

HEALTHCARE

POLICY

Politiques de Santé

*Health Services, Management and Policy Research
Services de santé, gestion et recherche de politique*

Volume 13 + Number 3

**Research on Human Embryos and Reproductive Materials: Revisiting
Canadian Law and Policy**

UBAKA OGBOGU ET AL.

**Medicine, Body Fluid and Food: The Regulation of Human Donor
Milk in Canada**

MARTHA J. PAYNTER AND KATHRYN HAYWARD

**Medicare Cost Drivers during the 2004–2014 Health Accord Period
in Canada: What Is the Evidence?**

RUOLZ ARISTE

The Medical Devices Special Access Program in Canada: A Scoping Study

ROLAND K. MAIER ET AL.

Data Matters + Discussion and Debate + Research Papers

HEALTHCARE QUARTERLY: Best practices, policy and innovations in the administration of healthcare. For administrators, academics, insurers, suppliers and policy leaders. *Edited by* Dr. G. Ross Baker, University of Toronto, Toronto + **CANADIAN JOURNAL OF NURSING LEADERSHIP:** Covering politics, policy, theory and innovations that contribute to leadership in nursing administration, practice, teaching and research. Peer reviewed. *Edited by* Dr. Lynn Nagle, University of Toronto, Toronto. + **HEALTHCARE PAPERS:** Review of new models in healthcare. Bridging the gap between the world of academia and the world of healthcare management and policy. Authors explore the potential of new ideas. *Edited by* Prof. Adalsteinn Brown, University of Toronto, Toronto. + **HEALTHCARE POLICY:** Healthcare policy research and translation. Peer reviewed. For health system managers, practitioners, politicians and their administrators, and educators and academics. Authors come from a broad range of disciplines including social sciences, humanities, ethics, law, management sciences and knowledge translation. *Edited by* Dr. Jennifer Zelmer, Adjunct Faculty, University of Victoria, Victoria. + **WORLD HEALTH & POPULATION:** Best practices, policy and innovations in the administration of healthcare in developing communities and countries. For administrators, academics, researchers and policy leaders. Includes peer reviewed research papers. *Edited by* Dr. Judith Shamian, President Emeritus, International Council of Nurses, Geneva, CH + **ELECTRONIC HEALTHCARE:** Best practices, policy and innovations exploring e-models, e-practices and e-products for e-health. For administrators, academics, insurers, suppliers and policy pundits. + **LAW & GOVERNANCE:** Within the framework of the law and the role of governance providing policies, programs, practices and opinions for the providers, administrators and insurers of healthcare services. *Editorial Chair,* Dr. Kevin Smith, McMaster University, Hamilton. + **HRRESOURCES:** Cases, commentary and policy reviews for healthcare clinicians, human resources managers and the policy leaders, insurers, academics, administrators, boards and advisors of all healthcare organizations. + **LONGWOODS.COM:** Enabling excellence in healthcare. Providing electronic access to news, information, career opportunities, conference schedules, research, case studies, policy reviews and commentary that cover politics, policy, theory, best practices and innovations in healthcare.

POLICY

Politiques de Santé

Health Services, Management and Policy Research
Services de santé, gestion et recherche de politique

VOLUME 13 NUMBER 3 • FEBRUARY 2018

Healthcare Policy/Politiques de Santé seeks to bridge the worlds of research and decision-making by presenting research, analysis and information that speak to both audiences. Accordingly, our manuscript review and editorial processes include researchers and decision-makers.

We publish original scholarly and research papers that support health policy development and decision-making in spheres ranging from governance, organization and service delivery to financing, funding and resource allocation. The journal welcomes submissions from researchers across a broad spectrum of disciplines in health sciences, social sciences, management and the humanities and from interdisciplinary research teams. We encourage submissions from decision-makers or researcher–decision-maker collaborations that address knowledge application and exchange.

While *Healthcare Policy/Politiques de Santé* encourages submissions that are theoretically grounded and methodologically innovative, we emphasize applied research rather than theoretical work and methods development. The journal maintains a distinctly Canadian flavour by focusing on Canadian health services and policy issues. We also publish research and analysis involving international comparisons or set in other jurisdictions that are relevant to the Canadian context.

Politiques de Santé/Healthcare Policy cherche à rapprocher le monde de la recherche et celui des décideurs en présentant des travaux de recherche, des analyses et des renseignements qui s'adressent aux deux auditoires. Ainsi donc, nos processus rédactionnel et d'examen des manuscrits font intervenir à la fois des chercheurs et des décideurs.

Nous publions des articles savants et des rapports de recherche qui appuient l'élaboration de politiques et le processus décisionnel dans le domaine de la santé et qui abordent des aspects aussi variés que la gouvernance, l'organisation et la prestation des services, le financement et la répartition des ressources. La revue accueille favorablement les articles rédigés par des chercheurs provenant d'un large éventail de disciplines dans les sciences de la santé, les sciences sociales et la gestion, et par des équipes de recherche interdisciplinaires. Nous invitons également les décideurs ou les membres d'équipes formées de chercheurs et de décideurs à nous envoyer des articles qui traitent de l'échange et de l'application des connaissances.

Bien que *Politiques de Santé/Healthcare Policy* encourage l'envoi d'articles ayant un solide fondement théorique et innovateurs sur le plan méthodologique, nous privilégions la recherche appliquée plutôt que les travaux théoriques et l'élaboration de méthodes. La revue veut maintenir une saveur distinctement canadienne en mettant l'accent sur les questions liées aux services et aux politiques de santé au Canada. Nous publions aussi des travaux de recherche et des analyses présentant des comparaisons internationales qui sont pertinentes pour le contexte canadien.

FROM THE EDITOR-IN-CHIEF

- 6 Curious Silences in Healthcare Policy and Research
JENNIFER ZELMER

DISCUSSION AND DEBATE

- 10  Research on Human Embryos and Reproductive Materials: Revisiting Canadian Law and Policy
UBAKA OGBOGU, AMY ZARZECZNY, JAY BALTZ, PATRICK BEDFORD, JENNY DU, INSOO HYUN, YASMEEN JAAFAR, ANDREA JURISICOVA, ERIKA KLEIDERMAN, YONIDA KOUKIO, BARTHA MARIA KNOPPERS, ARTHUR LEADER, ZUBIN MASTER, MINH THU NGUYEN, FOROUGH NOOHI, VARDIT RAVITSKY AND MAEGHAN TOEWS
- 20  Medicine, Body Fluid and Food: The Regulation of Human Donor Milk in Canada
MARTHA J. PAYNTER AND KATHRYN HAYWARD

RESEARCH PAPERS

- 27  Medicare Cost Drivers during the 2004–2014 Health Accord Period in Canada: What Is the Evidence?
RUOLZ ARISTE
- 40  The Medical Devices Special Access Program in Canada: A Scoping Study
ROLAND K. MAIER, DEVIDAS MENON AND TANIA STAFINSKI
- 59  Understanding Patient Referral Wait Times for Specialty Care in Ontario: A Retrospective Chart Audit
CLARE LIDDY, NIKHAT NAWAR, ISABELLA MOROZ, SHELAGH MCRAE, CHRISTOPHER RUSSELL, ARIANA MIHAN, FANNY MCKELLIPS, DEREK MCLELLAN, LOIS CROWE, AMIR AFKHAM AND ERIN KEELY

 Peer Reviewed

DE LA RÉDACTRICE EN CHEF

- 8 De curieux silences dans la recherche et les politiques de santé
JENNIFER ZELMER

DISCUSSION ET DÉBAT

- 10  Recherche sur l'embryon et le matériel reproductif humains : examen des lois et politiques canadiennes
UBAKA OGBOGU, AMY ZARZECZNY, JAY BALTZ, PATRICK BEDFORD, JENNY DU, INSOO HYUN, YASMEEN JAAFAR, ANDREA JURISICOVA, ERIKA KLEIDERMAN, YONIDA KOUKIO, BARTHA MARIA KNOPPERS, ARTHUR LEADER, ZUBIN MASTER, MINH THU NGUYEN, FOROUGH NOOHI, VARDIT RAVITSKY ET MAEGHAN TOEWS
- 20  Médicaments, liquides organiques et alimentation : réglementation du don de lait maternel au Canada
MARTHA J. PAYNTER ET KATHRYN HAYWARD

RAPPORTS DE RECHERCHE

- 27  Inducteurs de coûts pour l'assurance maladie pour la période 2004–2014 de l'Accord sur la santé au Canada : quels sont les faits?
RUOLZ ARISTE
- 40  Programme canadien d'accès spécial aux instruments médicaux : étude de l'étendue
ROLAND K. MAIER, DEVIDAS MENON ET TANIA STAFINSKI
- 59  Comprendre le temps d'attente pour les patients recommandés auprès des soins spécialisés en Ontario : audit rétrospectif des dossiers
CLARE LIDDY, NIKHAT NAWAR, ISABELLA MOROZ, SHELAGH MCRAE, CHRISTOPHER RUSSELL, ARIANA MIHAN, FANNY MCKELLIPS, DEREK MCLELLAN, LOIS CROWE, AMIR AFKHAM ET ERIN KEELY



Examen par les pairs

POLICY

Politiques de Santé

EDITOR-IN-CHIEF

JENNIFER ZELMER, BSC, MA, PHD
Adjunct Faculty, University of Victoria, Victoria, BC

SENIOR EDITOR

FRANÇOIS BÉLAND, PHD
Professor, Department of Health Administration, Faculté de médecine, Université de Montréal, Member, Groupe de recherche interdisciplinaire en santé (GRIS), Co-Director, Groupe de recherche Université de Montréal–Université McGill sur les personnes âgées, Montréal, QC

EDITORS

ROGER CHAFE, PHD
Director of Pediatric Research and Assistant Professor, Faculty of Medicine, Memorial University of Newfoundland, St. John's, NL

RAISA B. DEBER, PHD
Professor, Institute of Health Policy, Management & Evaluation, University of Toronto, Toronto, ON

MARK DOBROW, PHD
Director, Analysis and Reporting, Health Council of Canada
Associate Professor, Institute of Health Policy, Management & Evaluation, University of Toronto, Toronto, ON

ERIC LATIMER, PHD
Researcher, Douglas Institute
Associate Professor, Department of Psychiatry, McGill University
Associate Member, Department of Epidemiology, Biostatistics, and Occupational Health, McGill University
Montréal, QC

JOEL LEXCHIN, MSc, MD
Professor and Associate Chair, School of Health Policy and Management, Faculty of Health, York University, Emergency Department, University Health Network, Toronto, ON

CLAUDE SICOTTE, PHD
Professor, Department of Health Administration, Faculty of medicine, Université de Montréal
Researcher, Groupe de recherche interdisciplinaire en santé (GRIS), Montréal, QC

CONTRIBUTING EDITOR

STEVEN LEWIS
President, Access Consulting Ltd., Saskatoon, SK
Adjunct Professor of Health Policy, University of Calgary & Simon Fraser University

EDITORIAL DIRECTOR

DIANNE FOSTER-KENT
dkent@longwoods.com

MANAGING EDITOR

ANIA BOGACKA
abogacka@longwoods.com

COPY EDITING

CENVEO PUBLISHING SERVICES

TRANSLATOR

ÉRIC BERGERON

PROOFREADER

NATHALIE LEGROS

EDITORIAL ADVISORY BOARD

TONI ASHTON
Associate Professor Health Economics, School of Population Health, The University of Auckland, Auckland, NZ

LUC BOILEAU, MD, MSc, FRCPC
President and Chief Executive Officer, Agence de la santé et des services sociaux de la Montérégie, Montréal, QC

PHILIP DAVIES
Government Social Research Unit, London, UK

MICHAEL DECTER
Founding and Former Chair, Health Council of Canada, Toronto, ON

ROBERT G. EVANS
Professor, Department of Economics, University of British Columbia, Member, Centre for Health Services and Policy Research, University of British Columbia, Vancouver, BC

KENNETH FYKE
Victoria, BC

STEFAN GREß
Department of Health Sciences, University of Applied Sciences Fulda, Germany

CHRIS HAM
Professor of Health Policy and Management, Health Services Management Centre, The University of Birmingham, Birmingham, UK

PAUL LAMARCHE
Professor, Departments of Health Administration & Social and Preventive Medicine, Director, GRIS, Faculté de médecine, Université de Montréal, Montréal, QC

DAVID LEVINE
Président directeur général, Agence de développement de réseaux locaux de services de santé et de services sociaux de Montréal-Centre, Montréal, QC

CHRIS LOVELACE
Senior Manager, World Bank, Kyrgyz Republic Country Office, Central Asia Human Development, Bishkek, Kyrgyz Republic

THEODORE R. MARMOR
Professor of Public Policy and Management, Professor of Political Science, Yale School of Management, New Haven, CT

VICENTE ORTÚN
Economics and Business Department and Research Center on Health and Economics (CRES), Pompeu Fabra University, Barcelona, Spain

ROBIN OSBORN
Vice President and Director, International Program in Health Policy and Practice, Commonwealth Fund, New York, NY

DOROTHY PRINGLE
Professor Emeritus and Dean Emeritus, Faculty of Nursing, University of Toronto, Toronto, ON

MARC RENAUD
Lisbon, Portugal (on sabbatical)

JEAN ROCHON
Expert associé, Systèmes de soins et services, Institut national de santé publique du Québec, Sainte-Foy, QC

NORALOU P. ROOS
*Manitoba Centre for Health Policy
Professor, Community Health Sciences
University of Manitoba, Winnipeg, MB*

RICHARD SALTMAN
*Professor of Health Policy and Management, Rollins School
of Public Health, Emory University, Atlanta, GA*

HON. HUGH D. SEGAL, CM
Senator, Kingston-Frontenac-Leeds, Ottawa, ON

ALAN WOLFSON
South Africa

LONGWOODS PUBLISHING CORPORATION

FOUNDING PUBLISHER AND CHAIRMAN (RETIRED)
W. ANTON HART

PUBLISHER & CEO
MATTHEW HART
mhart@longwoods.com

PUBLISHER & COO
REBECCA HART
rhart@longwoods.com

EDITORIAL DIRECTOR
DIANNE FOSTER-KENT
dkent@longwoods.com

ASSOCIATE PUBLISHER, CAREERS & WEB
SUSAN HALE
shale@longwoods.com

**ASSOCIATE PUBLISHER, CUSTOMER SERVICE
& ADMINISTRATION**
BARBARA MARSHALL
bmarshall@longwoods.com

DESIGN AND PRODUCTION
ANTONY F. BICKENSON
abickenson@longwoods.com

CREATIVE
ERIC HART

HOW TO REACH THE EDITORS AND PUBLISHER

Telephone: 416-864-9667 Fax: 416-368-4443

ADDRESSES

All mail should go to: Longwoods Publishing Corporation, 260
Adelaide Street East, No. 8, Toronto, Ontario M5A 1N1, Canada.

