Adapting the Joint Task Force Core Competency Framework for Clinical Research Professionals: A Canadian Paediatric Research Perspective

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Abstract: *Over the past 20 years, there has been a significant increase in the number and complexity of clinical research studies. As a result, Clinical Research Professionals (CRPs), a workforce critical to the success of clinical research, have seen commensurate increases in workload and responsibilities. Unfortunately, there has not been a parallel increase in the 'professionalization' of CRPs, and the lack of professional recognition and career development opportunities remain primary motivators for voluntary turnover in this workforce. The development of the Joint Task Force (JTF) Core Competency Framework (2014) was a seminal step in addressing these issues and has changed the dialogue within the clinical research enterprise from a focus on regulatory compliance to one of professional competency. Encouraged by peers in academic health science centres in the United States, the Hospital for Sick Children (SickKids) in Toronto, Canada undertook an initiative to adapt the JTF Framework to suit the Canadian context as well as incorporate the unique scientific and ethical considerations pertinent in child health research. The SickKids Clinical Research Competency Framework (SickKids CR-CF) is being used to support the professionalization of the local CRP workforce through 1) a standardized onboarding and orientation program for new hires; 2) creation of a novel, competency-based clinical research curriculum; 3) development of tools and processes to leverage the framework for professional development and career progression; and 4) job roles that are descriptive of the required competencies. The overall aim of such initiatives is to help increase participant safety, research quality and regulatory compliance as well as improve job satisfaction and institutional engagement among our clinical research workforce at SickKids.*

Keywords: *clinical research professionals, Joint Task Force Competency Framework, competence, competency, workforce development, professional development*

Background

The number and complexity of clinical trials has increased dramatically in recent years. From 2010 to 2020, the number of clinical trials registered on clinicaltrials.gov increased by over 300% (National Library of Medicine, 2021). Greater scientific and methodological sophistication coupled with the globalization of research has also significantly expanded the expertise required to manage a clinical trial safely and effectively (Brouwer et al., 2017; Getz et al., 2011; Sonstein & Jones, 2018; Speicher, et al., 2012). The majority of day-to-day activities for clinical trials are conducted by a highly diverse workforce, which may collectively be referred to as Clinical Research Professionals (CRPs). CRPs have a wide variety of job roles and titles, work in settings spanning the academic, industry, public and private sectors, and enter the field with diverse educational and experiential backgrounds (Sonstein & Jones, 2018).

As the number and complexity of trials has increased over time, the responsibilities of CRPs have grown. In today's clinical research environment, CRPs must have technical expertise in scientific communications, finance, ethics, data management, laboratory skills and so forth, but also require considerable strength in 'soft skills' such as problem solving, critical thinking, teamwork, and conflict management (Baer et al., 2011). CRPs working with vulnerable populations, such as children, need additional skills and knowledge to manage their unique complexities, including the maintenance of informed consent and assent across changes in cognitive capacity, or the need to engage with a broader network of family caregivers to ensure successful participant recruitment and retention.

For industry, CRP skills directly impact profitability, and they have been quick to implement formal training and certification requirements, as well as robust onboarding and training programs (Owens Pickle et al., 2017). However, only 40% of research conducted in the United States and Canada is sponsored by industry, despite their large economic footprint (National Library of Medicine, 2021). In contrast, academic researchers, who are heavily reliant on limited public funding, have been less inclined to seek professional qualifications over salary cost savings. In most academic institutions, beyond some form of post-secondary education, there is no required educational background or defined set of competencies to become a CRP and clinical research job descriptions do not necessarily reflect skill, experience or responsibility (Sonstein & Jones, 2018).

In academic settings, most CRPs acquire their skills 'on the job' as they are delegated responsibilities by the Principal Investigator (PI) (Speicher et al., 2012). Often, there are few institutional oversight mechanisms to ensure a new CRP's skills are a match for the demands of the research study onto which they are hired, and training for new CRPs is typically minimal and poorly organized (Owens Pickle et al., 2017; Sonstein & Jones, 2014). In a survey of over 450 CRPs based in academic health centres across North America, Owens Pickle et al. (2017) found that while 75% had baccalaureate or graduate degrees, 67% had no more than three years of clinical research experience when hired; 42% had less than a year. Training programs did not address this gap: 74% received less than two months of training in their new role, or no training at all (Owens Pickle et al., 2017).

