

**MICYRN Research Coordinator Environmental Scan
2009**

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This report is based on qualitative telephone interviews conducted in late 2008 and early 2009. The purpose of this environmental scan was to understand the roles of research coordinators currently involved in child health research in Canada, as well as to understand the learning needs of this diverse group of research support staff.

Environmental Scan Participants

Seven individuals who worked in a supervisory capacity with Clinical Research Coordinators (CRCs) involved in Canadian child health research were interviewed. These individuals were from the following organizations:

1. CanChild Centre for Childhood Disability, McMaster University, Hamilton, ON
2. Izaak Walton Killam (IWK) Health Centre, Halifax, NS
3. Child Health Research Office (University of Calgary and Alberta Health Services-Calgary Zone), Calgary AB
4. BC Children's Hospital, Vancouver BC
5. Women and Children's Health Research Institute (WCHRI), Edmonton, AB
6. Children's Hospital of Eastern Ontario (CHEO) Ottawa, ON
7. Manitoba Institute of Child Health (MICH), Winnipeg, MB

All of the individuals interviewed directly supervised a number of CRCs and many also served as a mentor or resource for other CRCs not directly under their supervision. All had

considerable experience in either conducting or coordinating research studies, and served as the point of first contact for investigators within their organization. Most were responsible for assigning CRCs to various research projects (i.e. matching the skill level/experience of the CRC to the requirements of the investigator), providing orientation and continuing education for CRCs, and assisting investigators and CRCs in navigating the research process. Interviewees based their answers on their own experiences, however, one managed to conduct an informal survey of the CRCs under her supervision and those responses are also included in this report.

Definition of the Clinical Research Coordinator (CRC) role:

For the purposes of this environmental scan, CRCs were defined as individuals who, under the immediate direction of the principal investigator, oversee and monitor the conduct of clinical research. Depending on the size and scope of the study, the CRC may have research nurses that they in turn supervise. In general, CRCs may be responsible for some or all of the following tasks¹:

- data collection (may include specific clinical skills e.g. venipuncture)
- analysis, or monitoring
- case management of protocol participants
- development and submission of IRB applications
- recruitment and enrollment of human subjects
- protection of subjects and subjects' rights through IRB relations
- development of informed consents
- preparation of adverse event experience reports
- construction or monitoring of case report forms

- maintenance of drug accountability records
- grant and budget development
- report preparation
- education of other health-care professionals, patients or families regarding clinical trials, protocol development, program administration
- research program audit
- development and writing of Standard Operating Procedures (SOPs)

Nature of the CRC position:

The number of CRCs at each site varied from 8 to more than 20, with the average being about 13. Most CRCs were nurses, and many had worked as research nurses prior to becoming research coordinators. Research coordinators were almost exclusively trust funded, meaning that their salary was tied to the funds that were provided by the study sponsor to conduct a specific research study. When the study concluded, so did the CRC position on that study. Many CRCs worked on multiple studies (e.g. smaller studies may only require a 0.2 FTE). The tenuous nature of the CRC position sometime made it difficult to recruit qualified individuals. At most sites, at least some of the CRCs were employed full time, with the remainder working either part time or on a casual basis. At one site, CRCs were hired to work part-time only. This meant that some CRCs were not qualified to receive benefits. One of the interviewees observed that the nurses who gravitated towards research positions were those who were 'sick and tired' of hospital nursing (due to issues such as mandated overtime, rising patient acuity, lack of appreciation, high stress levels on the job, etc.) and enjoyed the more flexible and relaxed

atmosphere that the CRC position provided—this despite the fact that the CRC position often meant lower wages and less permanence.

Organization:

The interviewees acknowledged that many CRCs worked independently with investigators (i.e. not part of a research group or organization) on specific studies. While these CRCs did not have formal access to the resources offered by the research groups, they sometimes ‘informally’ sought out help with when issues arose. All of the organizations represented in this report had some sort of infrastructure developed to provide assistance to CRCs and investigators (e.g. help with ethics applications, health economists, statisticians, etc.). Within the larger, hospital-wide research organizations, CRCs were usually arranged by clinical group (i.e. oncology, rheumatology, infection/immunity, endocrine, etc.). In smaller organizations, they were arranged by the research ‘themes’ that were associated with the major research studies within the organization.

Communication:

Irrespective of how the CRCs were organized, formal communication networks between the CRCs had not been established in the majority of sites, although informal communication occurred frequently (e-mails, phone calls, ‘water cooler’ conversations, etc.). Communication usually centered around problem-solving, with the more senior CRCs providing mentorship to the more junior in the group. The general lack of written or electronic resources available along with the unique nature of the information required contributed to this pattern of communication. Interviewees acknowledged that while the principles of the research process

were consistent across sites, how these principles were applied varied from site to site. Most of these differences were administrative in nature.

The majority of interviewees admitted that they had limited knowledge of what other research groups outside of their own organization were doing, both in terms of research content and process. One individual said that in her experience, most people tend to work in 'silos' and that most people operate with the 'head down, get your work done' attitude, and that they only seek out others when they have issues to deal with. No one knew of any formal network of CRCs that existed within Canada. The exception would be those CRCs associated with national research groups such as PERC (Pediatric Emergency Research Canada) or those involved in large multi-site studies. These relationships are usually with CRCs within the same clinical area (critical care, oncology etc.) or are disease-specific (e.g. diabetes, asthma, etc.).

