

maternal infant
child & youth
research network



réseau de recherche
en santé des
enfants et des mères

Annual Report



12

*Connecting minds,
transforming outcomes*

VISION

Formal collaborative networks of investigators and integrated infrastructure spur tremendous advances in research that are unattainable by individual groups working in isolation.

MISSION

To foster and enhance national and international collaborations by removing barriers and building capacity for the conduct of high quality health research.

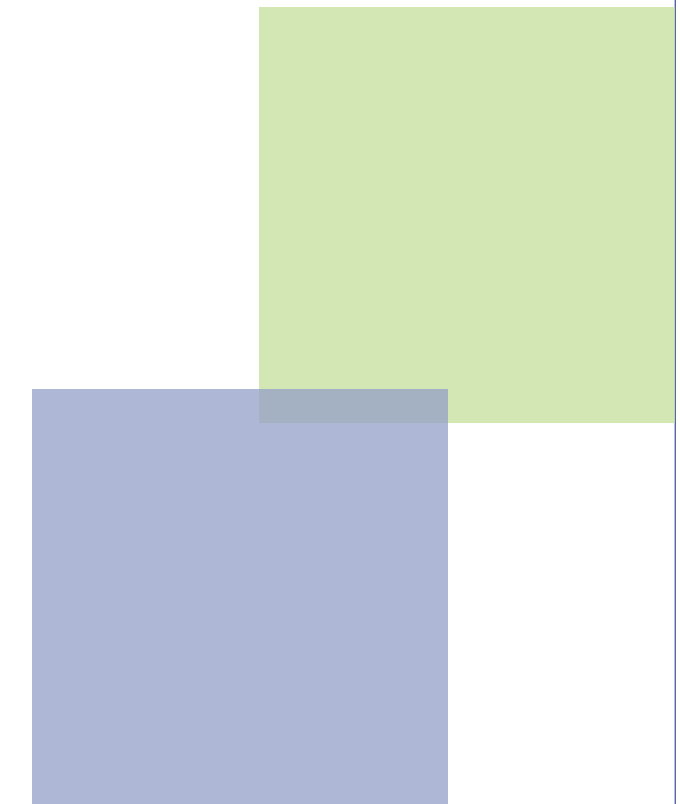
MICYRN was founded in 2006 to benefit maternal and child health and well-being by building capacity for applied health research and advancing knowledge through collaborative research. It is federally incorporated as a non-profit society, and joins together the 19 child/child-maternal research organizations in Canada. The MICYRN member organizations are committed to harmonizing research processes, implementing best practices, and supporting collaborations both nationally and beyond, in order to improve the quality, effectiveness, and uptake of research.



2012 annual report

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Message from the Director and Chair

Research on many child health conditions and pregnancy complications cannot be tackled in the absence of a national network, as no center or region in Canada has a critical mass of patients or expertise to conduct statistically meaningful studies in a timely fashion. Moreover, every year, new discoveries made in maternal, infant, child and youth health care have the potential to improve or even save lives. However, realizing this potential is dependent on our ability to translate knowledge into practice on a scale that benefits all Canadians.

MICYRN is committed to streamlining and improving processes across Canada, fostering collaboration, and developing national standards in ethics, data sharing, and quality systems to ensure we are able to dramatically accelerate the path to better maternal and child health and health care. By working together we will effect the greatest change.

We are pleased to report back to you on the achievements made in these areas for 2012. It was a pivotal year with the addition of key staff members, a growing network, and collaboration between our committed members that ensured the advancement of a number of strategies.

We would like to take this opportunity to thank our members and partners for their contributions, and our volunteers who have generously contributed their time and energy.

Sincerely,



Anne Junker, MD
Scientific Director



Aubrey Tingle, MD, PhD
Chairman of the Board



2012 Highlights

MICYRN benefits from an extremely engaged and effective Board of Directors. The Board had a very active year with a number of key accomplishments; chief among these include the establishment of regular board processes, formalization of key initiatives, fiscal oversight including supporting an application of MICYRN to Canada Revenue Agency for charitable status, and expansion of MICYRN membership.

MICYRN welcomed the two largest maternal health research organizations in Canada as new members — Sunnybrook Health Sciences Centre and the Lunenfeld-Tanenbaum Research Institute of Mount Sinai Hospital, represented by Dr. Elizabeth Asztalos and Dr. Stephen Lye, respectively.

