourcing start-up and operational funds, accessing relevant study populations, equipping physicians with research skills and protecting time for clinical researchers. A wide range of resources and best practices – many of which are described herein – are now available to support hospitals in surmounting many of these barriers and realizing the patient, hospital and health system benefits of participating in clinical research.

As community hospitals establish or strengthen clinical research capabilities, there is a further opportunity to prepare for participation in emerging avenues of health research, such as big data/artificial intelligence, health technology and personalized medicine. Although each research area will have unique requirements to enable contribution, community hospitals may need to consider the development of new policies (e.g., data privacy), processes (e.g., piloting/innovation hubs) and partnerships (e.g., private sector) to be full participants in the future of health research. Ultimately, a clinical research enterprise that both addresses the immediate challenges in healthcare delivery and empowers hospitals to contribute actively to healthcare innovation will be a critical enabler of a nimble, future-proofed community hospital. HQ

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