Requirements for the position of CRC:

There are no established standard requirements for the position of CRC. Interviewees stated that the minimum educational requirement is generally a Bachelor's degree in a healthcare discipline (almost always nursing). Several individuals mentioned that they had CRCs with Master's degrees and at least one site had a CRC with a Doctoral degree. While the preference was for an individual with research experience (e.g. a research nurse), most interviewees said that if they had to choose between clinical experience and research experience, having experience in the clinical area associated with the study was more important. Most said that research skills could be taught as needed. Only one site gave preference to research skills over clinical skills. For the most part, the skills required by the CRCs

tended to be project driven, with the PI contributing significantly to the hiring process in many cases. Specific skills mentioned by the interviewees included:

- leadership/management skills
- organizational skills
- ability to prioritize
- problem solving
- ability to balance competing demands
- ability to work with others collaboratively
- project management skills

Most of those interviewed admitted that there is only a small pool of individuals who have the skills or the experience that is required, so most new hires will require some type of training and/or mentoring by senior staff.

Training currently provided at the 7 sites :

All of the sites said that they provided some in-house training to the new CRCs lasting anywhere from a half day to a three day course. Topics of study mentioned by the interviewees included:

- Research ethics
- Good Clinical Practice (GCP) Guidelines
- Development of Standard Operating Procedures (SOPs)
- Tri-Council Policy Statement (TCPS)
- Budget development and administration
- Documentation
- Basic statistics
- Research design
- Safety courses (e.g. handling of infectious substances)

- Topics specific to the research process at the site

Additionally, some sites also recommended certain web-based resources for their staff

including:

- Health Canada's TCPS (Tri-Council Policy Statement) Tutorial found at: <http://www.pre.ethics.gc.ca/english/tutorial/welcome.cfm>
- NIH (National Institute of Health) Tutorials found at: <http://bioethics.od.nih.gov/casestudies.html#research>
- NACTRC (Northern Alberta Clinical Trials and Research Centre) –Resources and Tools page found at: http://www.clinicaltrials.ualberta.ca/resources_tools.php

Some of the sites also took advantage of industry-run courses, specifically those conducted by pharmaceutical companies (e.g. Pfizer). These training courses were study specific, and were provided by the sponsoring company. While the previously listed training courses/resources were considered important to the development of the knowledge base of the CRC, it was stressed that much of the expertise in research coordination occurred 'on the job', which highlighted the need for on-going mentoring and informational support for CRCs.

Accreditation:

Two organizations were mentioned as accrediting agencies for CRCs: SOCRA (Society of Clinical Research Associates) and ACRP (Association of Clinical Research Professionals). While the organizations are US-based, they both offer workshops and provide opportunities to write the accreditation exams several times a year at locations within Canada. There are no accrediting agencies that are strictly Canadian, and this was one of the criticisms that emerged from the interviews concerning the imposing of an accreditation requirement to the position of CRC. The content of the courses were thought to be based on American research regulations

and policies, with the addition of specific content for Canadian research professionals when offered in Canada. Undoubtedly the biggest barrier to adopting accreditation as a requirement is the cost involved. It costs approximately \$600 to become certified (includes association membership, exam fee and certification). All of those interviewed said that the cost of certification would have to be borne by the individual, and since certification was not a job requirement, very few CRCs had pursued this credential.

Learning opportunity wish list for CRCs:

The question asked that generated the greatest amount of discussion, was the one related to the learning needs of the CRCs. I asked each interviewee to produce a 'wish list' of educational topics that they (or their CRCs) would like to see offered, and in what format (e.g. workshop, web-based, written materials etc.). As was mentioned earlier, one interviewee informally surveyed the CRCs under her supervision and their responses are included in the list:

- Research ethics (including recruitment, confidentiality, rights of participants etc.)
- Developing and submitting an ethics application
- Health information and privacy issues (including interpretation of new legislation)
- Good clinical practice (GCP) guidelines
- Tri-council policy statement (and revisions) (TCPS)
- How to write Standard Operating Procedures (SOPs)
- Going through a mock audit
- Contract and sub-contract basics (as it applies to research study administration)
- Statistics
- Basic bookkeeping
- Program/project management
- SPSS data analysis
- Leadership skills
- Qualitative research skills (NVivo)
- Software skills and training
- Strategies for filing and storing data
- People management (human resource issues)
- Grant preparation and writing skills
- Issues related to knowledge translation, dissemination plans for research results to various stakeholders

- Writing in plain language
- Incorporating KT into grant proposals

While some of these topics are already covered to some extent in each of the sites, many more are not due to time and financial constraints. Many of those interviewed stated that developing training material for new staff was both expensive and time-consuming. The majority said that they would welcome any assistance that could be provided in this area. Web-based learning (in module form) was the most popular choice in terms of learning formats, because of its convenience and portability. Another advantage would be that learning would become more standardized. A few mentioned that a central repository for resources ('one stop shopping') would be convenient. There was also an expressed need for networking opportunities for CRCs. Because their role is often performed in isolation (i.e. few or no colleagues to confer with), having a venue to discuss challenges unique to the role of the CRC was seen as being very beneficial.

Another issue that was seen as problematic for CRCs was the lack of harmonization between different institutions and different jurisdictions in terms of the research process, more specifically, the procedures involved in obtaining ethics approval.

References :

1. Society of Clinical Research Associates [SOCRA]. Accessed November 10, 2009 from :

<http://www.socra.org/html/certific.htm#StandardsOfPractice>