For deliveries to our studio: 54 Berkeley St., Suite 305, Toronto,
Ontario M5A 2W4, Canada.

SUBSCRIPTIONS

Individual subscription rates for one year are [C] \$123 for online
only and [C] \$204 for print + online. Institutional subscription
rates are [C] \$535 for online only and [C] \$729 for print + online.
For subscriptions contact Barbara Marshall at telephone 416-864-
9667, ext. 100 or by e-mail at bmarshall@longwoods.com.

Subscriptions must be paid in advance. An additional tax
(GST/HST) is payable on all Canadian transactions. Rates
outside of Canada are in US dollars. Our GST/HST number
is R138513668.

SUBSCRIBE ONLINE

Go to www.healthcarepolicy.net and click on "Subscribe."

REPRINTS

Reprints can be ordered in lots of 100 or more. For reprint infor-
mation call Barbara Marshall at 416-864-9667 or fax 416-368-
4443 or e-mail to bmarshall@longwoods.com.

Return undeliverable Canadian addresses to: Circulation
Department, Longwoods Publishing Corporation, 260 Adelaide
Street East, No. 8, Toronto, Ontario M5A 1N1, Canada.

EDITORIAL

To submit material or talk to our editors please contact
Ania Bogacka at 416-864-9667 or by e-mail at abogacka@longwoods.com. Author guidelines are available
online at <http://www.longwoods.com/pages/hpl-for-authors>.

ADVERTISING

For advertising rates and inquiries, please contact Matthew Hart
at 416-864-9667, ext. 113 or by e-mail at mhart@longwoods.com.

PUBLISHING

To discuss supplements or other publishing issues contact
Rebecca Hart at 416-864-9667, ext. 114 or by e-mail at
rhart@longwoods.com.

Healthcare Policy/Politiques de Santé is published four times per year
by Longwoods Publishing Corp., 260 Adelaide St. East, No. 8,
Toronto, ON M5A 1N1, Canada. Manuscripts are reviewed
by the editors and a panel of peers appointed by the editors.
Information contained in this publication has been compiled from
sources believed to be reliable. While every effort has been made
to ensure accuracy and completeness, these are not guaranteed.
The views and opinions expressed are those of the individual
contributors and do not necessarily represent an official opinion
of *Healthcare Policy* or Longwoods Publishing Corporation.
Readers are urged to consult their professional advisors prior
to acting on the basis of material in this journal.

Healthcare Policy/Politiques de Santé is indexed in the following:
PubMed/Medline, CINAHL, CSA (Cambridge), Ulrich's, Embase,
IndexCopernicus, Scopus, ProQuest, EBSCO Discovery Service,
is archived in PubMed Central, and is a partner of HINARI.

No liability for this journal's content shall be incurred by
Longwoods Publishing Corporation, the editors, the editorial
advisory board or any contributors.

ISSN No. 1715-6572
eISSN No. 1715-6580

Publications Mail Agreement No. 40069375
© February 2018

Curious Silences in Healthcare Policy and Research

Scotland Yard Inspector: “Is there any other point to which you would wish to draw my attention?”

Sherlock Holmes: “To the curious incident of the dog in the night-time.”

Inspector: “The dog did nothing in the night-time.”

Holmes: “That was the curious incident.”

AS SHERLOCK HOLMES DID IN *THE ADVENTURE OF SILVER BLAZE* (DOYLE 1893), André Picard, health reporter and columnist at *The Globe and Mail*, recently drew attention to the importance of reflecting on curious silences. During a January 2018 panel, he encouraged focus on issues that may go unreported or understudied, not just those regularly in the headlines.

Every Monday, I am reminded of one such issue. I start the week by volunteering in a program for people who are experiencing chronic pain. Their stories of how being in pain affects their lives are powerful, as is their drive to find a path forward.

While the opioid crisis is getting much-needed attention, there is less talk about the rise in the number of Canadians with chronic pain. Statistics Canada data show that 4.9 million Canadians aged 12 and older reported having pain or discomfort that prevented activities in 2014, up from 2.8 million in 2003 (Statistics Canada 2016). That reflects a rise from 10.6% of teens and adults to 14.9%.

What’s happening? The change is not explained by population aging. Age-standardized rates are also higher now than in 2003; rates have risen for both women and men. Nor is it because of changes in arthritis rates (17.6% of teens and adults said that they had arthritis in 2003, compared to 16.5% in 2014). Statistics Canada data also rule out injuries as a material explanation since the proportion of people who sought medical attention for injuries over the period was relatively stable. One would have to go further to understand what the true drivers are.

Authors in this issue of *Healthcare Policy/Politiques de Santé* followed their curiosity in pursuit of answers to a broad range of topical questions. Their work uses a variety of methods and approaches to address ethical, healthcare financing, quality, and other issues.

As you pursue understanding of the curious healthcare policy silences that have peaked your own interest, please join these authors in submitting high-quality research and debate for publication in the journal’s pages. Whether your work illuminates an important issue

From the Editor-in-Chief

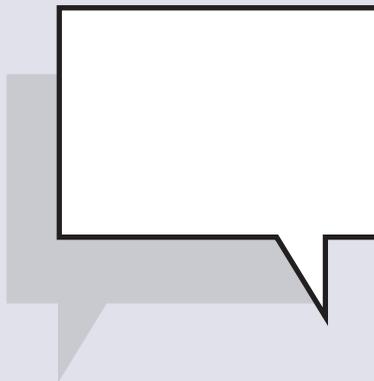
already in the headlines or brings attention to a new topic, we can collectively build the broader understanding that helps to drive change by sharing new insights and perspectives with a wider community.

JENNIFER ZELMER, PHD
Editor-in-Chief

References

Doyle, A.C. 1893. *The Memoirs of Sherlock Holmes*. London, UK: George Newnes.

Statistics Canada. 2016. "Table 105-0501: Health Indicator Profile, Annual Estimates, by Age Group and Sex, Canada, Provinces, Territories, Health Regions (2013 Boundaries) and Peer Groups." Retrieved February 6, 2018. <<http://www5.statcan.gc.ca/cansim/a47>>.



Let's talk.

Longwoods.com



De curieux silences dans la recherche et les politiques de santé

Inspecteur de Scotland Yard : « Y a-t-il quelque autre point sur lequel vous désirez attirer mon attention? »

Sherlock Holmes : « Oui, sur le curieux incident du chien, cette nuit-là. »

Inspecteur : « Le chien? Mais il n'a rien fait. »

Holmes : « C'est justement ce qu'il y a de curieux. »

COMME SHERLOCK HOLMES LE FAIT DANS *FLAMME D'ARGENT* (DOYLE 1893), André Picard, journaliste et chroniqueur spécialiste des questions de santé au *Globe and Mail*, attirait récemment l'attention sur l'importance de réfléchir aux curieux silences. Au cours d'une rencontre en janvier 2018, il invitait à se pencher sur les enjeux qui sont sous-représentés ou peu étudiés, pas seulement ceux qui paraissent régulièrement dans les manchettes.

Chaque lundi, je suis témoin d'un de ces enjeux. Ma semaine commence par du bénévolat dans un programme pour les gens qui vivent avec une douleur chronique. Les récits relatant l'effet de la douleur sur leur vie sont impressionnants, tout comme leur volonté de trouver moyen d'aller de l'avant.

Alors que la crise des opioïdes fait la manchette, on parle peu du nombre croissant de Canadiens qui vivent avec une douleur chronique. Les données de Statistique Canada montrent qu'en 2014, 4,9 millions de Canadiens de 12 ans et plus indiquaient vivre avec une douleur ou un malaise qui gêne leurs activités, comparativement à 2,8 millions en 2003 (Statistique Canada 2016). Cela représente une hausse de 10,6 % à 14,9 % des adolescents et adultes.

Que se passe-t-il? Ces changements ne s'expliquent pas par le vieillissement de la population. Les taux corrigés en fonction des effets dus à l'âge sont, eux aussi, plus élevés maintenant qu'en 2003; et la hausse s'observe tant chez les femmes que chez les hommes. Ce n'est pas non plus à cause des changements dans les taux pour l'arthrite (17,6 % des adolescents et adultes indiquaient souffrir d'arthrite en 2003, comparativement à 16,5 % en 2014). Les données de Statistique Canada permettent aussi d'écarter les blessures, comme explication, puisque la part de personnes qui ont demandé des soins médicaux pour blessure est demeurée relativement stable au cours de la période visée. Il faut donc approfondir la question pour en connaître les véritables causes.

Les auteurs présents dans ce numéro de *Politiques de Santé/Healthcare Policy* ont tenté de satisfaire leur curiosité en cherchant réponse à plusieurs questions d'actualité. Leurs travaux font appel à une variété de méthodes et d'approches pour traiter des enjeux liés à l'éthique, au financement ou encore à la qualité des services de santé.

De la rédactrice en chef

Alors que vous souhaitez mieux comprendre les étranges silences qui ont piqué votre curiosité dans le secteur des politiques de santé, joignez-vous à ces auteurs en soumettant à cette revue vos recherches ou discussions de pointe. Que votre travail éclaire un enjeu important qui figure déjà dans les manchettes, ou qu'il attire l'attention sur un nouveau sujet, nous pouvons tous ensemble contribuer aux connaissances qui permettront d'apporter des changements, et ce, en partageant de nouvelles pistes et points de vue avec un auditoire élargi.

JENNIFER ZELMER, PHD

Rédactrice en chef

Références

Doyle, A.C. 1894. *The Memoirs of Sherlock Holmes*. Londres, R-U: George Newnes.

Statistique Canada. 2016. « Tableau 105-0501 : Profil d'indicateurs de la santé, estimations annuelles, selon le groupe d'âge et le sexe, Canada, provinces, territoires, régions sociosanitaires (limites de 2013) et groupes de régions homologues. » Consulté le 6 février 2018. <<http://www5.statcan.gc.ca/cansim/a47>>.



Research on Human Embryos and Reproductive Materials: Revisiting Canadian Law and Policy

Recherche sur l'embryon et le matériel reproductif humains : examen des lois et politiques canadiennes



UBAKA OGBOGU, SJD

Assistant Professor

Faculties of Law and Pharmacy & Pharmaceutical Sciences

University of Alberta

Edmonton, AB

AMY ZARZECZNY, LL.M.

Associate Professor

Johnson-Shoyama Graduate School of Public Policy

University of Regina

Regina, SK

JAY BALTZ, PHD

Senior Scientist and Professor

Ottawa Hospital Research Institute

Faculty of Medicine, University of Ottawa

Ottawa, ON

PATRICK BEDFORD, MBHL

Manager of Clinical Translation and Regulatory Affairs

Centre for Commercialization of Regenerative

Medicine (CCRM)

Toronto, ON

JENNY DU, BSc

Research Trainee, Faculty of Law

University of Alberta

Edmonton, AB

INSOO HYUN, PHD

Associate Professor, Department of Bioethics

Case Western Reserve University

Cleveland, OH

YASMEEN JAAFAR, BA

Research Trainee, Faculty of Law

University of Alberta

Edmonton, AB

ANDREA JURISICOVA, PHD

Associate Professor

Department of Obstetrics and Gynecology

University of Toronto

Investigator, Lunenfeld-Tanenbaum Research Institute

Mount Sinai Hospital

Toronto, ON

ERIKA KLEIDERMAN, LLB

Academic Associate, Centre of Genomics and Policy

Faculty of Medicine, Human Genetics

McGill University

Montreal, QC

YONIDA KOUKIO

LLM Candidate

Osgoode Hall Law School

Toronto, ON

Research on Human Embryos and Reproductive Materials: Revisiting Canadian Law and Policy

BARTHA MARIA KNOPPERS, PHD

*Professor and Director, Centre of Genomics and Policy
Faculty of Medicine, Human Genetics, McGill University
Montreal, QC*

FOROUGH NOOHI, MSc

*PhD Candidate, Centre of Genomics and Policy
Faculty of Medicine, Human Genetics, McGill University
Montreal, QC*

ARTHUR LEADER, MD

*Professor of Reproductive Medicine
Department of Obstetrics and Gynecology
University of Ottawa
Ottawa, ON*

VARDIT RAVITSKY, PHD

*Associate Professor, Bioethics Programs
School of Public Health
University of Montreal
Montreal, QC*

ZUBIN MASTER, PHD

*Associate Consultant II, Biomedical Ethics Research Program
Mayo Clinic
Rochester, MN*

MAEGHAN TOEWS, LL.M.

*Lecturer, Faculty of Law
University of Adelaide
Adelaide, AU*

MINH THU NGUYEN, LL.M.

*Academic Associate, Centre of Genomics and Policy
Faculty of Medicine, Human Genetics, McGill University
Montreal, QC*

Abstract

Research involving human embryos and reproductive materials, including certain forms of stem cell and genetic research, is a fast-moving area of science with demonstrated clinical relevance. Canada's current governance framework for this field of research urgently requires review and reconsideration in view of emerging applications. Based on a workshop involving ethics, legal, policy, scientific and clinical experts, we present a series of recommendations with the goal of informing and supporting health policy and decision-making regarding the governance of the field. With a pragmatic and principled governance approach, Canada can continue its global leadership in this field, as well as advance the long-term health and well-being of Canadians.

Résumé

La recherche utilisant des embryons et du matériel reproductif humains, notamment la recherche sur certaines formes de cellules souches ainsi que la recherche génétique, constitue un secteur qui progresse rapidement et dont la pertinence clinique est démontrée. Face à l'émergence de nouvelles applications dans ce domaine, il est urgent d'examiner le cadre politique actuellement en vigueur au Canada. En s'appuyant sur les fruits d'un atelier qui réunissait des spécialistes en éthique, en droit, en politiques, en science et en recherche clinique, nous présentons une série de recommandations dont l'objectif est d'éclairer et de soutenir les politiques de santé et la prise de décisions liées à la gouvernance dans ce domaine. Avec une approche pragmatique et basée sur des principes, le Canada peut continuer d'assurer un leadership à l'échelle mondiale dans ce domaine de même que faire progresser, à long terme, la santé et le bien-être des Canadiens.