Dr. Guy Rouleau (CHU Ste Justine) announced his exciting move to head the Montreal Neurological Institute and Hospital, and thus resigned from the MICYRN Board of Directors (BOD). With Drs. Terry Klassen (Manitoba Institute for Child Health) and Roger Chafe (Janeway, Newfoundland) completing their terms, the MICYRN BOD developed a slate of new nominees for presentation at the MICYRN annual general meeting (June 2013).

MICYRN welcomed three new staff members in 2012. Stephen Barbazuk joined as Executive Director in January, bringing extensive experience in project management and development of strategic initiatives. Leah Harrison joined in October as the lead of the Young Person's Research Advisory Program, and in November, Erika Goldt was appointed Research Director in a Children with Intestinal and Liver Disorders (CH.I.L.D) Foundation-funded role, providing research analytical capacity and evaluation leadership to support strategic planning and performance measurement for networks.

A process for initiating and managing MICYRN's strategic initiatives was also developed when the BOD held their first strategic priority-setting retreat in February. Each strategic initiative involves the development of a project charter, which lays out the purpose and objectives of the strategy, scope of the project, performance metrics, key milestones, and timelines. The Board then names an executive sponsor and identifies a project lead and subject matter working group comprised of representatives across the Network. Status reports highlighting achievements and any issues are presented at quarterly board meetings and are then shared with the MICYRN network members. All MICYRN activities and related budgets are approved by the Board. In 2012, the three existing strategic initiatives—Ethics, Clinical Research Informatics, and Quality—were confirmed, and a new initiative to build the Coalition of Networks, was launched through the same process.

Knowledge Translation

Fostering knowledge translation is an objective of all MICYRN initiatives. Through the development of systems that improve the generation, exchange, and mobilization of maternal-child research, better trials and therapeutics are becoming available. All of our work supports awareness of and collaboration on these research activities being carried out across Canada, spurring advances that would be unobtainable by individual groups working in isolation. Through meetings and workshops, investigators and other stakeholders have the opportunity to meet and share resources and best practices. Opportunities to further collaborate are also created by implementing new data management and sharing systems.

A number of the documents and meeting reports referenced in the initiatives below are available online at micyrn.ca.

CURRENT INITIATIVES

Ethics

Sponsor/Lead: Anne Junker (MICYRN) with Denise Avard & Bartha Knoppers (CGP, McGill)

MICYRN is working to enhance the ethics context for reproductive and child health research by improving ethics guidance and facilitating the development of streamlined review processes. The MICYRN ethics core is based in the Centre of Genomics and Policy (CGP), Faculty of Medicine, Department of Human Genetics, at McGill University, and is led by Drs. Bartha Knoppers (MD, LL.B) and Denise Avard (PhD). The first component of the Ethics strategy is to provide guidance on best practices, and began in 2008, with a "Best Practices" project orchestrated through the National Council for Ethics in Human Research (NCEHR) Emerging Issues Analysis Committee, and performed in collaboration with the Canadian Institutes of Health Research Institute of Human Development, Child and Youth Health (CIHR-IHDCYH), the CIHR Ethics Office, Health Canada, and other key organizations. MICYRN was represented on the "Best Practices" Steering Committee and subsequently supported consultation and dissemination of recommendations.

The second component is to improve the consistency of ethics review across



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Multijurisdictional research is common in the Canadian reproductive and child health research community – network and research team studies often involve 17-22 sites across the country.

However, the ethics approval process for a multi-site study is inefficient: with the amount of paperwork and deliberation involved, it can take upwards of two years for a study to be approved at all sites.

jurisdictions. The working group was established in February 2011, and is comprised of chairs from six self-standing reproductive and child health research ethics boards in Canada, as well as other experts in ethics and law. A first workshop was supported through a meeting grant from CIHR, and regular meetings continue to be held. The working group is developing and evaluating new approaches to ethics review and providing input into new recommendations on emerging ethics issues. The following are some of the year's key achievements.

1. Completion of broad consultation and revisions to the "Best Practices for Health Research Involving Children and Adolescents" document with the intent to launch in early 2013.
2. Analysis of "Practices in Consent of Children and Adolescents" (Lead, Denise Avard) provided valuable insight and evidence into how consent forms address current ethical issues, and informed the development of recommendations on consent, in order to reduce gaps and facilitate harmonized, yet contextualized, approaches to pediatric health research.
3. Review of "Best Practices: Return of Results" (Lead, Bartha Knoppers) to inform the development of a universal approach for practices related to findings in genetic studies and recommended consent clauses.
4. Presentation of progress and engagement of stakeholders outside of child and maternal organizations at the annual Canadian Association of Research Ethics Boards meeting (April).
5. Establishment of a Pediatric Rare Diseases P3G (Public Population Project in Genomics) online platform hosted by P3G, that provides research tool for researchers and REBs concerned with pediatric biobanking. Using model documents in informed consent, data sharing, and biobank governance, the platform facilitates harmonization, provides practical value for researchers, works to improve ELSI management in pediatric biobanking, and facilitates REB review.