Job satisfaction, engagement and retention are most negatively affected by the dissonance between responsibility and compensation (Coomber & Barriball, 2007; Cowin, 2002, as cited in Owens Pickle et al., 2017). CRPs are a critical workforce that has seen workload and responsibilities increase dramatically while salary levels have remained relatively flat historically (Getz et al., 2012). A SoCRA analysis published in 2015 found that, once adjusted for inflation, the median salary for CRPs actually decreased by 3.3% between 2010 and 2015. While salaries have been adjusted in many institutions and networks, low salary levels continue to be reported in others (i.e., the Children's Oncology Group (COG)—the National Cancer Institute's only paediatric clinical trial network) (Getz et al., 2012; Owens Pickle et al., 2017). Opportunities for achievement, stimulation, responsibility and advancement significantly affect an individual's valuation of the position and their engagement in the work (Owens Pickle et al., 2017; Pepe, 2010), whereas lack of role clarity, ambiguity of responsibility and poor recognition of achievement can result in demoralization. Among CRPs in particular, the lack of professional recognition and career development opportunities have been cited as primary motivators for voluntary turnover (Stroo et al., 2020).

Akin to the situation at original hire, some academic health research centres, organizations (i.e., Duke University) and networks (i.e., Oncology Nursing Society, United Kingdom NIHR, Regulatory Affairs Professional Society, and the Global Health Network) have developed a transparent institutional framework for recognizing growth in knowledge, skill and/or experience among CRPs over time (Sonstein & Jones, 2018). Such frameworks and resulting initiatives have been found to have a positive effect, decreasing CRP turnover by up to 30% in some cases (Stroo et al., 2020). However, there are still significant gaps and inconsistencies in the development and employment of such frameworks in academic health settings contributing to low job satisfaction, poor institutional engagement, and high attrition in these settings (Hornung et al., 2018; Sonstein & Jones, 2018). For example, it was reported that CRPs working in academic or private research settings had higher retention (10 times greater odds) in comparison to those employed in hospitals or academic health research centres (Buchanan et al., 2020). Retention of CRPs is critically important for the entire institution from a safety, regulatory and financial perspective. Not only is staff turnover incredibly expensive—estimated by one source to be $25,000 per CRP (Duke University, Stroo et al., 2020)—retention of skilled CRPs is a key factor in improving the overall quality of the research (i.e., participant retention, safety, data integrity and regulatory compliance) (Speicher et al., 2012; Stroo et al., 2020).

A Competency Framework for Clinical Research Professionals

To date, there has been limited 'professionalization' of the CRP role. Professionalization requires a focus on competencies—observable behaviours derived from the combination of an individual's knowledge, training and experience in a particular work process or environment (CIPD, 2021; Bullock & Trombley, 1999). A competency framework is defined as selected competencies and qualifications, knowledge, skills, and attitudes that embody a particular profession (Benayoune, 2017; Calvin-Naylor et al., 2017). Competency frameworks are like a road map to develop, enhance and/or refine an individual's capabilities incrementally, often progressing from

fundamental to advanced. The use of competencies and competency frameworks in performance management and development emerged in the early 1980s (Bolden & Gosling, 2006; Boyatzis, 1982), and the practice has increased over time, particularly in health-related professions (Batt et al., 2019). A framework approach ensures transferability and recognition of skills across jurisdictions, and often specifies maintenance of qualification requirements or pathways for professional advancement. Competency frameworks are now often seen as essential to achieving high institutional performance, and are used to support consistent recruitment practices, fair performance reviews, professional mobility, and the development of education and training initiatives, among other institutional best practices (Benayoune, 2017; CIPD, 2021).