IN CANADA, RESEARCH INVOLVING HUMAN EMBRYOS AND REPRODUCTIVE MATERIALS, including certain forms of stem cell and genetic research, is governed primarily by the *Assisted Human Reproduction Act* (AHRA) and the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) (Government of Canada 2014). The AHRA, enacted in 2004 following considerable debate (Cattapan and Snow 2017), criminally prohibits several assisted reproductive activities and related research, including the creation of embryos for purposes other than reproductive use or improving or providing instruction in assisted reproduction procedures, the creation of human clones or chimeras and maintaining a human embryo *in vitro* for more than 14 days. Health Canada is charged with implementing and enforcing the AHRA. The TCPS lays out rules for the ethical conduct of permitted research involving human reproductive materials. These rules include consent to research involving such materials, privacy and confidentiality protections for identifiable materials and guidance on managing conflicts of interest. The TCPS applies to research supported by or conducted in institutions supported by federal funds and thus has a broad reach. The Stem Cell Oversight Committee (SCOC) oversees compliance with TCPS rules governing research involving human pluripotent stem cells. Together, this governance framework maintains prohibitions and funding restrictions against various research activities, including the creation of embryos for research, somatic cell nuclear transfer and the creation and use of non-human chimeras for research.

Canada, having deep expertise in this field of research, is also a global leader of research involving human reproductive materials (KPMG 2015). However, these prohibitions affect current basic research activities and will impact emerging areas of research aimed at developing novel reproductive technologies and improving our knowledge of human developmental biology, such as studies investigating *in vitro* derivation of gametes from human pluripotent stem cells (Yang et al. 2012), or the creation of embryo-like entities from stem cell cultures (Harrison et al. 2017; Pera et al. 2015; Warmflash et al. 2014). Recognizing the need to ensure continued relevance, the AHRA mandated a Parliamentary Review within three years of the establishment of its regulatory agency. However, this review never occurred. While the reasons why the review never took place are unclear, we speculate it may be because of a lack of a stable framework for implementation and enforcement and a legal challenge to the constitutionality of the Act initiated by the Province of Quebec in the period following enactment. As such, it is unclear whether the concerns that triggered the prohibitions remain current, especially in relation to basic research activities. The AHRA has also been criticized for its lack of clarity regarding its application to novel and emerging research activities (Rugg-Gunn et al. 2009), and these concerns remain.

With the goal of informing and supporting health policy and decision-making regarding the governance of embryo and reproductive materials research in Canada, we convened a workshop of ethics, legal, policy, scientific and clinical experts to consider reform options. The workshop was a principal activity under a Public Policy Impact Research Grant funded by the Stem Cell Network and part of a larger workshop series aimed at revisiting the AHRA (Knoppers et al. 2017a). Participants were identified and selected through

consultations with Canadian and international collaborators on the grant, including leading scientific, legal and public policy research experts, and with the health law and science policy research teams at the Health Law Institute, University of Alberta and the Centre of Genomics and Policy (CGP) at McGill University. Participants completed an anonymized questionnaire prior to the workshop, which was used to structure the workshop deliberations and ensuing recommendations. The questionnaire was based on a format prepared by the CGP and used in the other workshops in the series. This paper presents key areas of consensus at the workshop and builds on earlier workshops and recommendations (Knoppers et al. 2017a, 2017b). A draft of the recommendations presented in the paper was developed at the workshop and refined through a process of e-mail consultation with and feedback from the workshop participants. We argue it is time for the federal government to revisit the regulation of this field of research in Canada. We further propose that when considering reforms, it is appropriate to take a principled and pragmatic approach that relies less on overly rigid (and often shifting) lines in the sand and more on clear legal and ethical principles to guide governance of biomedical research.

Reasons for Action

There are several reasons to reform the current governance framework. Scientific developments are pushing legislative boundaries and highlighting problematic ambiguities and uncertainties that are particularly concerning when criminal liability is at stake. For example, in addition to the uncertainty noted above regarding the legal status of embryo-like entities, there is confusion regarding whether the ban on human germline editing in the AHRA extends to non-clinical research. Clarity in this area is important, especially given the research possibilities enabled by CRISPR/Cas9 (Knoppers et al. 2017a). There are also clinical demands where currently prohibited research activities, such as creation of human embryos, clones and chimeras for research purposes, have the long-term potential to improve the health and well-being of Canadians. The ban on human germline editing also appears to foreclose scientific exploration of clinical research studies of innovative fertility treatments, such as mitochondrial replacement therapy (Knoppers et al. 2017b). Though difficult to quantify, limits to promising fields of research may also constrain associated economic opportunities and result in loss of research talent and commercial prospects to other jurisdictions (Longstaff et al. 2013). Further, in Canada's growing, pluralistic society, public interests and priorities cannot be assumed to be static. Shifts in public understanding of science and its clinical potential underscore the need to regularly engage with Canadians to ensure policy is responsive to public interests and values.

Guiding Principles for Reform

Limitations on scientific and clinical progress should be justified. Where linked to ethical or other socially based arguments (as has so often been the case with this area of research), the goal should be to achieve an appropriate balance that reflects Canada's diverse society

in which a plurality of perspectives exists on key issues such as the point at which life begins, obligations to use science and medicine to ease human suffering and the sanctity (or lack thereof) of the human genome, among others. A principled approach to decision-making can be of immense value when striving for a balance between such diverse and sometimes conflicting priorities and perspectives. Recognizing that democratic engagement and appropriate consultation are vital when identifying guiding principles, we do not propose a definitive framework here. As a starting point, we suggest drawing on existing and tested guiding principles, including those of the International Society for Stem Cell Research (ISSCR), which focus on integrity of the research enterprise, primacy of patient welfare, respect for research subjects, transparency and social justice (ISSCR 2016). We also propose the following complementary principles for consideration.

Research policy limits should be proportional, with appropriate balancing of risks and benefits, as well as of possible penalties for harm. They should be guided by evidence, rather than speculation about hypothetical risks. They should be consistent, so that like activities are treated similarly and exceptionalism is avoided. They should be responsive rather than static, and amenable to flexible interpretation as circumstances change. They should be clear and supported by substantive criteria guiding how to interpret and apply them. Finally, they should be grounded in recognition of the value of scientific discovery and the interests of citizens in benefiting from science and its applications.

Recommendations

The recommendations that follow are not exhaustive. Rather, our focus is on identifying governance approaches and priority areas for a revised policy framework. The priority areas include clarifying the definition of embryo and restrictions on creation and use of embryos for research, the 14-day limit on the use of embryos for research, and rules governing creation and use of chimeras and human embryos created by cloning techniques for research purposes.

Governance approaches

A distributed governance model involving research ethics and professional regulation should be implemented. The mandate and representation of SCOC should be expanded to provide oversight in the interim.

As some of us and others have argued elsewhere, criminal prohibitions are generally not an appropriate tool for governance of biomedical research activities (Knoppers et al. 2017a, 2017b). They lack the flexibility required to respond to dynamic and evolving fields of research and are problematic for both principled and practical reasons. As such, the criminal prohibitions should be replaced with a more flexible oversight system.

In the absence of federal responsibility exercised via the criminal law powers, there would be space for provinces and territories to exercise jurisdiction in this area. However, to avoid

a patchwork of policies and/or provincial/territorial inaction, we recommend a continued system of federal oversight via a distributed governance model involving both research ethics oversight and professional regulation. A national, independent review body could be charged with the mandate of reviewing and approving applications for research involving human reproductive materials, using the framework of a continually updated TCPS.

The credibility of such a body would be enhanced by requirements for diverse representation and a transparent appointment process as well as policies addressing conflicts of interest and review criteria. With appropriate consultation and partnering with the Colleges of Physicians and Surgeons, this oversight could be supplemented by professional regulation to ensure compliance from clinician-researchers who conduct research in private settings. Though perhaps ideal in the long-term, it would not be immediately necessary to establish a new body. The structure and mandate of SCOC, which is tasked with reviewing human pluripotent stem cell research where cells have been derived from an embryonic source and/or will be transplanted in humans or animals for compliance with the TCPS, could be updated to fill this role.

The definition of embryo and related restrictions on creation and use for research

The current definition of embryo should be maintained. However, restrictions on the creation and use of embryos for research purposes should not extend to embryo-like structures patterned or derived from pluripotent stem cells, and which are not intended to create a human being.

The AHRA defines an embryo as “a human organism during the first 56 days of its development following fertilization or creation, excluding any time during which its development has been suspended, and includes any cell derived from an organism that is used for ... creating a human being” (s. 3). It is illegal under the AHRA to “create an *in vitro* embryo for any purpose other than creating a human being or improving or providing instruction in assisted reproduction procedures” (s. 5[1][b]). Anyone who contravenes this provision is guilty of an offence and liable for a fine of up to \$500,000 and/or imprisonment for up to 10 years (s. 60).

One new promising area of stem cell research involves the creation of structures that resemble embryos (Harrison et al. 2017; Warmflash et al. 2014). Commonly referred to as synthetic human entities with embryo-like features (SHEEFs) (Aach et al. 2017), these structures are not only a valuable research tool for understanding early embryo development and developmental disorders, but also raise ethical concerns (Pera et al. 2015). It is presently unclear whether (or at what point of development) these structures might be considered embryos under the AHRA and therefore illegal to create.

It seems unlikely that the harms the prohibition on creating embryos for research were originally intended to address, including concerns about exploitation of egg donors and the moral status of the embryo (Standing Committee on Health 2001), extend to synthetic

forms not requiring human eggs and likely incapable of developing into a human being. We recommend therefore that such synthetic forms be explicitly excluded from prohibitions in the AHRA. We further recommend that any limits on the creation and use of embryos or SHEEFs for research purposes be determined through an oversight process and based on criteria established through appropriate, transparent consultation. Meanwhile, Health Canada should issue public guidance regarding how the AHRA applies to SHEEFs to avoid an unnecessary chill on promising avenues of research while ensuring scientists are not risking criminal liability for work in currently ambiguous areas.

The 14-day limit on embryo research

The 14-day limit on embryo research should be maintained, with amendments to vest authority in the Minister or her delegate to grant exceptions.

Per the AHRA, it is illegal to “maintain an embryo outside the body of a female person after the fourteenth day of its development following fertilization or creation, excluding any time during which its development has been suspended” (s. 5[1][b]). Doing so risks the same criminal liability outlined above. The 14-day rule reflects considerable international consistency and was confirmed again in the latest ISSCR Guidelines for Stem Cell Research and Clinical Translation (ISSCR 2016, s. 2.1.3.3.a.). Until lately, it was relatively uncontroversial because the longest anyone could keep an embryo alive in culture was nine days. However, recent advances extending that time frame (Deglincerti et al. 2016) have led to debates about whether and how to reconsider this limit (Chan 2017; Hyun et al. 2016) which may be impeding research that could elucidate how early human embryos and bodily organs develop, provide models to study the etiology of birth defects and chronic disease, and allow the study of developmental stages not ethically accessible in developing human embryos *in vivo*.

Canada has an opportunity here to demonstrate policy innovation in a measured fashion. The 14-day limit on embryo research should be maintained, but with the addition of a possibility for exceptions in appropriate circumstances (e.g., depending on scientific rationale and proposed limits). If the current regulatory framework is maintained, an amendment to the AHRA could vest authority to grant exceptions to the Minister, with potential for delegation to an appropriate body.

Creation and use of chimeras and human clones for research

Restrictions on research uses of chimeras and human embryos created by cloning techniques (such as by somatic cell nuclear transfer) should be reconsidered and a more nuanced approach adopted. The ban on reproductive uses of clones and chimeras should be maintained.

The AHRA prohibits creation or transplantation of a human clone (s. 5[1][a]), defined as “an embryo that, [due to] the manipulation of human reproductive material or an *in vitro* embryo, contains a diploid set of chromosomes obtained from a single – living or deceased – human being, foetus or embryo” (s. 3). The AHRA defines a chimera as “(a) an embryo into which a cell of any non-human life form has been introduced; or (b) an embryo that consists of cells of more than one embryo, foetus or human being” (s. 3), and prohibits creation of a chimera and transplant of a chimera into a human or animal (s. 5[1][i]). Given that the definition of embryo in the AHRA captures only human organisms, the AHRA’s prohibitions regarding chimeras do not extend to transplantation of human cells into non-human embryos and animals. The TCPS permits grafting of human stem cells into non-human animals after birth (with conditions) but does not allow pluripotent human stem cells to be combined with non-human embryos or fetuses (Article 12.10). These prohibitions limit research into the development of human organs and the developmental origins of human disease.

Ascertaining what degree of chimerism, if any, may be acceptable to Canadians is complex and requires both education and consultation. The Interagency Advisory Panel on Research Ethics (PRE), which is responsible for developing, interpreting and implementing the TCPS, has relevant expertise in this regard. PRE could lead such an engagement exercise and consider afresh the TCPS policy on research involving the introduction of human pluripotent cells into non-human embryos or fetuses, in line with the guiding principles outlined above.

We suggest it is appropriate to separate basic research activities from clinical research and practice involving human reproduction, as they raise different issues and would benefit from separate governance schemes. Such a separation would allow for strict restrictions to remain with respect to clinical reproductive use while leaving room for broader allowances for research uses, and would be consistent with similar international approaches (ISSCR 2016). In line with this recommendation, the use for research purposes of human embryos created by cloning techniques, such as by somatic cell nuclear transfer, should be permitted, subject to strict monitoring and ethical oversight.

Conclusion

Regulating continually evolving and socially controversial fields of science such as stem cell research can be challenging. Hard law approaches are often ill-suited to the task given their inflexible and entrenched nature. Law and policy instruments that leave greater room for public collaboration, engagement and regular evaluation and updating offer considerable advantages for emerging areas of bioscience (Nichol et al. 2017). Criminal law is the most coercive instrument available to the state and should be reserved for the gravest of harms. It is not, we suggest, a suitable tool for regulating the avenues of research currently captured by the AHRA. We recognize that revising, amending and repealing the AHRA in whole or in part will require considerable time, effort and resources, as well as both public and political support. However, we suggest this task cannot be avoided any longer.