Clinical Research Informatics

Sponsor: Terry Klassen (MICH); Lead: Lawrence Richer (WCHRI)

MICYRN is building a national clinical research informatics platform with a suite of options to meet diverse research study needs. The MICYRN Clinical Research Informatics core is based in Edmonton at the Women and Children's Health Research Institute (WCHRI), and is led by Dr. Lawrence Richer, Director for Clinical Research. The Working Group consists of data managers and related professional staff from a majority of MICYRN sites. The following are some of the year's achievements.

1. Established regular meetings of the MICYRN Informatics core including a very successful first face-to-face meeting (June) in Calgary to prioritize opportunities to further develop the platform.
2. Broadened implementation of REDCap™ (a secure web application for building and managing online surveys and databases) (<http://project-redcap.org>) from two to 11 of the 19 MICYRN sites, resulting in over 1,000 studies using it, and provision of consults and regular webinars to assist new sites in its use.
3. Installed a MICYRN-licensed super-stable version of REDCap™ that is validated to meet regulatory requirements for investigator-initiated clinical trials.
4. Held a plenary session on data management at the Canadian Child Health



Effective data management is integral to every research study, but support tools, processes, and personnel often pose a high cost. In addition, security and standards consensus is paramount as data becomes increasingly electronic and the need to integrate information from routine clinical care grows.

Clinician Scientist training program's annual meeting in June, which included hands-on experience with REDCap™.

5. Responded to needs of a research team by leading an in-house development of E-PRO (Electronic Patient Reported Outcomes)—an electronic web-based system that manages sequential questionnaires for birth cohort follow-up studies, relieving mothers of the need to complete multiple paper questionnaires.
6. Developed draft consensus on clinical research information system infrastructure standards, for presentation to the MICYRN BOD in early 2013, with the intent to set best practices across the member organizations.

Quality

Sponsor: Brent Scott (ACHRI); Lead: Benoit Masse (Ste Justine)

MICYRN's Quality strategy was initiated to provide a framework that would enable its organizations to meet ISO 9001 certification. Three phases include: institutional assessment; provision of templates with accompanying standard operating procedures, forms, and basic quality management system training modules; and collaboration on a quality system development plan. Canada has attracted industry-sponsored clinical trials through its reputation for quality; however, pressure is increasing to provide evidence for meeting benchmark quality standards, with competition from Europe and developing countries. Quality management systems provide the infrastructure base needed to implement, carry out, and monitor quality programs. The following are some of the year's key accomplishments.

1. Developed a framework for institutional self-assessment of quality systems
2. Developed a Quality Systems Tool Box for members, which includes a manual to set organizational governance of quality, and eight quality management system modules associated with training material

Coalition of Networks

Sponsors: Alan Bocking (Mt Sinai), Stephanie Atkinson (McMaster); Lead: Stephen Barbazuk and Erika Goldt (MICYRN)

By establishing a Coalition of Networks, MICYRN is increasing attention to maternal and child health issues, leveraging opportunities, and addressing key issues affecting the conduct of maternal, infant, child, and youth health research across Canada and beyond.

Most practice-based networks of clinician investigators are self-described as "coalitions of the willing" because there is very limited support for networks in Canada, and thus clinicians participating in networks do so on the basis of collective need. In 2012, affiliation agreements were developed to create a more formal relationship between MICYRN and existing networks. Networks affiliated with MICYRN participate in workshops, teleconferences on specific topics, surveys, and projects that improve patient and family engagement in research studies. The following are some of the year's achievements.

1. Hosted first national meeting of acute and critical care networks (July)
2. Identified an initial 16 research networks which were invited for formal affiliation with MICYRN
3. Sponsored a *Sustaining Networks* meeting in October, with 13 networks represented and excellent engagement—outputs of the meeting have helped shape opportunities to respond to the needs of research networks

Most child health conditions and pregnancy complications are rare and each center has too few children with any given condition to conduct adequate clinical studies. Networks make substantive impacts on health care but are impeded by limited funding, system inefficiencies, and lack of infrastructure.