In most other health related professions (i.e., medicine and nursing), entry level professionals are required to have a specific academic degree, often an internship or other hands-on experience, and have passed an examination which is administered under the aegis of a representative professional or licensure organization (Sonstein & Jones, 2018). There is no such structure for CRPs. College-based training programs in clinical research and professional societies granting certification for CRPs (e.g., SoCRA, ACRP) are primarily focused on regulatory requirements and Good Clinical Practice (GCP) rather than observable behavioural competencies.

In 2014, the Joint Task Force for Clinical Trial Competency (JTF) began work to create a universally applicable, globally relevant competency framework for the clinical research enterprise—the Harmonized Core Competency Framework for the Clinical Research Professional (Multi-Regional Clinical Trials, 2020). This work has moved the clinical research enterprise from a focus on regulatory compliance to that of professional competency, based on the belief that the most effective method to ensure quality clinical trial design, conduct and compliance is to ensure that those responsible for the various aspects of a clinical trial are, in fact, competent (Sonstein & Jones, 2018).

The JTF Core Competency Framework provides 47 specific competency statements within eight functional domains that define the attitudes, skills and knowledge required to design and conduct safe, ethical, and high-quality clinical research (Multi-Regional Clinical Trials, 2020). The 47 competency statements are further broken down into three levels—fundamental, skilled, and advanced—to ensure applicability across various roles and levels of experience in the clinical research enterprise (Multi-Regional Clinical Trials, 2020). The JTF Core Competency Framework has been widely utilized as a tool to define performance criteria, standardize job descriptions, and guide the development of education and training-related initiatives (Brouwer et al., 2017; Calvin-Naylor et al., 2017). However, there are several noted limitations: 1) Although ACRP and SoCRA have re-aligned their certification exams to that of the Framework, it has not been transparently incorporated in their offered training nor explicitly championed (Sonstein et al., 2018); 2) Developed with input from international and American stakeholders, there is a lack of applicability to the Canadian regulatory context (i.e., Health Canada) (Multi-Regional Clinical Trials, 2020); 3) The Framework does not include competencies required to work with vulnerable populations such as children; and 4) The Framework does not include competencies required by research designs and methodologies other than clinical trials (i.e., non-interventional, quasi-experimental, mixed methods, and qualitative).

Given the significant influence CRP performance, engagement and retention has on research quality, we adapted the JTF framework to support the professionalization of CRPs at the Hospital for Sick Children in Toronto, Canada. This paper describes the adaptation of the Framework and its use in creating: 1) a standardized onboarding and orientation program for new hires; 2) a novel, competency-based clinical research curriculum; 3) tools and processes to leverage the Framework for professional development and career progression; and 4) job roles that are descriptive of the required competencies.

About the Hospital for Sick Children

Founded in 1964, the Hospital for Sick Children (SickKids) is home to the largest, hospital-based child health research institute in Canada and was recently ranked as the top paediatric health care centre in the world (Newsweek, 2022). In terms of research intensity (research spending per researcher and as a percentage of total hospital spending), SickKids has ranked among the top three research hospitals in Canada for over ten years, consistently topping the list among research hospitals of comparable size (Research Infosource, 2021). The research conducted at SickKids ranges from discovery science to public and population health, and is supported by state-of-the-art facilities, technologies, and expertise (SickKids, 2020). At present, the SickKids Research Ethics Board (REB) oversees over 3000 open research studies involving human participants, their health data and/or biological samples. These studies are supported by over 400 CRPs.

Direct consultations with clinical research staff revealed that many feel available Canadian certifications are only 'good on paper' and do not accurately reflect their technical skills, job responsibilities or career trajectory. In part, this may reflect the lack of specialized paediatric content in adult-focused clinical research training programs. However, respondents suggested it has more to do with the mismatch between a CRP's skills or qualifications and the responsibilities that might be delegated to them by the PI, consistent with the literature cited above.