Acknowledgements

This paper is the outcome of a workshop funded by the Stem Cell Network of Canada, with additional support from the University of Alberta Faculty of Law and the McGill Centre of Genomics and Policy, and is part of a larger research grant also funded by the Stem Cell Network. Ubaka Ogbogu is the grant holder and Ubaka Ogbogu and Amy Zarzeczny are the principal investigators. The views expressed in the paper are those of the authors and not those of any governmental or non-governmental organizations.

We would like to acknowledge and thank the following workshop participants: Janetta Bijl (Stem Cell Network), Stanislav Birko (University of Montreal), Wendy Burgess (Secretariat on Responsible Conduct of Research, Panel on Research Ethics), Alana Cattapan (University of Saskatchewan), Eric M. Meslin (Council of Canadian Academies), Peter Monette (Health Canada), Cate Murray (Stem Cell Network), Kyle Norrie (Health Canada), Cathy Parker (Health Canada), Lynne Scholten (Canadian Institutes of Health Research), Anu Shukla-Jones (Health Canada) and Susan Zimmerman (Secretariat on Responsible Conduct of Research, Panel on Research Ethics).

Correspondence may be directed to: Ubaka Ogbogu, Assistant Professor, Katz Research Fellow, Faculty of Law, Faculty of Pharmacy and Pharmaceutical Sciences, University of Alberta, 4th Floor Law Centre, Edmonton, AB T6G 2H5; e-mail: uogbogu@ualberta.ca; tel.: 780-492-9055; fax: 780-492-4924.

References

- Aach, J., J. Lunshof, E. Iyer and G. Church. 2017. "Addressing the Ethical Issues Raised by Synthetic Human Entities with Embryo-Like Features." *eLife* 6: e20674. doi:10.7554/eLife.20674.
- Assisted Human Reproduction Act*, S.C. 2004, c. 2.
- Cattapan, A. and D. Snow. 2017. "Everything and Nothing: Regulating Embryo Research in Canada." *New Genetics and Society* 36(1): 43–65. doi:10.1080/14636778.2017.1289469.
- Chan, S. 2017. "How to Rethink the Fourteen-Day Rule." *Hastings Center Report* 47(3): 5–6. doi:10.1002/hast.698.
- Deglincerti, A., G.F. Croft, L.N. Pietila, M. Zemicka-Goertz, E.D. Siggia and A.H. Brivanlou. 2016. "Self-Organization of the *In Vitro* Attached Human Embryo." *Nature* 533(7602): 251–54. doi:10.1038/nature17948.
- Government of Canada. 2014. "Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans." Retrieved February 14, 2018. <<http://www.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>>.
- Harrison, S.E., B. Sozen, N. Christodoulou, C. Kyprianou and M. Zernicka-Goetz. 2017. "Assembly of Embryonic and Extraembryonic Stem Cells to Mimic Embryogenesis *In Vitro*." *Science* 356(6334): eaal1810. doi:10.1126/science.aal1810.
- Hyun, I., A. Wilkerson and J. Johnston. 2016. "Embryology Policy: Revisit the 14-Day Rule." *Nature* 533(7602): 169–71. doi:10.1038/533169a.
- International Society for Stem Cell Research (ISSCR). 2016. "Guidelines for Stem Cell Research and Clinical Translation." Retrieved January 8, 2018. <<http://www.isscr.org/docs/default-source/guidelines/isscr-guidelines-for-stem-cell-research-and-clinical-translation.pdf?sfvrsn=2>>.

Knoppers, B.M., R. Isasi, T. Caulfield, E. Kleiderman, P. Bedford, J. Illes et al. 2017a. "Human Gene Editing: Revisiting Canadian Policy." *Regenerative Medicine* 2(3): 1–2. doi:10.1038/s41536-017-0007-2.

Knoppers, B.M., A. Leader, S. Hume, E. Shoubridge, R. Isasi, F. Noohi et al. 2017b. "Mitochondrial Replacement Therapy: The Road to the Clinic in Canada." *Journal of Obstetrics and Gynaecology Canada*. doi:10.1016/j.jogc.2017.05.007.

KPMG. 2015. "Following Through: Realizing the Promise of Stem Cells, A Canadian Stem Cell Strategy and Action Plan 2015-2025." Retrieved January 8, 2018. <<http://stemcellfoundation.ca/wp-content/uploads/2014/07/Following-Through-Realizing-The-Promise-of-Stem-Cells.pdf>>.

Longstaff, H., V. Khramova, M. Eijkholt, A. Mizgalewicz and J. Illes. 2013. "Hopes and Fears for Professional Movement in the Stem Cell Community." *Cell Stem Cell* 12(5): 517–19. doi:10.1016/j.stem.2013.04.016.

Nichol, D., R. McWhirter and J. Dickinson. 2017. "Implementing Values-Based Governance for a New Bioresource Model." *Journal of Law and the Biosciences* 4(2): 401–11. doi:10.1093/jlb/lxx007.

Pera, M.F., G. de Wert, W. Dondorp, R. Lovell-Badge, C. Mummery, M. Munsie and P. Tam. 2015. "What if Stem Cells Turn into Embryos in a Dish?" *Nature Methods* 12(10): 917–19. doi:10.1038/nmeth.3586.

Rugg-Gunn, P., U. Ogbogu, J. Rossant and T. Caulfield. 2009. "The Challenge of Regulating Rapidly Changing Science: Stem Cell Legislation in Canada." *Cell Stem Cell* 4(4): 285–88. doi:10.1016/j.stem.2009.03.004.

Standing Committee on Health. 2001. *Assisted Human Reproduction: Building Families*. Ottawa, ON: House of Commons. Retrieved January 8, 2018. <<http://www.ourcommons.ca/DocumentViewer/en/37-1/HEAL/report-2/page-5>>.

Warmflash, A., B. Sorre, F. Etoc, E.D. Siggia and A.H. Brivanlou. 2014. "A Method to Recapitulate Early Embryonic Spatial Patterning in Human Embryonic Stem Cells." *Nature Methods* 11(8): 847–54. doi:10.1038/nmeth.3016.

Yang, S., J. Bo, H. Hu, X. Guo, R. Tian, C. Sun et al. 2012. "Derivation of Male Germ Cells from Induced Pluripotent Stem Cells *In Vitro* and in Reconstituted Seminiferous Tubules." *Cell Proliferation* 45(2): 91–100.



Follow us
you'll never know where it may lead

Twitter.com/LongwoodsNotes

Medicine, Body Fluid and Food: The Regulation of Human Donor Milk in Canada

Médicaments, liquides organiques et alimentation : réglementation du don de lait maternel au Canada



MARTHA J. PAYNTER, MDE, MSC, RN
PhD Candidate in Nursing
Dalhousie University School of Nursing
Halifax, NS

KATHRYN HAYWARD, RN, MN, IBCLC
Assistant Professor
Dalhousie School of Nursing
Halifax, NS

Abstract

The use of peer-to-peer online networks to access both pasteurized and unpasteurized human donor milk is increasing in Canada. In the absence of a mother's own milk, donor milk is the next best nutrition available for all infants in need of supplementation. Limited supply and the cost of pasteurized milk puts it out of reach for many. Although milk banks in Canada all operate on a non-profit basis, there is a lack of regulatory safeguards regarding for-profit operations and private milk exchange. This paper describes regulation of human donor milk and identifies gaps putting families at risk.

Résumé

Le lait maternel de donneuses, pasteurisé et non pasteurisé, accessible sur les réseaux en ligne est de plus en plus utilisé au Canada. Dans les cas où la mère manque de lait, le lait de donneuses est la meilleure source de nutrition de remplacement pour tout nourrisson. L'offre limitée et le coût du lait pasteurisé le rend hors de portée pour plusieurs personnes.

Même si toutes les banques de lait au Canada sont des organismes à but non lucratif, il y a un manque de réglementation quant aux mesures de sécurité pour les transactions à but lucratif et pour les échanges privés de lait. Cet article décrit la réglementation touchant au lait maternel de donneuses et indique les lacunes qui mettent à risque les familles.

AFTER DECADES OF DORMANCY, THE USE OF PASTEURIZED HUMAN DONOR MILK (PHDM) is making a comeback in Canada. Recognized as a life-saving medicine for very low birthweight (VLBW) infants, PHDM is the best nutrition available, next to a mother's own milk, for all infants in need of supplementation. Pasteurization destroys some of the live components of human milk. At present, medical access to PHDM is decidedly unequal across the country even for the most fragile infants. Despite this, fears regarding disease transmission cause few health authorities to adopt a harm-reduction orientation to the growing phenomenon of online peer-to-peer milk-sharing. Gaps in access to PHDM from non-profit banks persist simultaneous to growing commercialization and reach of the human milk industry in North America.

This paper seeks to describe the current governance of human donor milk as a medicine, body fluid and food, and identify regulatory gaps that put families at risk. The use of human donor milk as medicine is governed by clinical discretion in prescribing pasteurized milk, bank triaging decisions and insurers' response to cover or not cover costs. As a shared body fluid, unpasteurized human milk presents potential harm to be monitored by Public Health authorities. Adding further to the regulatory complexities, as a food, the dominant legal status of human donor milk is governed by food safety regulations. With its growing use, there is an urgent need to optimize regulatory approaches to the three conceptualizations of human donor milk as a medicine, as a shared body fluid, and as food.

Milk banking is reaching its centennial anniversary in North America. The first milk bank opened in 1919 in Boston and early "donors" were paid (Jones 2003). Milk banking grew steadily throughout the 20th century: in the 1980s, there were 23 milk banks in Canada and 30 in the US (Jones 2003). The HIV/AIDS crisis led to the closure of all the Canadian banks except The BC Women's Provincial Milk Bank, open continuously since 1974. There has never been a documented case of HIV transmission through banked milk (Kim and Unger 2010). Four milk banks, described below, now operate in Canada.

Milk-sharing is an ancient practice that goes back to the use of wet nursing and is currently made more popular and potentially hazardous by the Internet. Popular milk-sharing sites include Facebook pages *Eats on Feets*, and *Human Milk 4 Human Babies* as well as the classifieds site *onlythebreast.com*. Parents turn to these sites when they are experiencing interruptions in lactation or prolonged need but are unable to qualify for or pay for pasteurized milk from a bank (Palmquist and Doehler 2015).

Regulation of PHDM as Medicine

Eligibility for in-patient PHDM when mother's own milk is unavailable is determined by institutional clinical leadership. Priority populations include preterm infants at low birth weights, some infants with surgical and cardiac conditions and infants at risk for necrotizing enterocolitis (NEC). In determining eligibility criteria, care providers weigh research evidence of effectiveness against costs. Systematic review of the evidence suggests human donor milk reduces the risk of NEC, the leading cause of morbidity and mortality in premature infants (Quigley and McGuire 2014). Meta-analysis of six studies found formula-fed preterm infants, in comparison to those fed donor-milk, experience a risk ratio for NEC of 2.77, risk difference of 0.04 and number needed to treat of 25 (Quigley and McGuire 2014: 11). The rate of NEC in the <33-week preterm population in Canada is 5.1% (Yee et al. 2012). Depending on mothers' ability to supply milk, cost to use the PHDM in the preterm population has been estimated at US\$27–\$590 per infant (Carroll and Hermann 2013). There are additional costs to milk storage, fortification and administration. Researchers have estimated the cost to treat NEC, over and above Neonatal Intensive Care Unit (NICU) treatment for a premature infant without NEC, as US\$78,000–\$198,000 (Ganapathy et al. 2012).

Milk banks make distribution decisions. In the past four years, three non-profit milk banks have opened in Canada: The Public Mother's Milk Bank operated by Héma-Québec in Montreal; the Rogers Hixon Ontario Human Donor Milk Bank in Toronto and the Northern Star Mother's Milk Bank, located in Calgary. Northern Star is the only community-based bank, independent of hospital governance or provincial oversight. It can and does accept milk donations and send PHDM to recipients anywhere in Canada at a cost of \$4.50/ounce; the other banks focus intra-provincially. There is no bank east of Québec. The BC, Northern Star and Rogers Hixon banks all belong to HMBANA, the Human Milk Banking Association of North America. HMBANA is a voluntary association that sets guidelines for donor screening, milk processing, storage, facilities, distribution and triage. The Québec bank has applied for HMBANA membership. Revised in 2013, the *Quebec Act Respecting Héma-Québec and the Biovigilance Committee* (CQLR, Chapter H-1.1) gives Héma-Québec, the province's blood bank, responsibility for the safety of human milk management for the province (Quebec 2013).

In provinces and territories without a milk bank, the perceived need to restrict eligibility hinges on dependence on Northern Star to meet demand. Although lactating women anywhere in Canada may donate to Northern Star, the bank's supply is generated largely by women residing in Alberta. This arrangement creates equity concerns and vulnerability to Northern Star's private business decisions. No provincial or federal regulation secures access or guarantees equal treatment of infants or even VLBW infants across jurisdictions.

At present, all the milk banks in Canada are non-profit, and set their own prices for in-patient and out-patient sale of PHDM. A regulated prescriber's order or prescription order is usually required to facilitate milk bank triage decisions. No third-party insurer in Canada includes PHDM as a benefit. Currently, it lacks a Drug Identification Number indicating

evaluation by the Therapeutic Products Directorate of Health Canada and identifying it as a possible insurable commodity. A few American states have Medicaid coverage for the cost of PHDM when medically indicated. In Canada, in-patient use of PHDM is publicly covered.

Regulation of PHDM as Food

As a food, the dominant risk of PHDM is spoilage and bacterial contamination. The milk banks are responsible for donor education about pump and hand hygiene and safe milk storage. Frozen milk is donated to banks. It is then thawed, pooled, sealed in sterile bottles, barcoded for traceability, pasteurized, cultured and tested for bacterial content. Spore-forming *Bacillus* bacteria survive pasteurization: if found, donors are identified, contacted and re-educated. Affected milk is discarded. Acceptable milk is then frozen and packaged for shipment.