A 'network of networks' provides a multi-pronged approach for greater impact, bringing economies of scale, accelerated exchange of knowledge between individual networks, and reduces risk of investment in a single team.

4. Provided infrastructure and administrative support to the Canadian Association of Pediatric Rheumatology Investigators (CAPRI), for which \$30,000 was provided by the Canadian Arthritis Society.
5. Provided logistical support to the Canadian Neonatal Follow-up Network (CNFUN) for a CIHR-sponsored Planning meeting (Spring, 2012).

IN DEVELOPMENT

Birth Cohort Collaborative

Sponsors: Alan Bocking (Mt Sinai) and Stephanie Atkinson (McMaster)

In 2009, a partnership between MICYRN, the CIHR-IHDCYH, and the Strategic Knowledge Cluster on Early Childhood Development was formulated to further develop an inventory of the then 17 identified pregnancy and birth cohort studies. This inventory was subsequently updated to identify 46 Canadian studies and include a searchable web-accessible database hosted by MICYRN (www.micyrn.ca/BirthCohorts.asp) in order to facilitate sharing of research design and measurement tools, as well as develop opportunities for research collaboration in maternal and child health research. The work on this inventory culminated in a publication that has raised awareness internationally of Canada's contribution to this field. [Marie-Pier Joly, Michel Boivin, Anne Junker, Alan Bocking, Michael S Kramer, Stephanie A Atkinson. An Inventory of Canadian Pregnancy and Birth Cohort Studies: Research in Progress. *BMC Pregnancy and Childbirth* 2012;117:1-8]. The opportunity to develop linkages between the Canadian cohort studies is being explored.

Engaging Young Persons as Advisors for Research

Sponsors: Peter Wall Solutions Initiative and BC Michael Smith Health Research Foundation; Lead: Leah Harrison

Modeled after a program of the same name and developed by the UK-Medicines for Children Research Network, young people—aged 10-20—volunteer to learn about research processes and then serve to provide advice to research teams and administrators. In 2012, MICYRN began the groundwork for a *Young Persons as Research*



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Advisors group (KidsCan), which will oversee the youth-inspired development of a mobile 'healthy-living' game (MobileKids), followed by youth recruiting and testing the product. Funding (PI Dumont) was secured because of the innovative nature of this proposal, as well as the potential of MICYRN to disseminate the program nationally across its member organizations. The process of engaging volunteer high school students who will be involved in bi-monthly meetings to develop the program curriculum, communication systems, and advisory processes began in late 2012.

Clinical Trials Platform

Sponsor/Lead: Anne Junker (MICYRN) with Stuart MacLeod (UBC)

Canada is second only to the United States in the number of pediatric and maternal clinical trials being conducted, and third after the Netherlands and Australia for the number of trials per million children (pediatric trials) or births (maternal trials). There is unanimous commitment of the MICYRN membership to develop an integrated, national trials platform. Towards this effort, the following is a list of linkages made in 2012.

- GRIP (Global Research in Paediatrics), an EU-funded project of the Seventh Framework Programme that aims to facilitate the development and safe use of pediatric medicines
- StaR Child Health (Standards for Research in Children), an international initiative to improve the quality of design, conduct, and reporting of pediatric clinical research
- the Canadian Pharmacogenomics Network for Drug Safety (CPNDS), a nation-wide research program that aims to identify genetic markers predictive of severe adverse drug reactions
- the Council of Canadian Academies expert panel

With the majority of medicines used in infants and children not tested for safety or efficacy in these populations, there is a growing need for clinical trials to ensure optimal treatment. New forms of trials are also needed to study orphan therapies, which have extremely high costs but cannot be studied by traditional methods.

Developmental disorders, mental health and obesity also require new forms of trials such as behavioural interventions or community clusters.

Consultation

In 2012, MICYRN continued to gain prominence as a national voice for maternal and child health research. We responded to a number of invitations and contributed to national and international discussions on key issues shaping research strategies, commitment of resources, and changing policy. MICYRN presented at the following events:

1. CAREB National Conference. (April 26-28, Toronto)
2. Society for Pediatric Research Special Interest Group meeting – *Pediatric Clinical Research Networks*. (April 30, Boston)
3. StaR (Standards for Research in) Child Health 3rd International Summit. (May 7-8, Winnipeg)
4. American Academy of Pediatrics workshop *Pediatric Networks: Optimizing Effectiveness through Collaboration* (November 8-9, Washington, DC)

MICYRN was also invited to participate in the following workshops and represent maternal-child health research.