About the Office of Clinical Research Professionals (OCRP)

The Office of Clinical Research Professionals (OCRP) was established in 2020 as a hub of professional support for all CRPs at SickKids. The OCRP is housed within Clinical Research Services (CRS) and is financially supported by the SickKids Research Institute. The OCRP provides networking, personal and professional growth-related opportunities as well as facilitates access to information about best practices, regulatory changes, and institutional initiatives. As the institutional 'voice' for CRPs, the OCRP drives multiple clinical research communication channels including a monthly newsletter with over 950 subscribers, monthly Open Forum seminars typically attended by over 80 people, a Clinical Research Advisory Committee (CRAiC) composed of 35 CRPs, and it maintains informative intranet and SharePoint sites. Programs and resources leveraging the Framework are offered to the clinical research community through the OCRP to give them brand recognition and a single point of access.

Adapting the JTF Core Competency Framework at SickKids

The JTF intentionally set out to develop a single set of standards that could be adapted locally; users are encouraged to adjust the framework to site-specific practice cultures (Sonstein & Jones, 2018). At SickKids, a systematic and strategic approach was taken to review and adapt the JTF Framework to integrate Canadian research requirements, institution-specific policies and procedures as well as competencies relevant to child health research. The approach included broad and focussed community engagement and consultation, coupled with investment in dedicated educational expertise.

Clinical Research Professional Development Specialists

Key to the success of this initiative was the investment in a Clinical Research Professional Development Specialist (CRPD) role. Roughly equivalent to other educator roles in healthcare (nurse educator, physician educator, etc.), these specialists have expertise in pedagogy, educational theory, adult learning principles, as well as experience in clinical research. The role of the CRPDs is twofold: 1) coordinating and driving the efforts of clinical research stakeholders and subject matter experts (SMEs) in the adaptation process of the JTF Framework by identifying key requirements, developing case studies and activities to guide the review process, and facilitating opportunities for expert review and content validation; and 2) using the revised competency framework to develop a novel, competency-based clinical research professional development program for the CRPs at SickKids.

Training and Education Working Group (Working Group)

The Training and Education Working Group was formed to assist in the review and adaptation of the JTF Framework. The Working Group convened bimonthly or monthly over a period of nine months and included clinician and senior scientists, staff physicians, research ethics and quality assurance staff, project managers and coordinators as well as research trainees. The members systematically reviewed the domains, competency statements, and learning objectives of the JTF Framework. This resulted in revisions to, or development of, competency statements. The Working Group proceeded to review the revised and new competency statements using Bloom's Taxonomy to ensure they were levelled appropriately—fundamental, skilled, and advanced (in keeping with the JTF Framework) (Bloom et al., 1956). The Working Group continues to meet regularly and now works to inform the overall education program for CRPs at SickKids.

Stakeholder Engagement

The detailed analysis performed by the Working Group was validated, refined, and socialized with a larger group of CRP stakeholders. The CRP stakeholders included clinical research administrators, clinical research coordinators, clinical research nurses, clinical research managers, statisticians, research ethics coordinators, and senior leadership for clinical research at SickKids. Several strategies were employed to attain feedback from the stakeholders, including surveys, feedback forms, focus groups, and one-on-one interviews. Engaging and collaborating with a wide variety of stakeholders was an essential step to ensure the competencies were applicable to all CRP roles and study designs as well as to validate the newly added content. The feedback

attained from the stakeholders was shared with the Working Group and integrated accordingly in the adaptation of the JTF Framework.

Key Adaptions to the JTF Core Competency Framework

The SickKids Clinical Research Competency Framework (SickKids CR-CF) is comprised of eight Domains with a total of 43 Competencies expressed in three levels of expertise: fundamental, skilled, and advanced (Figure 1).

Figure 1.

The adaptations integrated Canadian provincial and national research-related regulations, institutional policies and procedures, a broader range of research study types and designs, as well as paediatric-specific scientific and ethical considerations (Table 1). To ensure that the SickKids CR-CF continues to remain relevant and up to date with the ever-changing child health research landscape, the competencies are reviewed on an annual basis.