Perceptions about the scarcity of human donor milk and the cost result in triaging and limited access. HMBANA has issued a position statement that “every infant has the right to access banked pasteurized milk when maternal milk is unavailable” (HMBANA No Date). Although in-patient eligibility remains the purview of clinical leaders, there is clear public interest in broader access to PHDM. The BC bank and Northern Star distribute to full-term infants and out-patients with a prescription and when supply allows, triaging NICU infants first. Unable to access PHDM outside of the direct distribution area of these banks, families are seeking milk donations through online social networking sites dedicated to milk-sharing. Parents and guardians of in-patients who do not meet current institution eligibility criteria for PHDM and do not wish their infants to have formula when medical supplementation is required may also be accessing unpasteurized milk through these sites. Hospitals already purchasing PHDM must question the ethics of denying these requests, and of not offering PHDM up front.

Systematic reviews have found PHDM programs, largely focused on NICU infants, may increase rates of breastfeeding at discharge but lack impact on exclusive breastfeeding (William et al. 2016). Less is known about breastfeeding outcomes related to use of PHDM with the full-term infant population. Discussing the benefits of human donor milk with families provides education about the value of human milk and of breastfeeding generally. Advancing access to PHDM should be part of government and hospital policy to support breastfeeding.

PHDM is subject to the *Food and Drug Act*, section 4 of which prohibits the sale of food that is harmful, unfit for human consumption, adulterated or prepared in unsanitary conditions (Government of Canada 1985). Non-profit milk banks adhere to FDA regulations and are subject to inspection. Individuals engaged in milk-sharing could be held liable for food safety claims, but are not licensed or governed in their practices.

The Regulation of PHDM as a Body Fluid

The possibility of allergic reaction to or disease transmission through unpasteurized human milk is a serious concern. HIV, hepatitis, syphilis and most recently, Zika, can all be contracted

through unpasteurized human milk. Health regulators warn against milk-sharing (Health Canada 2014; Kim and Unger 2010). There is a lack of data on actual harm caused by online milk-sharing in Canada. British Columbia recently released a tool kit for healthcare providers to facilitate milk-sharing discussions with clients (Perinatal Services BC 2016). There is clinical value and an ethical requirement to advise families on safer milk-sharing practices (Akre et al. 2011).

Offers of unpasteurized human milk online may make unverifiable claims to safety or quality. Sometimes the requests and offers are specific, e.g., gluten-free, dairy-free, organic diet, etc. Ads on *onlythebreast.com* claim “non-drinker,” “natural breastmilk cheap” and “registered donor.” HMBANA member bank donors are screened verbally over the phone, must provide negative serology results for HIV, hepatitis and syphilis, and have their healthcare provider sign off on both mother and infant’s health. HMBANA member milk banks cannot and do not guarantee that the milk their donors provide informally through peer-to-peer networks is safe, as it has not been pasteurized or tested. Although Palmquist and Doehler (2015) found participants in milk-sharing can and do participate in screening to mitigate risk, there is no guarantee for the recipient of the shared milk.

The marketplace for human milk demonstrates the gendered costs of breastfeeding and the gendered exploitation of breastfeeding bodies (Allers 2014). Lack of regulation not only creates risks of disease transmission to infants, but of also sexual and economic exploitation of lactating women. Ads on *onlythebreast.com* claim the milk sale is to pay for an uninsured birth, to be able to stay home without a funded maternity leave, to make up the cost of the breast pump, etc. Online milk classifieds are saturated with replies from scammers and fetishists looking for adult wet nursing and explicit photos (McNeily 2016).

For-profit milk banking, in which donors are paid, and private milk sale, in which individuals charge for milk online, is increasingly normalized in the US. Selling human milk, like the sale of other body parts and products such as plasma, is problematic, as it potentially targets low-income individuals (Glauser 2014). Negative consequences may include dilution or contamination, misrepresentation of one’s health history or reduction in the amount available for one’s own children and crowding out altruistic donors (Stevens and Keim 2015).

For-profit milk banks have the means to dominate the human milk industry through compensation. For example, Prolacta Bioscience pays donors \$1/ounce. The company makes several milk by-products, including a fortifier it claims enhances growth in the preterm population. Utah-based company Ambrosia Labs paid women in Cambodia to pump twice a day, then ship the pasteurized milk across most US states. Cambodia banned the practice in March 2017 (The Guardian 2017). Several American states have enacted legislation requiring for-profit companies to adhere to HMBANA milk processing rules; to wait a designated minimum amount of time post-partum until they are permitted to pay women for donations (California Legislature 2016) and to distribute at least half of their supply to hospitals with an NICU (Michigan Legislature 2015).

Conclusion

Outside of Québec, PHDM safety and distribution is governed internally by milk banks following HMBANA guidelines. There is a need for further provincial regulation to improve equality of access to PHDM and to guard against for-profit industry entry. Public Health agencies should consider monitoring milk-sharing networks to provide guidance and support to improve safety and accountability. Health authorities and healthcare provider organizations should develop guidelines on PHDM and milk-sharing with the dual aims to improve equity and safety.

There has never been more research supporting medical use of PHDM, more demand from hospitals and communities, and more competition for donors from non-profit banks, milk-sharing social networks, informal milk sale and for-profit human milk companies. Now is the time to address gaps in our regulatory environment to ensure equity of access, safer milk-sharing and protection from economic exploitation through for-profit milk sale.

Correspondence may be directed to: Martha J. Paynter, School of Nursing, Forrest Building, Dalhousie University, P.O. Box 15000, 5869 University Avenue, Halifax, NS B3H 4R2; tel.: 902-292-7082; e-mail: martha.paynter@gmail.com.

References

- Akre, J.D., K.E. Gribble and M. Minchin, M. 2011. "Milk Sharing: From Private Practice to Public Pursuit." *International Breastfeeding Journal* 6(8): 1–3. doi:10.1186/1746-4358-6-8.
- Allers, K.S. 2014. "Inviting African-American Mothers to Sell Their Breastmilk, and Profiting." *New York Times*, December 3. Retrieved March 10, 2017. <<http://parenting.blogs.nytimes.com/2014/12/03/inviting-african-american-mothers-to-sell-their-breast-milk-and-profiting/>>.
- California Legislature. 2016. "Senate Bill 1316, An Act to Add and Repeal Article 2.5 (Commencing with Section 1642) to Chapter 4.1 of Division 2 of, the Health and Safety Code, Relating to Tissue Banks." Retrieved March 10, 2017. <https://leginfo.ca.gov/faces/billNavClient.xhtml?bill_id=201520160SB1316>.
- Carroll, K. and K.R. Hermann. 2013. "The Cost of Using Donor Human Milk in the NICU to Achieve Exclusively Human Milk Feeding to 32 Weeks Postmenstrual Age." *Breastfeeding Medicine* 8(3): 286–90. doi:10.1089/bfm.2012.0068.
- Ganapathy, V., J.W. Hay and J.H. Kim. 2012. "Costs of Necrotizing Enterocolitis and Cost-Effectiveness of Exclusively Human Milk-Based Products in Feeding Extremely Premature Infants." *Breastfeeding Medicine* 7(1): 29–37.
- Glauser, W. 2014. "Payment for Plasma Raises Ethical Issues." *CMAJ* 186(12): E446. doi:10.1503/cmaj.109-4855.
- Government of Canada. 1985. "Food and Drug Act." Ottawa, ON: Author. <<http://laws-lois.justice.gc.ca/eng/acts/F-27/index.html>>.
- Health Canada. 2014. "Safety of Donor Human Milk in Canada." Retrieved December 12, 2017. <<https://www.canada.ca/en/health-canada/services/food-nutrition/healthy-eating/infant-feeding/safety-donor-human-milk-canada.html>>.
- Human Milk Banking Association of North America (HMBANA). n.d. *HMBANA Position Paper on Donor Milk Banking*. Retrieved March 10, 2017. <<https://www.hmbana.org/sites/default/files/images/position-paper-donor-milk.pdf>>.
- Jones, F. 2003. "History of North American Donor Milk Banking: One Hundred Years of Progress." *Journal of Human Lactation* 19(3): 313–18.

- Kim, J.H. and S. Unger. 2010. "Human Milk Banking: Position Statement." *Canadian Pediatric Society*. Retrieved March 10, 2017. <<http://www.cps.ca/documents/position/human-milk-banking>>.
- McNeily, C. 2016. "Got Milk: The Underground Online Marketplace for Human Breast Milk." *Broadly*. Retrieved March 10, 2017. <https://broadly.vice.com/en_us/article/got-milk-the-underground-online-marketplace-for-human-breast-milk>.
- Michigan Legislature. 2015. *House Bill 4206*. *Michigan Legislature*. Retrieved March 12, 2017. <[http://www.legislature.mi.gov/\(S\(h1pqv0tn4e03rspeafjd0ni\)\)/mileg.aspx?page=GetObject&objectname=2015-HB-4206](http://www.legislature.mi.gov/(S(h1pqv0tn4e03rspeafjd0ni))/mileg.aspx?page=GetObject&objectname=2015-HB-4206)>.
- Palmquist, A.E.L. and K. Doehler. 2015. "Human Milk Sharing Practices in the US." *Maternal Child Health* 12: 278–90. doi:10.1111/mcn.12221.
- Perinatal Services BC. 2016. "Informal Peer-to-Peer Milk Sharing: The Use of Unpasteurized Human Donor Milk." Vancouver, BC: Author. Retrieved March 10, 2017. <http://www.perinatalservicesbc.ca/Documents/Guidelines-Standards/HealthPromotion/InformalMilkSharing_PracticeResource.pdf>.
- Quebec. 2013. *The Quebec Act Respecting Héma-Québec and the Biovigilance Committee* (CQLR, chapter H-1.1). Retrieved October 21, 2017. <<http://legisquebec.gouv.qc.ca/en/ShowDoc/cs/H-1.1>>.
- Quigley, M. and W. McGuire. 2014. "Formula Versus Donor Breast Milk for Feeding Preterm or Low Birth Weight Infants." *Cochrane Database of Systematic Reviews* 4: 1–96.
- Stevens, J. and S.A. Keim. 2015. "How Research on Charitable Giving Can Inform Strategies to Promote Human Milk Donations to Milk Banks." *Journal of Human Lactation* 31(3): 344–47.
- The Guardian. 2017. "Cambodia Bans Export of Human Breast Milk After US Operation Raises Concerns". *The Guardian*. <<https://www.theguardian.com/world/2017/mar/28/cambodia-breast-milk-us-export-ambrosia-labs>>.
- William, T., H. Nair, J. Simpson and N. Embleton. 2016. "Use of Donor Human Milk and Maternal Breastfeeding Rates: A Systematic Review." *Journal of Human Lactation* 32(2): 212–20. doi:10.1177/0890334416632203.
- Yee, W.H., A.S. Soraisham, V.S. Shah, K. Azir, W. Yoon and S.K. Lee. 2012. "Incidence and Timing of Presentation of Necrotizing Enterocolitis in Preterm Infants." *Pediatrics* 129(2): e298–304. doi:10.1542/peds.2011-2022.

Join the conversation



@longwoodsnotes



youtube.com/LongwoodsTV



pinterest.com/longwoods



facebook.com/LongwoodsPublishingCorporation

Medicare Cost Drivers during the 2004–2014 Health Accord Period in Canada: What Is the Evidence?

Inducteurs de coûts pour l'assurance maladie pour la période 2004–2014 de l'Accord sur la santé au Canada : quels sont les faits?



RUOLZ ARISTE, PHD

PhD Candidate

Researcher, Université Laval and Université du Québec en Outaouais (UQO)

Gatineau, QC

Abstract

As per the *Canada Health Act*, hospital and physician services (Medicare) are covered by the public sector. With the 2004 First Minister's Health Accord showcasing a 10-Year Plan to strengthen healthcare in Canada, significant investments have been made to improve access to these services. The average annual growth rate (AAGR) of spending between 2004 and 2014 was 5.1% for hospitals and 6.6% for physicians. The key policy question is whether or not these increases were just used to boost unit cost? An accounting approach was used to address this issue. Results suggest that for hospitals, wage per hour for staff (excluding physicians) accounted for 49% of the AAGR for hospitals (2.5 percentage points [pp]), while fee increases accounted for 47% of the AAGR for physician spending (3.1 pp). However, considering that general inflation was on average 1.8% per year, the health premium for physicians represented almost twice that for hospital staff.

Résumé

Conformément à la *Loi canadienne sur la santé*, les services hospitaliers et médicaux sont couverts par le secteur public. Avec l'Accord 2004 des premiers ministres sur la santé, qui présente un plan de 10 ans pour le renforcement des services de santé au Canada, d'importants investissements ont été faits afin d'améliorer l'accès aux services. Le taux de croissance annuel moyen (TCAM) des dépenses entre 2004 et 2014 était de 5,1 % pour les hôpitaux et de 6,6 % pour les médecins. La grande question de politiques publiques est de savoir à quel point ces augmentations ont servi à gonfler le coût unitaire. Une démarche comptable a été utilisée pour traiter cette question. Les résultats suggèrent que pour les hôpitaux, le salaire horaire des employés (à l'exception des médecins) a compté pour 49 % du TCAM de l'hôpital (2,5 points de pourcentage [pp]), tandis que l'accroissement des coûts comptait pour 47 % du TCAM des dépenses pour les médecins (3,1 pp). Cependant, puisque l'inflation générale était en moyenne de 1,8 % par année, la prime santé des médecins représente presque le double de celle des employés des hôpitaux.

Introduction

During the last 20 years, healthcare spending has gained increasing attention from policy makers in Canada and other industrialized countries because of its rising trends, both in dollar values and as a percentage of national income. Given government fiscal constraints, public spending on health is of particular interest. As per the *Canada Health Act*, a federal act that specifies the conditions and criteria with which the provincial and territorial health insurance programs must conform to receive federal health transfer payments, hospital and physician services in Canada (Medicare) are universally covered by the public sector. With the 2004 First Minister's Health Accord showcasing a 10-Year Plan to strengthen healthcare in Canada, significant investments have been made to increase operational capacity, improve access and reduce wait time for these services (CBC 2016). This situation makes the 2004–2014 period an interesting one on which to focus. The combined average annual growth rate (AAGR) of Medicare services between 2004 and 2014 was 5.6%. For the same period, the Gross Domestic Product (GDP) grew at an average annual rate of 4.1%.

