

Executive Summary

Maternal, Infant, Child and Youth Research Network (MICYRN)

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Our Vision

Healthy children and youth through high quality collaborative clinical research

Many problems that face our children and youth require solutions and knowledge that can only be gained through large, multi-centre studies performed in a trans-disciplinary context. Our objective is to create a national research network to facilitate high-quality clinical research.

Background and Rationale

Child health care decisions must be based on robust evidence to enhance the health of the nation's children. An evidence-based approach is developed through rigorous, randomized, controlled, multi-centre trials and well-designed observational studies. The best example of the impact of this collaborative research approach is in the field of childhood oncology, where the cure rate associated with acute lymphoblastic leukemia has been transformed from less than 1% to a greater than 80% in just one generation. Advances in the management of numerous other conditions including chronic diseases such as diabetes, asthma, and cystic fibrosis, as well as acute events such as accident prevention, meningitis, and childhood stroke have also benefited from large-scale multi-disciplinary research studies. When such large-scale, multi-centre research is not conducted, or when data from adult trials are extrapolated to clinical practice in children, significant safety issues may later emerge - as was seen in the use of anti-depressant medications (SSRIs) in adolescents and children. Furthermore, as understanding of molecular basis of disease increases, and as new interventions are developed, the need and opportunities to do innovative and rigorous clinical studies only increases.

Over the last 7 years, there has been unprecedented growth in collaboration in child health at the national level. The National Child and Youth Health Coalition, formed in 2004, is a coalition of five organizations who work collaboratively to advance the health and healthcare of children and youth across Canada. This coalition includes the Canadian Association of Paediatric Health Centres, Canadian Child Health Clinician Scientist Program, Council of Canadian Child Health Research, Paediatric Chairs of Canada, and the Paediatric Surgical Chiefs of Canada. While each organization holds distinct mandates, the Coalition shares many common goals and objectives. In addition, in the last 10 to 15 years many successful research networks focused on specific diseases or populations have emerged in Canada. The challenges to fully realize the benefits of these networks have been lack of durable funding and effective mechanisms to develop efficient network infrastructures. Without a formal unifying structure, there is limited opportunity to increase efficiency and build expertise through sharing of knowledge and resources. Additionally, the opportunities to be gained through cross fertilization of networks and research groups have been limited. Internationally, a number of national research networks have been recently launched in the US, Netherlands, United Kingdom, France and Germany. Part of the impetus for the creation of these networks has been legislation which has encouraged new agents to be tested in children in order to gain regulatory approval for use in adults.

The best way to ensure that children will receive high-quality care is to develop a national clinical research network which will provide infrastructure, create linkages, and leverage existing investment – including groups and centres of all sizes - to increase capacity so that Canada will play a leading role in improving global child and youth health.

Leadership

The principles, goals and priorities of the MICYRN have been guided by participants at two national "Build the Network" workshops held in 2006. An interim steering committee led by Dr. Terry Klassen and composed of representatives from across the country and from critical areas of expertise, has been formed to develop the network governance and operations model and to determine immediate priorities. The interim steering committee has identified eight areas of importance – including Data Management, BioBanking, Funding/Partnerships, Research Ethics/Regulatory Affairs, Statistics and Methodologies, Network Groups,

Knowledge Translation, and Training - and appointed Chairs to lead these working groups in helping to achieve the networks goals.

Goals

The MICYRN interim steering committee has established the following goals for the new national research network:

- To support high-quality, multi-centre, trans-disciplinary projects in clinical research
- To enable new Canadian research capacity through linkages of existing infrastructure and expertise and minimization of resource duplication
- To identify and remove or reduce barriers to clinical research
- To identify gaps and needs in existing infrastructure and expertise and develop innovative approaches to filling these gaps
- To build trust among diverse national stakeholders by encouraging contributions by all clinical researchers and research centres, regardless of size, and representing a broad array of research specializations (including perinatal research)
- To determine the optimal training pathways needed to enable clinician investigators to translate biological discoveries into innovative diagnostic and therapeutic strategies
- To have a significant impact on researcher career development through active and on-going mentorship, training, education, and knowledge transfer
- To include groups and initiatives from across the continuum of care, in both hospital-based and community settings
- To promote development and application of indicators of child and youth health and health care in high-priority areas, including chronic disease, disabilities, injury, mental health, patient safety, and primary care
- To facilitate regular and accessible communication of Canadian research successes, capacities, opportunities, and expertise
- To work towards a sustainable funding base for the network, with an early emphasis on leveraging existing funding by seeking matching funds from local, provincial, regional, and national partners

Short-to-Medium Term Deliverables

Over the next several months, the leadership of MICYRN will work to establish a national coordinating centre that will serve as the administrative core of the network, facilitate development of a communication strategy and governance model, and coordinate the activities of the interim steering committee and network development working groups. Our goal for the next year is to develop a functional network structure to link research sites, existing groups and networks, and interested researchers, while incorporating existing expertise, facilities, and resources.