Table 1. Adaptations to the JTF Core Competency Framework

1.	**Domain 2: Ethical and Participant Safety Considerations**
	a. Addition of 'standard of care': Due to a lack of pharmaceutical research in children, most standard paediatric treatment plans involve the use of medications 'off label'. However, the use of a drug 'off label' may also be part of a research protocol. CRPs in child health research require expertise in differentiating between the two and understanding how data acquisition, regulatory documentation and medical oversight might differ as a result.
	b. Inclusion of key research-related ethical processes in the child health research setting: assent, dissent, and capacity to consent.
	c. Integration of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS-2), the joint policy of Canada's three federal research agencies – the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC). As a condition of funding, the Agencies require that researchers and their institutions apply the ethical principles and the articles of this Policy.
2.	**Domain 3: Medical Product Development and Regulation of Research Studies using Medical Products**
	a. Included a wider range of products (drugs, devices, natural health, etc.) and to address the common practice of using marketed products in a new indication in the paediatric population.
	b. Added requirements for Canadian regulatory and oversight bodies, such as the institutional Research Ethics Board (REB), the Federal Health Canada Directorates, and their relevant application processes. United States-based references to IRBs and the FDA were retained as international multi-centre trials are common at SickKids.
3.	**Domain 4: Clinical Study Operations (GCP)**
	a. Included competencies related to handling biospecimens for clinical research
4.	**All Domains:**
	a. Inclusion of SickKids specific policies and procedures.
	b. Inclusion of Canadian Federal and Provincial privacy laws.
	c. Addition of patient and family/caregiver considerations
	d. Addition of a broader range of study types and designs beyond clinical trials (i.e., interventional, and non-interventional, mixed methods, and qualitative)

Implementation of the SickKids CR-CF

The application of the SickKids CR-CF to the clinical research enterprise has four lines of development to support the professionalization of the SickKids CRP workforce:

1. A standardized onboarding and training program for all new hires
2. A novel, competency-based clinical research curriculum
3. Tools and processes to leverage the framework for professional development and career progression
4. Job roles that are descriptive of the required competencies.

Standardized Orientation and Onboarding Program

The OCRP also tracks and manages the mandatory training for all new hires and applies a standardized orientation and onboarding program that introduces the competency framework as well as SickKids-specific processes and resources. More specifically, the onboarding program consists of the following key processes: 1) a one-on-one meeting with the OCRP Program Coordinator where the new CRP is welcomed to SickKids and is oriented to the nature and location of resources to support their work and role; 2) a comprehensive onboarding manual that includes information and resources about the SickKids CR-CF and its application(s) at SickKids; 3) automatic enrollment into an introductory course, "Getting Started with Clinical Research at SickKids," that addresses the foundational core competencies and highlights SickKids' clinical research processes, services and supports; and 4) subscription to the Clinical Research Newsletter and the OCRP mailing list. To date, 270 CRPs have had one-on-one onboarding meetings and 243 have attended Getting Started since its launch in 2020.

A Competency-Based Clinical Research Curriculum

The SickKids CR-CF was used to direct the development of a novel, competency-based clinical research curriculum for CRPs at SickKids. To our knowledge, this program is the first of its kind in Canada and in the paediatric context. The CRPDs, in collaboration with the Education and Training Working Group, SickKids stakeholders and SMEs developed and mapped out courses, workshops, tools, and resources to the respective Domain and level of expertise (i.e., fundamental, skilled or advanced) (Figure 2).