Based on the fact that Medicare spending has grown faster than GDP, some studies suggest that publicly funded healthcare would not leave room for growth for other important government programs and therefore is unsustainable (Drummond and Derek 2010; Skinner and Rovere 2008).¹ On the other hand, others argue that GDP growth can shoulder the spending pressures from healthcare (Lee 2007; Ruggeri 2006) and it is basically a question of public choice (Evans 2007; Romanow 2002). So, there are different perspectives on the issue of sustainability (Di Matteo 2010). Nonetheless, Medicare spending growth can be broken down into different factors in order to assess the weight of each one relative

to total growth. A few studies have addressed the physician cost drivers issue in Canada (CIHI 2011; Contandriopoulos and Perroux 2013; Grant and Hurley 2013). However, cost drivers for Medicare services combined have not been studied, particularly in the context of the 2004–2014 Health Accord.

The objective of the study is to determine whether increases in spending were used mainly to boost unit prices or to buy more services over the 2004–2014 period. In fact, an increase in expenditure may arise from a price change, which can be caused by a higher compensation rate for staff. On the other hand, it can be caused by increased utilization of healthcare services due to demographic, morbid, technological or fiscal changes. The distinction between these two components of expenditure changes can be the key information in the process of finding policy solutions to the health sustainability issue because increased utilization of quality health services may improve access to health services and health outcomes. Cost drivers are those underlying factors that have an impact on healthcare costs. They include the effects of general and sector-specific inflation, population growth, aging and other utilization-related factors such as income or fiscal capacity, morbidity, new technologies, etc. Health decision-makers have only minimal control on some of these factors, such as general inflation and aging, while they can exercise a greater control on others, such as sector-specific inflation or new technologies.

Some drivers are more pronounced during the expansion phase of the business cycle (fluctuation of economic activity) than during the contraction phase. The 2004–2014 period can be seen as a complete business cycle, as it includes both an expansion and a contraction period. After the 2008 recession, due to fiscal constraints, governments tended to rein in healthcare costs, which could result in weak growth in hospital and physician spending or services. Breaking down spending growth on Medicare services over the 10-year Health Accord period can inform policy makers about what the additional money has bought, independent of the business cycle. The rest of the report is organized as follows: section 2 presents an overview of the data and methodology for the assessment of the impact of different factors on healthcare costs; in section 3, we review the level and growth rate of Medicare spending; the impact of the different factors – sector-specific inflation, population growth, aging and others – is assessed and discussed in section 4; section 5 addresses the limitations of the study and is followed by the conclusion.

Methods

The main data sources were the National Physician Database (NPDB), the Canadian Management Information System (MIS) Database (CMDDB) and the National Health Expenditures Database (NHEX) from the Canadian Institute for Health Information (CIHI). The Survey of Employment, Payroll and Hours (SEPH), Economic Accounts and Demography Division data from Statistics Canada were also used. The framework for the analysis consists of breaking down Medicare spending growth into its different measurable components, by using the natural logarithm of the following equation:

$$\text{Total spending}_i = \text{Unit cost}_i \times \frac{\text{Volume of service}_i}{\text{Population}} \times \text{Population (1)}$$

Where *i* refers to either the hospital or the physician sector.

Change in unit cost permits to determine sector-specific inflation (including general inflation). Population change in this equation refers not only to change in the size of the population (population growth), but also to change in its structure (aging). Note that the volume of services, which is a key factor in assessing cost drivers, is not explicitly measured in this paper. It is proxied by the residual called “utilization/other” which is adjusted for demographic factors (population growth and aging) and includes factors such as technology, fiscal capacity, morbidity, etc.

Sector-specific inflation is measured using SEPH (for hospital staff) and NPDB compensation index (for physicians). General inflation is measured by the consumer price index (CPI); all-items. The use of a price index to deflate expenditures is generally controversial. The all item-CPI was chosen because it takes into account all the consumer goods and services; therefore, it is a better representation of the general public. Moreover, it is a well-known index generally used to assess changes in the cost of living and adjust government programs such as pensions.

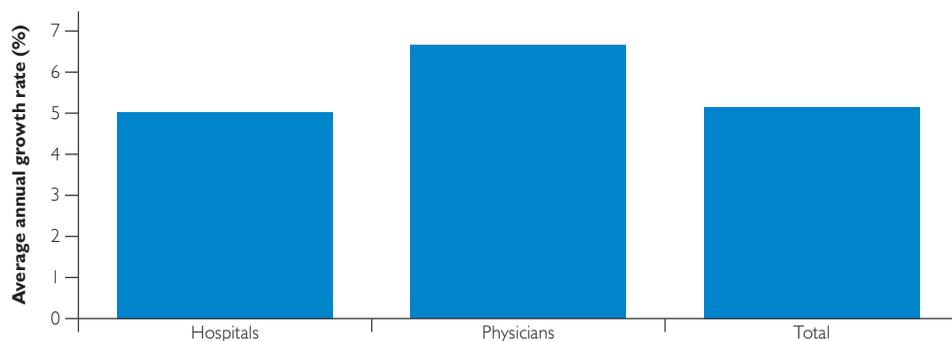
For the aging effect, the 2004 population, broken down by province, gender, and 5-year age groups, was multiplied by the 2014 expenditure per capita for each of the corresponding age group and sex. The results were summed for each sex. The totals for each sex were added to have the 2014 estimates of expenditure at the 2004 population structure (simulated expenditures).

After these factors have been estimated, the other factors such as technological change, fiscal capacity, level of morbidity, etc., are considered as a residual. The latter is referred in some studies as the enrichment factor (Askari et al. 2010; Constant et al. 2011). It should be noted that the framework used in the current study is relatively similar to the one used in several studies on healthcare cost drivers (Barer and Evans 1983; CIHI 2011; Newhouse 1992).² This paper innovates in the sense that it pulls hospital-based payments to physicians out of hospital spending and re-allocates it to physician spending, offering a complementary, more comprehensive way to consider physician spending. Moreover, the accounting decomposition approach and the CPI-adjustment applied to Medicare spending in this pivotal moment in the Canadian healthcare system represents a contribution in the analysis of health spending.

What Was the Level, Growth Rate and Share of Medicare Spending?

Public sector hospital spending amounted to \$35.3 billion in 2004 and \$57.7 billion in 2014. This represents an AAGR of 5.1%. As for physicians, spending was \$17.0 and \$32.3 billion, respectively, in 2004 and 2014, corresponding to an AAGR of 6.6%. Combining the two results in an amount of \$52.3 and \$90.0 million for Medicare spending, respectively, in 2004 and 2014; an AAGR of 5.6%. Figure 1 shows that AAG of physician spending was higher than that of hospitals or total spending.

FIGURE 1. Average annual growth rate of hospital, physicians and total public sector spending, 2004–2014



Sources: The National Physician Database and the National Health Expenditure Database from the Canadian Institute for Health Information.

Public sector total spending was estimated at \$152 billion in 2014; of which Medicare spending represents a share of 59.3% (37.9% for hospitals and 21.3% for physicians). The physician spending in this figure excludes physicians working in hospitals. That’s because the NPDB scope captures only physicians paid under the medical care plan (MCP). Compensation for physicians on hospital budget is not captured in NPDB. Even if we have chosen NHEX as a source for physician spending, those physicians on hospital budget would have still been excluded. In fact, in the NHEX framework, physicians on hospital budget are captured in the hospital category, and not in the physician category.

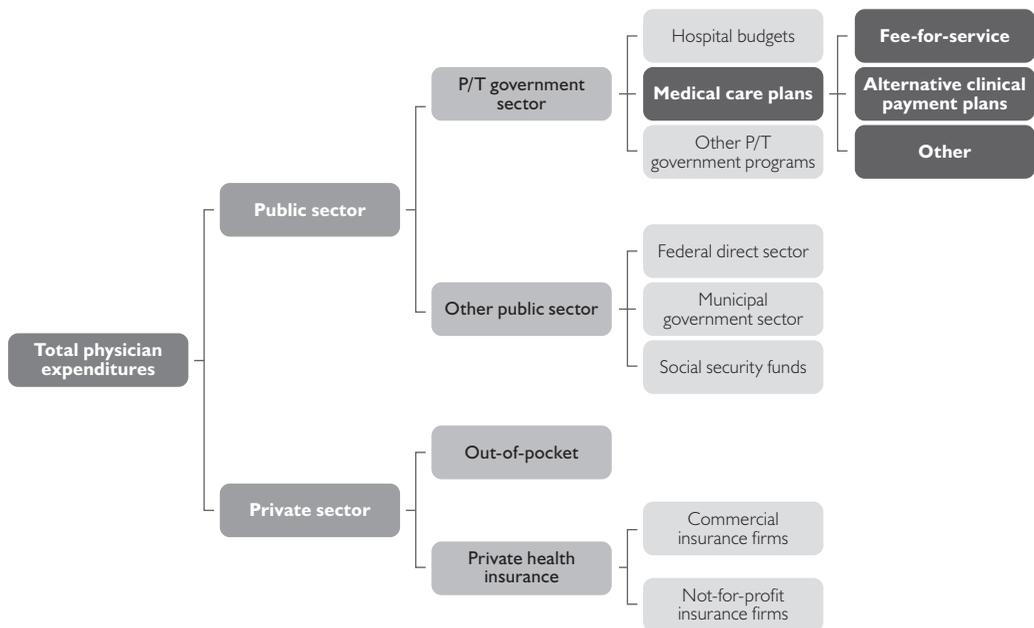
In order to know how much Canada spends on physician services, it is not enough to take the NPDB or NHEX figure for physicians, because neither is comprehensive of all physician expenditures in the country. The physician payment reported in NPDB includes only the amount reimbursed by the MCP. On the other hand, the physician category reported in NHEX is not comprehensive of all physician expenditures in the country. Canada’s National Health Accounts are based on an international system of health accounting that includes the hospital category expenditures for the services of physicians that are employed and paid by hospitals. Figure 2 presents a modified framework that pulls hospital-based payments to physicians out of hospital spending and re-allocates it to physician spending. It shows expenditures by all major sources of finance in Canada.

Table 1 is based on this structure and shows a more comprehensive distribution of physician expenditure that includes estimates of payments to physicians paid through the major sources of finance from 2004–2005 to 2014–2015. With the inclusion of physician expenditure paid through hospital budgets, overall expenditure on physician services in Canada is estimated to have been \$38.1 billion in fiscal year 2014–2015, or 17.7% of total health spending (\$37.7 billion from public sector or 24.8% of total public sector health spending).

Based on this framework, estimate of expenditure paid through hospital budgets amounted to \$4.9 billion (or 13.0% of public spending on medical care) in fiscal year 2014. Much of this expenditure is for the salaries of doctors such as pathologists, radiologists, medical biochemists and medical microbiologists, who are employed and paid by hospitals rather than by the provincial or territorial medical care plan. The \$37.7 billion on physician

public-sector spending in 2014 includes physicians on hospital budgets, MCP as well as “Other Public Sector” spending on physicians, such as direct medical services financed by the federal government for targeted populations (e.g., the Indigenous population), and medical aid expenditures financed by social security funds such as Workers Compensation Boards. This represents a share of 24.8% of public sector total spending; a 3.5-percentage point (pp) increase compared to the NPDB limited scope or the NHEX framework (of course, Medicare spending remains at the same level of \$90.0 billion, which means that hospital spending was proportionally reduced).

FIGURE 2. Sources of finance of physician services



P/T = provincial/territorial.

The nuance described above permits to distinguish between the AAGR of spending on physicians working in hospitals (on hospital budgets) versus those who are non-hospital based on MCP, either fee-for-service (FFS) or alternative payment plans (APPs). Figure 3 presents the AAG of compensation for hospital personnel: unit-producing personnel (UPP), management and operational support (MOS) and medical personnel (MP) as well as FFS physicians.

Spending on hospital-based physicians grew at an AAGR of 7.1% during the 10-year period under study while it was 6.6% for physicians paid under the MCP, 5.7% for physicians on FFS and 10.4% for physicians on APP (remember that this AAGR in spending could be due to unit price increase, volume of services or a combination of both). Even though the AAGR was the lowest for physicians on FFS, it was still higher than that of other professionals working in hospitals. However, higher pace of growth in payment for physicians on APP in the MCP or on hospital budgets suggests that the FFS scheme in the MCP has become less attractive.

TABLE 1. Physician expenditure, by source of finance, Canada, from 2004–2005 to 2014–2015

Year	Public sector							Private sector (NHEX table C.2.1)	Total (including physicians working in hospitals)
	P/T government sector					Other public sector (NHEX table C.5.1)	Total public sector		
	Paid through hospital budgets (CMDB-MP Comp)	Paid through MCPs		Other P/T government programs (residual)	Subtotal				
		Fee-for-service payments	Alternative clinical payments			E (A + B + C + D)	F		
A	B	C	D	E (A + B + C + D)	F	G (E + F)	H	I (G + H)	
Year	Expenditure (\$'000,000,000)								
2004–2005	2.4424	10.3959	2.6444	3.9354	19.4181	0.3362	19.7543	0.2324	19.9867
2005–2006	2.7389	11.1141	2.9611	4.1566	20.9707	0.3849	21.3556	0.2539	21.6095
2006–2007	3.0912	11.5753	3.3761	4.7294	22.7720	0.4246	23.1966	0.3040	23.5006
2007–2008	3.4306	12.1583	4.1292	4.9823	24.7004	0.4362	25.1366	0.2442	25.3808
2008–2009	3.8791	12.9207	5.0061	5.5086	27.3144	0.4956	27.8100	0.3903	28.2004
2009–2010	4.1661	13.9944	5.2832	5.9553	29.3990	0.4923	29.8913	0.3981	30.2895
2010–2011	4.3030	14.7025	5.8004	6.6005	31.4065	0.5174	31.9239	0.2959	32.2198
2011–2012	4.5778	15.7414	6.3568	6.6565	33.3326	0.5206	33.8532	0.3642	34.2174
2012–2013	4.6681	16.1430	6.7152	6.6500	34.1763	0.5377	34.7139	0.4432	35.1572
2013–2014	4.8127	17.1534	6.9370	7.0484	35.9514	0.5219	36.4733	0.3898	36.8631
2014–2015	4.8787	17.8832	7.0973	7.3332	37.1925	0.5159	37.7084	0.4092	38.1176

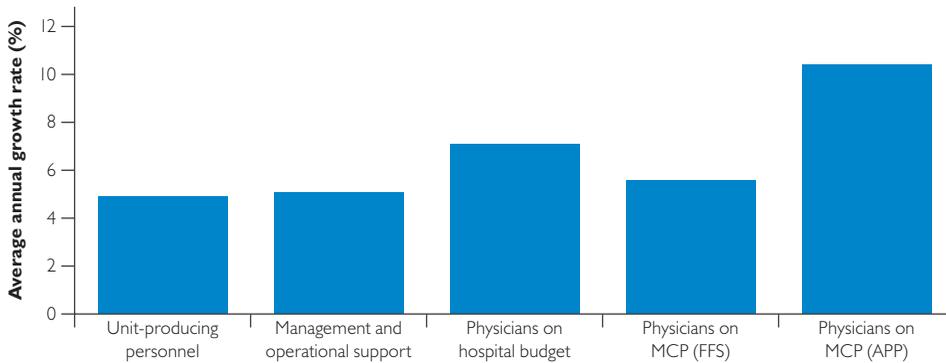
MCPs = medical care plans; MP = medical personnel; P/T = provincial/territorial.
 Sources: The Canadian Management Information System Database (CMDB), the National Physician Database and the National Health Expenditure Database (NHEX) from the Canadian Institute for Health Information.