1. European Network for Pediatric Research of the European Medicines Agency (Enpr-EMA) Meeting/Launch: *Developing Collaborations between Inter/National Pediatric Research Networks*. (March 21-22, London UK) Enpr-EMA was developed in response to European legislation (2007) that mandated conduct of clinical trials in children. This meeting was the second annual meeting of Enpr-EMA with stakeholders, including families, industry, and the Coordinating Group, of which MICYRN is a member.
2. Canadian Institutes for Health Research (CIHR) – Institute for Human Development Child & Youth Health (IHDCYH) strategic planning (September 21).

Connections

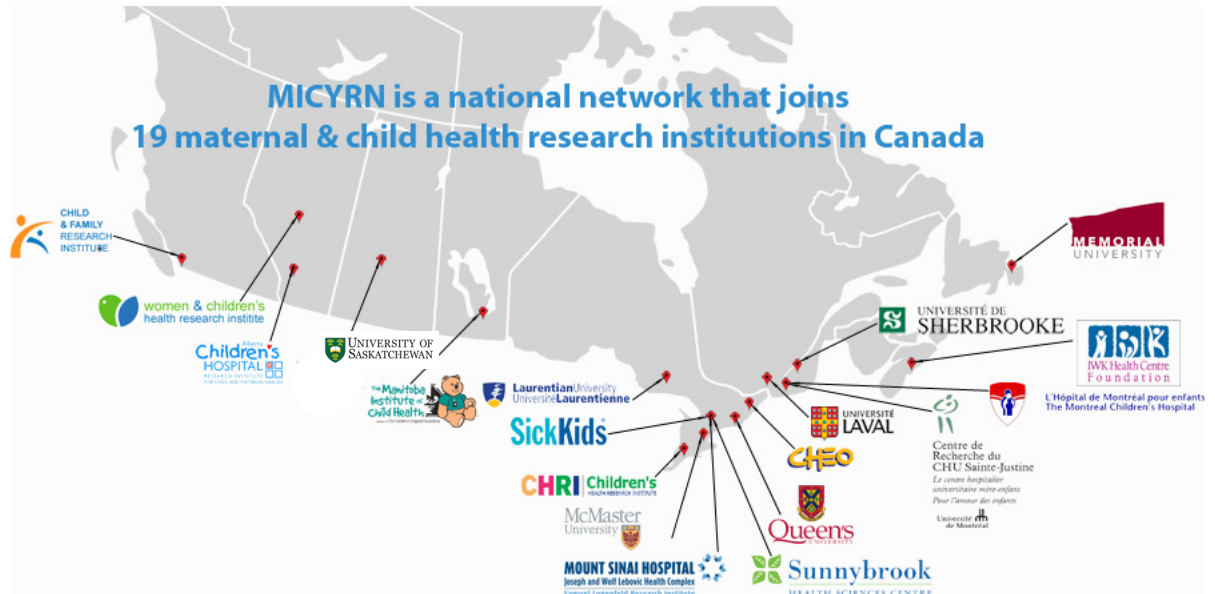
Health Canada: With the strong support and encouragement of Dr. Stuart MacLeod, one of the founding institute directors of MICYRN, and through the support of Health Canada's Pediatric Expert Advisory Committee of the Office of the Pediatric Initiative, several meetings were held during the year with Health Canada officials to raise awareness about MICYRN and its activities, and discuss opportunities for improving the infrastructure support of clinical trials.

Rx&D: Communication was established and meetings were held in September with executive representatives from Rx&D, the Canadian association of research-based pharmaceutical companies, to raise awareness about MICYRN and share information about Canadian pediatric and maternal clinical trials experience.

Canadian Association of Research Ethics Boards (CAREB): MICYRN joined CAREB as a member. At the annual CAREB meeting in April, several posters highlighted MICYRN's work to improve ethics guidance, and Dr. Junker was asked to present on the MICYRN model for federated ethics review of multi-jurisdictional research.



MICYRN Members



MICYRN 2012 Board of Directors

Aubrey Tingle (<i>chair</i>)	MICYRN
Stephanie Atkinson (<i>vice-chair</i>)	McMaster University, Ontario
Alan Bocking	Lunenfeld-Tanenbaum Research Institute, Mt.Sinai, Ontario
Roger Chafe	Memorial University, Newfoundland
Victor Han	Children's Health Research Institute, Ontario
Terry Klassen	Manitoba Institute of Child Health
Guy Rouleau	Centre de Recherche CHU, Ste-Justine, Quebec
Brent Scott	Alberta Children's Hospital Research Institute

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