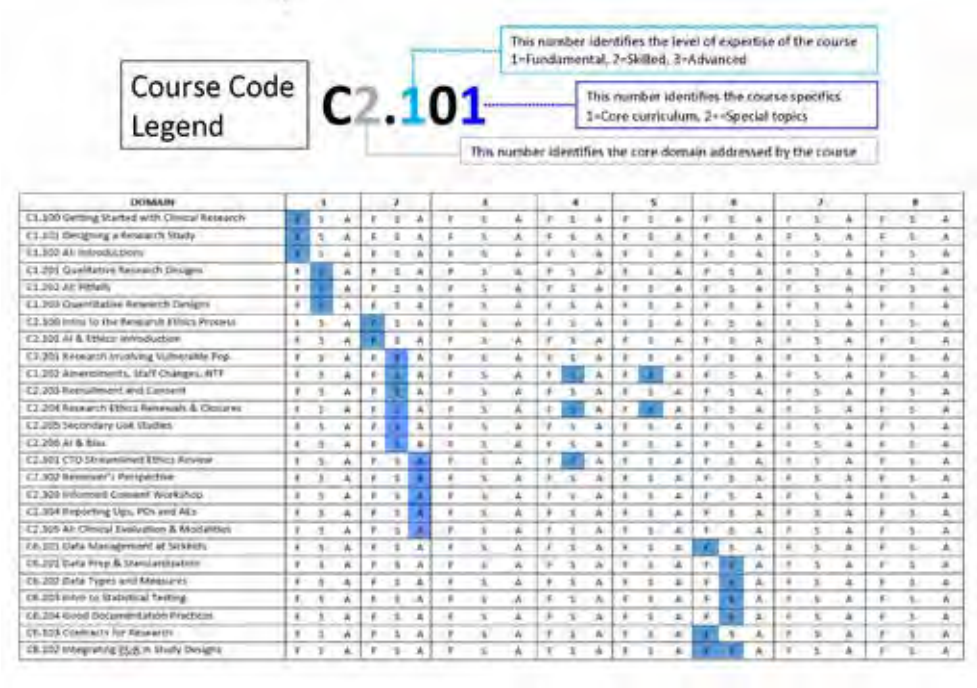

Figure 1. Education and training course domain and level matrix.

Click here for larger image

For example, for Domain 1: Scientific Concepts and Research Design, courses were developed pertaining to designing a research study, quantitative and qualitative research methodology as well as artificial intelligence and data science methodology. The courses were developed in-house and complimented by external courses purchased from the Collaborative Institutional Training Initiative (CITI) Program. A sample of the courses, course description, learning objectives and level of expertise are presented in Table 2.

Table 2. Sample of Courses for Domain 1

Course Title	Level of Expertise	Course Description	Learning Objectives
Designing a Research Study	Fundamental	A research design is the "blueprint" of a study as it provides the structure, framework, and systematic planning for the entire research process. The purpose of this module is twofold. First, the module will provide an overview of best practices for developing a research question and defining outcomes of interest; describe various clinical research designs; and approaches to assess the feasibility of the proposed research study. Second, the module will describe the key elements to be included in a research study proposal. Using case scenarios and interactive activities, learners will attain an understanding of the research design process and how to apply it in their own respective research studies.	1. To identify best practices for developing a research question, defining outcomes of interest & assessing feasibility. 2. To describe the key elements in a research study protocol. 3. To describe the importance of patient & family engagement in designing a study. 4. To differentiate between quality improvement projects & research projects.
Artificial Intelligence (AI): Introductions	Fundamental	The course provides learners with an introduction to Artificial Intelligence (AI), Machine Learning, Deep Learning, and Algorithms. Using different examples and case scenarios, learners will broaden their understanding of these topics in the context of health care and research.	1. To differentiate between Artificial Intelligence, Machine Learning, and Deep Learning. 2. To understand what is meant by an "algorithm". 3. To describe a machine learning "pipeline". 4. To gain insight into AI projects at the hospital.
Qualitative Research Design	Skilled	The course provides learners with an introduction to qualitative research, qualitative research designs and the respective strengths and weaknesses.	1. To describe what is qualitative research. 2. To describe the various qualitative research designs/approaches. 3. To understand the strengths and weaknesses of the various qualitative research designs/ approaches.
Artificial Intelligence: Pitfalls	Skilled	The course provides learners with an overview of Artificial Intelligence (AI)-related pitfalls. Using different examples and case scenarios, learners will broaden their understanding of these topics in the context of health care and research.	1. To be able to describe examples of AI pitfalls. 2. To understand what are confounders in AI. 3. To understand why some algorithms fail to "generalize".

Courses are delivered both synchronously (either in person or virtually) by various SMEs (i.e., Machine Learning Specialists, Research Ethics Analysts, and Research Educators) and asynchronously in self-paced modules either on CITI or the SickKids' learning management system (SABA iLEARN). Synchronous courses are regularly offered to CRPs following an academic calendar year and asynchronous learning is available on demand. Our ultimate goal is to offer a full curriculum mapped across all domains and levels to enable CRPs to plan their own professional development progression through the curriculum.