What is the Contribution of Different Factors to Increases in Medicare Spending?

As previously mentioned, AAGR in hospital and physician spending has been estimated, respectively, at 5.1% and 6.6% for the years 2004 and 2014. Figure 4 shows the contribution of each factor to this overall increase.

In the case of hospitals, wage per hour for staff (excluding physicians) accounted for 2.5 pp of the total AAGR while demographic factors were responsible for 2.2 pp (1.1 pp for population growth and 1.1 pp for aging). The residual (0.4 pp) is attributed to other factors such as increased use due to technology, mix of services, level of morbidity, etc. As for physicians, average unit fee was responsible for 3.1 pp of the total AAGR; demographic factors accounted for 1.8 pp (1.1 pp for population growth and 0.7 pp for aging). This leaves 1.7 pp for other factors (among others, higher number of physicians) and suggests that unit cost was a relatively important cost driver in hospital and physician spending growth.

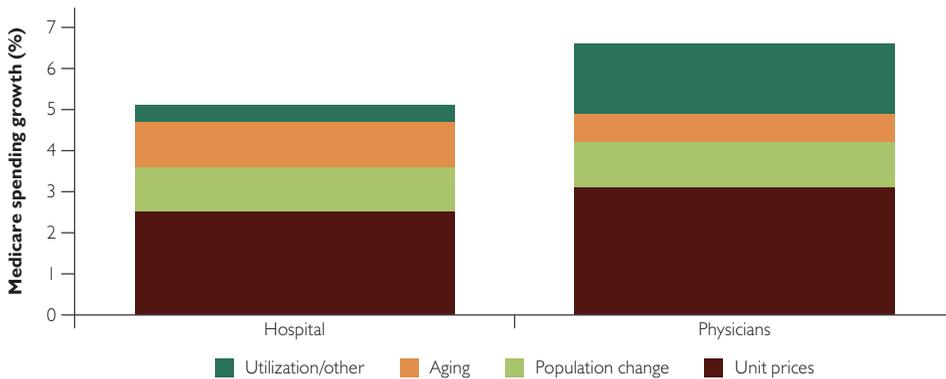
FIGURE 3. Average annual growth of compensation for hospital personnel (unit-producing personnel, management and operational support, and medical personnel) and physicians on MCP



APP = alternative payment plan; FFS = fee-for-service; MCP = medical care plan.

Sources: The Canadian Management Information System Database and the National Physician Database from the Canadian Institute for Health Information.

FIGURE 4. Breaking down Medicare spending growth, 2004–2014



Sources: The Canadian Management Information System Database, the National Physician Database and the National Health Expenditure Database from the Canadian Institute for Health Information, and the Survey of Employment, Payroll and Hours (Demography Division) from Statistics Canada.

Sector-specific inflation, including general inflation

It should be noted that AAG in unit cost represents sector-specific inflation. As such, it includes two components: general inflation and a “health premium” defined as inflation above and beyond general inflation.

$$\text{Health premium} = \text{Sector-specific inflation} - \text{General inflation (2)}$$

Considering that general inflation (as measured by the CPI—all items) was on average 1.8% per year, growth in inflation-adjusted unit cost for physicians was 1.3% per year. This can be considered as a “health premium” for physicians which represented almost twice that for hospital staff.

Population growth and aging

Population growth and aging are two demographic factors responsible for increasing health-care costs. Population growth, which was on average 1.1% per year over the 2004–2014 period, has been traditionally accounted for in healthcare funding. On the other hand, aging arises from changes in the population distribution that results in a larger fraction of the population being in the older, high-health-cost age groups, for a given profile of health expenditures across age. The aging effect, which is not usually considered in healthcare funding, accounted, respectively, for 21.6% and 10.6% of the growth in hospital and physician spending.

Other factors

As previously stated, the “Other” category is a residual, which may include utilization-related factors such as: technology, fiscal capacity, efficiency level, etc. This section provides an overview of possible impact of these utilization-related factors in driving costs.

Technological change is commonly believed to be one of the factors responsible for increases in health spending because of price rigidity and latent demand that leads to increased utilization. The size of its effect is difficult to quantify² and its role in driving healthcare costs is not a clear-cut picture (Sorenson et al. 2013). The RAND Corporation suggests that two related policy goals should be pursued when addressing medical technology as a cost driver: (1) reduce total healthcare spending with the smallest possible loss of health benefits, and (2) ensure that new medical products that increase spending are accompanied by health benefits that are worth the spending increases (Garber et al. 2014).

Between 2004 and 2014, real GDP per capita has increased at an AAGR of 0.8% in Canada (CANSIM Tables from Statistics Canada: 384-0037 for nominal GDP at market prices, 380-0102 for GDP index and 051-0001 for population). In terms of Medicare, this *fiscal capacity* was translated to increase the number of earned hours for hospital staff (1.0% when adjusted for population) as well as the number of physicians (1.7% when adjusted for population). More physicians would translate into more services. AAGR in total number of services adjusted for population growth and aging was estimated at +0.5%.³ From the payer perspective, efficiency in providing Medicare services should also be considered. A crude measure of productivity that is commonly used is the number of output per hour (or in the health sector: number of services per full-time equivalent [FTE] worker). In the case of physicians, crude productivity may have decreased because of the significant increase in the number of physicians (Ariste 2015).⁴ However, quality-adjusted output generally results in an increase in productivity compared to crude productivity (which is not adjusted for quality). This could give a different picture of physician productivity. Baumol (2012) suggests that crude productivity is more pertinent when we want to know how much money consumers must pay for a product (if we want to know how desirable the product is, then quality-adjusted productivity is more appropriate). In the case of hospitals, no measure of crude productivity is available for the period under study. However, Gu and Morin (2012) estimate that labour productivity, based on a quality-adjusted output, has increased 2.6% annually over the 2002–2010 period.

Discussion and Policy Implications

Cost drivers are generally complex and it's even more the case for the category "Other." Factors should be interpreted as estimated contribution. Although discussed separately, they can interact with each other to form sophisticated dynamics. For example, technology and efficiency tend to interact and reinforce each other. Likewise, technology and fiscal capacity can interact, resulting in an overall interaction among the three. Nonetheless, these results are generally in line with other similar studies which found that unit price is the main driver of physician spending (CIHI 2011; Grant and Hurley 2013).⁵ The "Other" (enrichment) factor was also an important one in the literature (Constant et al. 2011).

Increased federal spending through the Canada Health Transfer tends to increase provincial Medicare spending because of the sheer expectation of wage/fee increase by unions and medical associations. It is not surprising to see almost half the increase in Medicare spending being driven by wage/fee increase. Federal government could negotiate a percentage increase in hourly wage/unit fee during the existence of a particular health accord that should not exceed that expected in the general economy or in the public sector, as suggested by Leonard and Sweetman (2015).

Our finding suggests that the FFS scheme in the MCP has become less attractive. This could be exacerbated by the fact that physicians on this scheme generally incur higher overhead costs than their counterparts on APP or hospital budgets. Even though this study does not make the distinction between family medicine physicians and specialists, the differing rates in payments likely matter more for family medicine physicians than specialists (the reason is that throughout time, the latter inherently benefit more from technological progress and consequently can produce more services per unit of time [Ariste 2015]). This could lead to a shortage of family medicine physicians willing to start practising in the FFS scheme, as recently suggested in a *CBC News* article for Nova Scotia (Ray 2017).

Limitations of the study

Sector-specific inflation for hospitals is measured from payroll data. While compensation made up to 74% of hospital costs, there are other items involved in running a hospital, such as drugs, medical equipment and supplies, etc. These items were not disaggregated into unit price and volume. However, given their relatively weaker weight, they would not substantially change the main results.

Physician compensation represents gross payments. Physicians incur overhead costs that should be accounted for. To the extent that these costs remained proportionally the same throughout time, this should not significantly alter the results. Using the Physician Office category in the SEPH, hourly wage for employees in physician offices has increased at an AAGR of 2.6%; virtually the same as for hospital employees and less than the unit price of physician services. While overhead costs include other components, their growth is not likely to surpass the 3.1% AAG in unit fee for physician services, which suggests that the "health premium" is not likely reduced by considering overhead costs.

Conclusion

This paper has reviewed the role of different factors in explaining Medicare spending growth. Unit price was a relatively important factor that accounts for the overall spending increase. In the case of both hospitals and physicians, it was responsible for almost 50% of the total cost increase. Yet, this unit price increased more substantially for physicians than for hospital staff, which translates to a physician “health premium” of 1.3 pp (almost twice that of hospital staff). Aging did not represent a major cost driver for the Medicare system (about 11% of total cost increase for physicians, but up to 22% for hospitals). Other factors such as technological change or fiscal capacity (e.g., higher number of health workers per capita) accounted for about 26% of the overall growth for physician spending, but only 8% for hospital spending. Key issues to watch for in the future include ensuring that unit price increases for Medicare services stay in-line with that in the rest of the economy or better, get adjusted for technological improvement (e.g., if a given procedure originally took one hour to perform and thanks to technological improvement now takes 15 minutes, the time is reduced by 75%. The unit fee could be reduced by 10%, not by the full 75%, to allow for equipment amortization, learning curve cost and providers’ incentives); breaking silos between hospital and physician spending for resource allocation that targets relatively similar unit price for physicians on FFS, APP or hospital budgets in a given specialty; and population aging having a potentially higher impact on Medicare expenditures at the peak of the baby boom effect.

Correspondence may be directed to: Ruolz Ariste, Université Laval and Université du Québec en Outaouais (UQO), 283 Boulevard Alexandre Taché, PO Box 1250, Hull division, local C3700 Gatineau, QC J8X 3X7; tel.: 819-595-3900 ext. 1894; e-mail: arir03@uqo.ca.

Acknowledgement

The author wishes to acknowledge Geoff Ballinger from CIHI for his contribution to the modified framework to comprehensively capture physician expenditures. However, the views expressed in the paper are those of the author and do not represent those of any institution or other person.

Notes

1. A well-accepted definition of sustainability used by various authors is the “sufficiency of resources over the long term to provide timely access to quality services that address Canadians’ evolving health needs” (Marchildon et al. 2004).
2. Health economists have tried to decompose individual cost drivers using two main approaches: regression-based or accounting-based. In the regression-based approach, the typical method is to estimate a linear regression model of healthcare expenditures on a set of known cost drivers, such as demographics, income, price inflation and variables, intended to capture the residual component directly, such as R&D spending (AGPC 2005; Okunade and Murthy 2002), or indirectly, such as year dummies (Di Matteo 2005; Grootendorst and Nguyen 2011) or a linear time trend (Di Matteo 2010). This residual is generally believed to

include mostly technological change. The accounting approach approximates the annual rate of change in spending as the sum of the annual rates of change in the respective cost drivers. The unexplained portion is considered a residual. This approach is a good approximation of the discrete changes in cost drivers actually seen in the data, has been prominently used and is more easily understood by policy makers. It has been chosen for these reasons.

3. Volume of services per capita by physicians on FFS has slightly declined (on average -0.05% per year) (CIHI 2017). However, when accounting for physicians on APP (by assuming same unit fee as physicians on FFS), the volume of services has increased, even when adjusted for population growth and aging.
4. For example, the number of FFS FTE physicians increased at an AAGR of 0.7% when adjusted for population. This suggests that the number of physicians on APP has also increased during the 2004–2014 period (CIHI 2017).
5. For example, the CIHI study found that unit price was responsible for 53% of the AAGR of physician spending between 1998 and 2008. Grant and Hurley (2013) looked at the historical trends to find out that the gap between an average doctor and the average worker's pay increased from three-and-a-half times to nearly four-and-a-half times between 2000 and 2010. They noted that all of this has occurred while physicians have actually provided slightly fewer services to patients. The level of decomposition for hospital spending is not so much detailed in the literature.

References

- Australian Government Productivity Commission (AGPC). 2005. *Impacts of Advances in Medical Technology in Australia*. Melbourne, AU: Author.
- Ariste, R. 2015. "Fee-Schedule Increases in Canada: Implication for Service Volumes among Family and Specialist Physicians." *Journal of Health and Human Service Administration* 38(3): 381–407.
- Askari, M., R. Barnett, J. Danforth, C. Matier, B. Recker and S. Tapp. 2010. *Fiscal Sustainability Report*. Ottawa, ON: Parliamentary Budget Officer.
- Barer, M.L. and R.G. Evans. 1983. "Prices, Proxies and Productivity: An Historical Analysis of Hospital and Medical Care in Canada." In Diewert, W.E. and C. Montmarquette, eds., *Price Level Measurement: Proceedings from a Conference Sponsored by Statistics Canada*. Ottawa, ON: Statistics Canada.
- Baumol, W.J. 2012. *The Cost Disease: Why Computers Get Cheaper and Health Care Doesn't*. New Haven, CT: Yale University Press.
- Canadian Institute for Health Information (CIHI). 2011. *Healthcare Cost Drivers – the Facts*. Ottawa, ON: Author.
- Canadian Institute for Health Information (CIHI). 2017. "National Physician Database Data Release, 2015–2016." Ottawa, ON: Author.
- CBC News. 2016 (December 19). *What is the Health Accord and What's at Stake in Monday's Talks?* Retrieved December 10, 2017. <<http://www.cbc.ca/news/politics/federal-health-accord-1.3903027>>.
- Constant, A., S. Petersen, C. Mallory and J. Major. 2011. *Research Synthesis on Cost Drivers in the Health Sector and Proposed Policy Options*. Ottawa, ON: Canadian Health Services Research Foundation.
- Contandriopoulos, D. and M. Perroux. 2013. "Fee Increases and Target Income Hypothesis: Data from Quebec on Physicians' Compensation and Service Volumes." *Healthcare Policy* 9(2): 30–35.
- Di Matteo, L. 2005. "The Macro Determinants of Health Expenditure in the United States and Canada: Assessing the Impact of Income, Age Distribution and Time." *Health Policy* 71(1): 23–42.