An immediate priority of the coordinating centre will be to build an interactive and educational website that will serve as a portal for information regarding MICYRN goals and activities, partners, funding opportunities, and educational resources. In addition, the MICYRN leadership will conduct a needs assessment and inventory of existing resources supporting clinical research in Canada. We plan to investigate creation of core facilities with specialized expertise through partnerships with existing groups, as well as network-supported centralized services to fill critical needs.

MICYRN working groups will focus on the following goals and deliverables over the next 6 – 12 months:

Funding/Partnerships: Seek matching funds from local, provincial, regional, and national partners. Consult with potential partners and collaborators - including universities, hospitals, institutes, foundations, government agencies, regulators, charitable organizations, industry and patient associations, and all interested parties – regarding opportunities to share resources and leverage funding. Promote success in multi-centre research by providing network resources and support to projects that address major child health issues (e.g. injury, mental health, obesity).

Networks and Groups: Conduct an environmental scan to determine what pediatric and perinatal networks exist in Canada and learn of their structure and function. Approach representatives from existing and emerging networks to participate in MICYRN working groups and initiatives. Conduct a qualitative study to uncover and document the determinants of a successful and sustainable clinical research network. Hold a national meeting of research networks and team grants in child health to establish a framework to encourage sharing of infrastructure and experience. Make recommendations to the MICYRN steering committee regarding a model for how existing and emerging networks will interact with and contribute to MICYRN. Hold a competition to provide seed funding for emerging networks representing areas of significant disease burden to organize grant planning and network development meetings.

Data Management: Develop a framework and strategy for data management for the clinical research network. Work with the MICYRN coordinating centre to develop website, and establish mechanisms for gathering input regarding clinical data management platforms from stakeholders. Evaluate existing platforms and identify desired additional functions or linkages.

BioBanking: Conduct an inventory of existing institutional and national tissue (and derivative sample) repositories and determine the various mechanisms and ethical/legal ramifications of tissue retrieval and distribution among different networks and institutions. Develop strategies to harmonize tissue retrieval and distribution and explore opportunities for centralized versus decentralized BioBanks.

Training: Gather expert advice regarding optimal training pathways for clinician investigators and develop recommendations regarding these pathways and implementation of training programs. Develop mid-career training recommendations for clinicians to develop the skills necessary to perform excellent clinical research. Investigate pathways for research assistant and study coordinator training. Build curriculum – using on-line tools and workshops – to support recommended training programs. Collaborate with CCHCSP and other partners to harness existing training resources and collaborate in new training initiatives. Evaluate the need for support for new investigators to promote involvement in high-quality, multi-disciplinary research.

Research Ethics and Regulatory Affairs: Establish a national office to collect and prepare review articles and policy documents, develop FAQs regarding ethical, legal and scientific aspects of pediatric research, and contribute informational and guidance documents to the MICYRN website. Develop strategies to harmonize and streamline research ethics and regulatory processes nationally. Host a workshop to assess emerging ethical issues.

Statistics and Methodologies: Identify a team of methodological experts (statisticians, methodologists and health economists) who will provide expertise in supporting national, collaborative clinical research efforts. Host a workshop regarding current methodologies.

Knowledge Translation: Develop a research communication strategy for promoting knowledge translation of existing and newly generated research results. Identify barriers to knowledge translation in community and hospital-based settings.

Summary

The degree of cooperation and collegiality that currently exists in the community of Canadian pediatric clinical care and research groups makes this the perfect time to launch MICYRN. Development of a productive and effective network will require the active participation of many stakeholders - including individual researchers, partner groups and networks, institutions and foundations - as well as strong leadership from a group of committed individuals with diverse expertise and a shared vision. We will build upon our existing strengths and successes to create a national network to facilitate the highest quality clinical research which will result in improved care for children and youth.