From April 2020 to March 2021, approximately 373 CRPs completed asynchronous courses and approximately 970 CRPs attended synchronous education sessions. Of the 970 CRPs, 690 were clinical research coordinators, 228 were clinical trainees (i.e., residents and clinical fellows) and 52 were research administrative staff. The value of combined pedagogical and clinical research expertise is reflected in participants' feedback:

> *"Presenter's knowledge about the topic was excellent, and material was presented in a manner that was easy to understand even by non-experts."*

> *"I liked that the presentation slides were detailed and easy to follow. The flow of the presentation was also very easy to understand and made this intimidating process feel a lot simpler."*

Our approach to curriculum development and delivery within the program is flexible and can be tailored to meet the unique needs, interests and responsibilities of the various CRP roles in the clinical research enterprise (i.e., clinical research coordinators, residents, fellows, junior clinician-scientists, research nurses, data management staff, administrators and so forth). Each role can be uniquely described by adjusting the relative weight of each competency domain, and then a leveled curriculum that is tailored to progression in that role can be created. For example, the Education and Training Working Group and CRAiC determined that the responsibilities of Clinical Research Coordinators, the largest group of CRPs at SickKids, are primarily focussed on Domains 2, 4, 6 and 8 of the SickKids CR-CF. Based on this feedback, content specifically targeting these domains was developed, with courses offered in all levels (fundamental, skilled, and advanced). Similarly, with guidance from scientists, medical faculty, and recent paediatric residents, the CRPDs developed a three-year, competency-based clinical research education program for paediatric residents. Domains 1, 2, 6, 7 and 8 from the SickKids CR-CF and the CanMED Physician Competency Framework were used to identify the competencies and create a leveled curriculum residents complete as they progress through their training and scholarly projects. This relatively inexperienced and time-strapped group appreciated this tailored approach:

> *"I thought that from the perspective of a trainee with minimal research experience, these sessions were quite comprehensive and thoughtful."*

> *"The program gives a nice and insightful summary of the research processes and protocols plus supportive entities that work in favor of research at SickKids. Also, I believe that all the provided tools, links and contacts are quite valuable for new researchers and residents."*

Competency-Based Professional Development Tools

Several tools and processes were developed to leverage the Framework for professional development and career progression, and transparently recognize the skills of this important workforce. This aspect of the project is particularly important because poor recognition of achievement is one element found to contribute to employee demoralization and disengagement (Hornung et al., 2018; Sonstein & Jones, 2018; Stroo et al., 2020). Our goals for this endeavour were: 1) raise the visibility and focus on competencies among CRPs; 2) increase and focus performance management activities among CRPs and their managers; and 3) heighten institutional recognition of achievement.

The first step was a Competency Tracking Tool. This tool enables CRPs to assess their own competency and plot an intentional course of professional development through the clinical research core curriculum. Constellations of achievement for CRPs across fundamental, skilled and advanced levels are recognized with an institutional Certificate of Achievement. To promote broader application of clinical research core competencies, the OCRP also provides templates and guidance for competency-based conversations and goal setting during performance assessments between CRPs and their respective manager/supervisor.

Finally, a micro-credentialing program is being developed. The program is in its infancy but will provide recognition of specialized skill development among CRPs. Micro-credentials recognize, by way of a digital seal or badge, skills and accomplishments that are not normally captured in resumes or academic transcripts. They are recognized outside of the conferring institution and can be publicly showcased in digital portfolios or social media feeds (eCampus Ontario, 2019). In our application, micro-credentials acknowledge the consistent application of time and effort across multiple clinical research core competencies to develop expertise in a particular skilled practice. Multiphase learning pathways including content education, practical/experiential training as well as formative and summative assessment are being developed for an internal pilot program focussed on the areas of teaching/training and clinical trial monitoring. Upon completion of the pilot phase of this program, SickKids will work with local institutions (i.e., colleges that provide clinical research diploma programs) to expand the internal micro-credentialling program to one that is industry-recognized and shareable/accepted with other employers or education institutions.

Refinement of the CRP Job Descriptions/Roles

As in most academic institutions, PIs function within SickKids as individual business units, so there is no institutional line-of-sight to the full complement of CRPs, their characteristics, qualifications, or activities. Further, there is no mechanism to ensure that new hires have the skills to manage the research activities assigned to them by their PI. Job descriptions provided by human resources are not based on clinical research competencies and span multiple pay categories. Without dedicated clinical research expertise within HR, or a technological force-function (such as that employed at Duke University; see Brouwer et al., 2017), investigators are free to choose whatever job role they wish within the 'research support' category. The outcome of such an arrangement is predictable: In 2018, we identified more than 80 job titles in use across the

organization describing a range of clinical research positions (i.e., administrators, coordinators, managers, and associates) carrying out a wide variety of research-related functions. To address these issues, CRS and SickKids' Human Resources (HR) are using the SickKids CR-CF to create competency-based job descriptions and the institutional processes necessary to best fit new hires to the skills actually required by the PI, similar to the seminal work described by Brouwer et al. (2017) at Duke University School of Medicine.

Lessons Learned

There have been several lessons learned in the process of adapting the JTF Core Competency Framework and applying it to the development of internal processes to support clinical research professionals. None of this work would have been possible without the deep, consistent and long-term engagement of a range of stakeholders. Frontline staff and PI researchers understand best what the needs, interests and capacity are for potential end users and supervisors. However, investment in dedicated pedagogical expertise was also critical: The CRPD specialists merged this input with the Framework to create a comprehensive yet flexible curriculum that is in keeping with the principles of adult education and sensitive to the challenges of busy healthcare professionals.

The independence and autonomy of PIs in most academic health science centres makes institutional initiatives of this nature uniquely challenging. Executive endorsement from multiple portfolios (Research, HR, Learning Institute in our case) is necessary, but that endorsement is not sufficient for successful implementation. While PIs may readily support objective competencies and continuing education (especially when it is offered on site and free), where application of the Framework impacts research funding, as it does with the job roles initiative, a great deal of communication and an extended timeline is needed to enable integration with the cadence of funding cycles. Institutional support and resources are critical over this period.

Constant evaluation and communication are integral to ensuring the clinical research community informs and adopts the program as it is developed, recognizing it as an iterative process that will continue to evolve as additional data and resources become available. Demonstrating return on investment for initiatives such as this can be difficult, especially in early days. Careful consideration of the data valued by various stakeholders at the outset is time well spent.

Conclusion

CRPs are a critical workforce within the clinical research enterprise. Over the years, CRPs have seen a significant increase in their workload and responsibilities without concomitant increases in average salaries. Coupled with limited professional recognition and career development opportunities, this environment has led to high levels of job dissatisfaction and turnover in this workforce, particularly in academic health care settings. Shifting the culture of the CRP workforce is imperative as it has implications on the quality, rigour, safety, and ethical conduct of clinical and translational research, which in turn, impacts patient care, treatment, and outcomes. The JTF Framework was developed to align the CRP workforce around a single and comprehensive

set of competencies, skills, and attitudes for conducting safe, ethical, and high-quality clinical research. The JTF Framework has been a seminal step in addressing the challenges encountered in this workforce and professionalizing CRPs by shifting the focus from regulatory compliance to professional competency. By engaging multiple stakeholders and expertise in adult education, SickKids adapted the JTF Framework to the Canadian context and the unique considerations presented by child health research. The SickKids CR-CF is being used to professionalize the local CRP workforce through several initiatives: 1) a formalized and standardized onboarding and training program for all new hires; 2) a novel, competency-based clinical research curriculum; 3) tools and processes to leverage the framework for professional recognition and career progression; and 4) competency-based job descriptions to match competency to responsibilities. The collective goal of these initiatives is to provide a professional environment that recognizes the unique skills of CRPs and encourages ongoing professional development. This in turn, will improve patient care, treatment and outcomes and support the SickKids mission of 'Healthier Children; A Better World' through high-quality innovation, research and discovery.

Authors' Note

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