- Di Matteo, L. 2010. "The Sustainability of Public Health Expenditures: Evidence from the Canadian Federation." *European Journal of Health Economics* 11(6): 569–84. doi:10.1007/s10198-009-0214-x.
- Drummond, D. and B. Derek. 2010. *Charting a Path to Sustainable Health Care in Ontario: 10 Proposals to Restrain Cost Growth without Compromising Quality of Care*. Toronto, ON: TD Economics.
- Evans, R.G. 2007. *Economic Myths and Political Realities: The Inequality Agenda and the Sustainability of Medicare*. Vancouver: UBC for Centre Health Services and Policy Research.
- Garber, S., S.M. Gates, E.B. Keeler, M.E. Vaiana, A.W. Mulcahy, C. Lau et al. 2014. *Redirecting Innovation in U.S. Health Care: Options to Decrease Spending and Increase Value*. Santa Monica, CA: RAND Corporation.
- Grant, H. and J. Hurley. 2013. *Unhealthy Pressure: How Physician Pay Demands Put the Squeeze on Provincial Healthcare Budgets* (Volume 6, Issue 22). Calgary, AB: The School of Public Policy Research Papers, University of Calgary.
- Grootendorst, P. and V.H. Nguyen. 2011. *Health Technologies as a Cost-Driver in Canada. Final Report to the Strategic Policy Branch, Office of Pharmaceuticals Management Strategies, Health Canada*. Retrieved December 6, 2017. <<http://individual.utoronto.ca/grootendorst/pdf/grootendorst-et-al-final-report.pdf>>.
- Gu, W. and S. Morin. 2012. *Experimental Measures of Output and Productivity in the Canadian Hospital Sector, 2002 to 2010*. Ottawa, ON: Statistics Canada. Retrieved November 23, 2017. <<http://www.statcan.gc.ca/pub/15-206-x/15-206-x2014034-eng.pdf>>.
- Lee, M. 2007. *How Sustainable is Medicare? A Closer Look at Aging, Technology and Other Cost Drivers in Canada's Health Care System*. Vancouver, BC: Canadian Centre for Policy Alternatives.
- Leonard, P. and A. Sweetman. 2015. "Paying the Health Workforce." In G.P. Marchildon and L. Di Matteo, eds. *Bending the Cost Curve in Health Care: Canada's Provinces in International Perspective*. Toronto, ON: University of Toronto Press.
- Marchildon, G.P., T. McIntosh and P.-G. Forest (eds). 2004. *The Fiscal Sustainability of Health Care in Canada. The Romanow Papers Vol. 1*. Toronto, ON: University of Toronto Press.
- Newhouse, J. 1992. "Medical Care Costs: How Much Welfare Loss?" *Journal of Economic Perspectives* 6(3): 3–21.
- Okunade, A.A. and V.N.R. Murthy. 2002. "Technology as a 'Major Driver' of Health Care Costs: A Cointegration Analysis of the Newhouse Conjecture." *Journal of Health Economics* 21(1): 147–59.
- Ray, C. 2017. "Why Young Doctors Aren't Taking over from Retiring Physicians." *CBC News*, November 7, 2017. Retrieved December 6, 2017. <<http://www.cbc.ca/news/canada/nova-scotia/why-young-doctors-aren-t-taking-over-from-retiring-physicians-1.4389906>>.
- Romanow, R.J. 2002. *Building on Values: The Future of Health Care in Canada*. Ottawa, ON: Commission on the Future of Health Care in Canada.
- Ruggeri, J. 2006. "Health Care Spending, Fiscal Sustainability, and Public Investment." *Public Policy Paper*. Regina, SK: Saskatchewan Institute of Public Policy.
- Skinner, B.J. and M. Rovere. 2008. *Paying More, Getting Less. Measuring the Sustainability of Government Health Spending in Canada 2008 Report*. Vancouver, BC: Fraser Institute. Retrieved November 17, 2017. <<https://www.fraserinstitute.org/sites/default/files/PayingMoreGettingLess2008.pdf>>.
- Sorenson, C., M. Drummond and B.B. Khan. 2013. "Medical Technology as a Key Driver of Rising Health Expenditure: Disentangling the Relationship." *ClinicoEconomics and Outcomes Research* 5: 223–34. doi:10.2147/CEOR.S39634.

The Medical Devices Special Access Program in Canada: A Scoping Study

Programme canadien d'accès spécial aux instruments médicaux : étude de l'étendue



ROLAND K. MAIER, BSc, MLT

Graduate Student

School of Public Health, University of Alberta

Edmonton, AB

DEVIDAS MENON, PhD, MHSA

Professor, Health Technology and Policy Unit

School of Public Health, University of Alberta

Edmonton, AB

TANIA STAFINSKI, MSc, PhD

Director, Health Technology and Policy Unit

School of Public Health, University of Alberta

Edmonton, AB

Abstract

New health technologies enter Canadian healthcare organizations in various ways, and understanding them is essential to the development of a pan-Canadian Health Technology Management (HTM) Strategy, now a priority of governments across Canada. One way is through Health Canada's Medical Devices Special Access Program (MDSAP), which permits unlicensed devices to be obtained by healthcare professionals. However, the circumstances around and implications of the current use of this program are not clear. A scoping literature review was conducted to clarify these and identify important roles and issues related to the MDSAP. Limited information was found on the MDSAP. Nevertheless, three themes demonstrating the roles of the MDSAP in HTM emerged: arbiter in technology selection, a route to technology procurement and facilitator of health technology innovation.

No information suggesting that MDSAP is used to circumvent licensing was found. Rather, it enables desired patient outcomes and product commercialization.

Résumé

Les nouvelles technologies de la santé font leur entrée dans les organismes de santé de plusieurs façons qu'il est essentiel de comprendre pour le développement d'une stratégie pancanadienne pour la gestion des technologies de la santé (GTS), laquelle est devenue une priorité pour les gouvernements au Canada. Un des chemins d'entrée de ces technologies est le programme d'accès spécial aux instruments médicaux (PASIM) de Santé Canada, qui permet aux professionnels de la santé d'avoir accès à des instruments non homologués. Toutefois, les circonstances et les répercussions de l'usage actuel du programme ne sont pas claires. Ainsi, une revue de la littérature a été menée pour clarifier ces questions et déterminer les rôles et enjeux importants liés au PASIM. Peu d'informations ont été trouvées sur le PASIM. Néanmoins, trois thèmes se sont dégagés pour démontrer les rôles du PASIM dans la GTS : un arbitre pour le choix d'une technologie, une route pour l'obtention d'une technologie et un facilitateur d'innovation dans les technologies de la santé. Aucune information suggérant que le PASIM est employé pour éviter l'homologation n'a été trouvée. Il aide plutôt à atteindre les résultats souhaités pour les patients ainsi que la commercialisation d'un produit.

ALTHOUGH HEALTHCARE ORGANIZATIONS ACROSS CANADA HAVE MADE SIGNIFICANT progress in developing health technology assessment (HTA) systems, there has been growing concern that their capacity to better manage health technology, more broadly, is lacking. In December 2016, the Federal/Provincial/Territorial Conference of Deputy Ministers of Health tasked the Canadian Agency for Drugs and Technologies in Health (CADTH) to propose a pan-Canadian health technology management (HTM) strategy. HTM extends beyond HTA, and essentially involves the management of a health technology through its life cycle (research and development, HTA, adoption, use and disinvestment). According to the 2017–2018 Business Plan of CADTH, one priority initiative is the transition of CADTH to an HTM enterprise, which is “an organization that supports real-world decision-making at all levels, monitors drug and non-drug utilization over the technology lifecycle, and supports implementation at the policy and practice levels” (CADTH 2017).

HTM requires knowledge of how new health technologies enter organizations. A recent survey of 47 healthcare organizations across Canada revealed a variety of mechanisms, one of which was the MDSAP (Report to Health Canada, funded through a Contribution Agreement #6804-15-2013/10810069; Stafinski et al. 2017). Other mechanisms include piloting (providing a technology for a fixed number of cases) and clinical trials under protocol; neither of these involves the SAP process.

The MDSAP is laid out in Part 2 of the Canadian *Medical Devices Regulations* under the *Food and Drugs Act* – Custom-Made Devices and Medical Devices Imported or Sold for Special Access (defined as “access to a medical device for emergency use or if conventional therapies have failed, are unavailable or are unsuitable”) (Government of Canada 1985, 1998b; McAllister and Jeswiet 2003; Gibson and Lemmens 2015). While the program has existed for almost 20 years, how it has been perceived and used remain unclear.

The objective of this study was to determine the landscape of information related to the MDSAP in Canada using scoping review methodology, and gain insights into its role in HTM.

Methods

The scoping study approach (initially developed in 2005 by Arksey and O’Malley) was selected because it is ideally suited to situations where the field of evidence is anticipated to be small and when a wide range of research and non-research material needs to be consulted (Anderson et al. 2008; Davis et al. 2009; Levac et al. 2010). It consists of an iterative design with up to six stages.

Stage 1 – Identify the research question

The study question was developed iteratively while simultaneously keeping in constant focus the underlying aims of the review (Mays et al. 2005). Because the overall aim was to understand broadly what scholarly work had been done to date, and what the sources, volume and types of information were, the research question was defined as, “What is known from the existing literature about Health Canada’s Medical Devices Special Access Program (MDSAP)?”

Stage 2 – Identify relevant studies

The search for relevant material was not limited to peer-reviewed sources, as the research purpose was to capture the breadth and range of information available. A list of keywords was developed iteratively, and a search strategy developed with the assistance of an information specialist. For peer-reviewed references, 13 electronic bibliographic databases were searched. A number of approaches to searching the grey literature were attempted with Google Scholar providing the most fruitful results. Links within web pages were also explored.

Searches were conducted between April 2015 and December 2017 (see Appendix 1, available at: <https://www.longwoods.com/content/25398>).

Stage 3 – Select studies

As recommended by Levac et al. (2010), the broad research question was then “[combined] with a clearly articulated scope of inquiry in order to guide the search strategy and establish parameters around study selection and data extraction.” Inclusion and exclusion criteria were developed *post hoc* and were applied to all material by two reviewers. Material was considered in-scope if it related directly to Health Canada’s MDSAP, including custom-made devices accessed through

the program. Conversely, material was considered out-of-scope if it did not meet the inclusion criteria. Topics that were explicitly identified as being out of scope included:

- programs from other countries;
- special access programs for drugs or biologics (e.g., blood products);
- investigational trials access;
- healthcare delivery programs;
- off-label use (when a technology has received marketing approval for one indication but is used for another indication); or
- reimbursement mechanisms.

Press releases, patents, book chapters and non-English material were also excluded.

Importantly, the quality of the material was not formally assessed and did not form a basis for exclusion.

Stage 4 – Chart the data

A standardized form was developed to record extracted information (see Appendix 2, available at: <https://www.longwoods.com/content/25398>). Two reviewers independently pilot-tested the form prior to full use. It contained two sections: one for general data (type and purpose of document, location, date of publication, authorship and sponsorship or affiliation disclosure) and one for specific data about medical devices (device name, type, and manufacturer; dates and quantities used) where these were provided.

Stage 5 – Collate, summarize and report the results

Two separate “maps” were produced (Davis et al. 2009). The first, a literature map, characterized the range and depth of literature. The second, a device map, compiled the MDSAP-authorized medical devices found in the literature and categorized them by medical specialty using the Preferred Name Code classification system used by Health Canada (Health Canada 2006)

In addition to these two mapping constructs, a thematic analysis using open coding based on first impressions of the data (Saldana 2012) and synthesis was conducted, which yielded a concept map (Attride-Stirling 2001; Gale et al. 2013; Thomas and Harden 2008).

Stage 6 – Consult expert opinion

A subject matter expert consultation exercise was conducted. In stable contexts such as the health management field, relevant stakeholders are often “visible” (Varvasovsky and Brugha 2000), and the aim in selecting stakeholders is to secure competencies rather than to assure representativeness of all possible interest groups (Welp et al. 2006). Accordingly, individuals with extensive background in regulatory affairs and Health Canada’s MDSAP were required. A representative from the medical devices industry and a regulator were consulted.

The subject matter experts were presented with background information on study rationale, methods and preliminary findings, and were asked to consider the completeness of the literature search and to identify additional references (Levac et al. 2010). No respondent identified any additional resources.

Results

Literature map

A total of 173 documents were retrieved (see Appendix 3, available at: <https://www.longwoods.com/content/25398>).

Medical device map

No single source of information comprehensively listed the names of all medical devices obtained through the MDSAP. Information published by Health Canada was limited to national aggregate numbers of device applications processed annually (Health Canada 2013, 2014).

Fifty-three devices were identified, although some devices had more than one associated manufacturer or vendor because of corporate mergers and acquisitions. Forty-one of these devices were in the cardiovascular category (see Appendix 4, available at: <https://www.longwoods.com/content/25398>).

Literature themes

Most of the peer-viewed papers that were found focused on individual technologies, and not on the MDSAP, which was frequently referenced only as the means to obtain access to the unlicensed technology. However, basic themes still emerged, and were categorized into organizing themes and then into “global” themes. The resulting concept map contained the following three global themes described below (Figure 1).

THEME #1: THE MDSAP AS AN ARBITER IN HEALTH TECHNOLOGY SELECTION, PLAYING AN “APPROVAL” ROLE

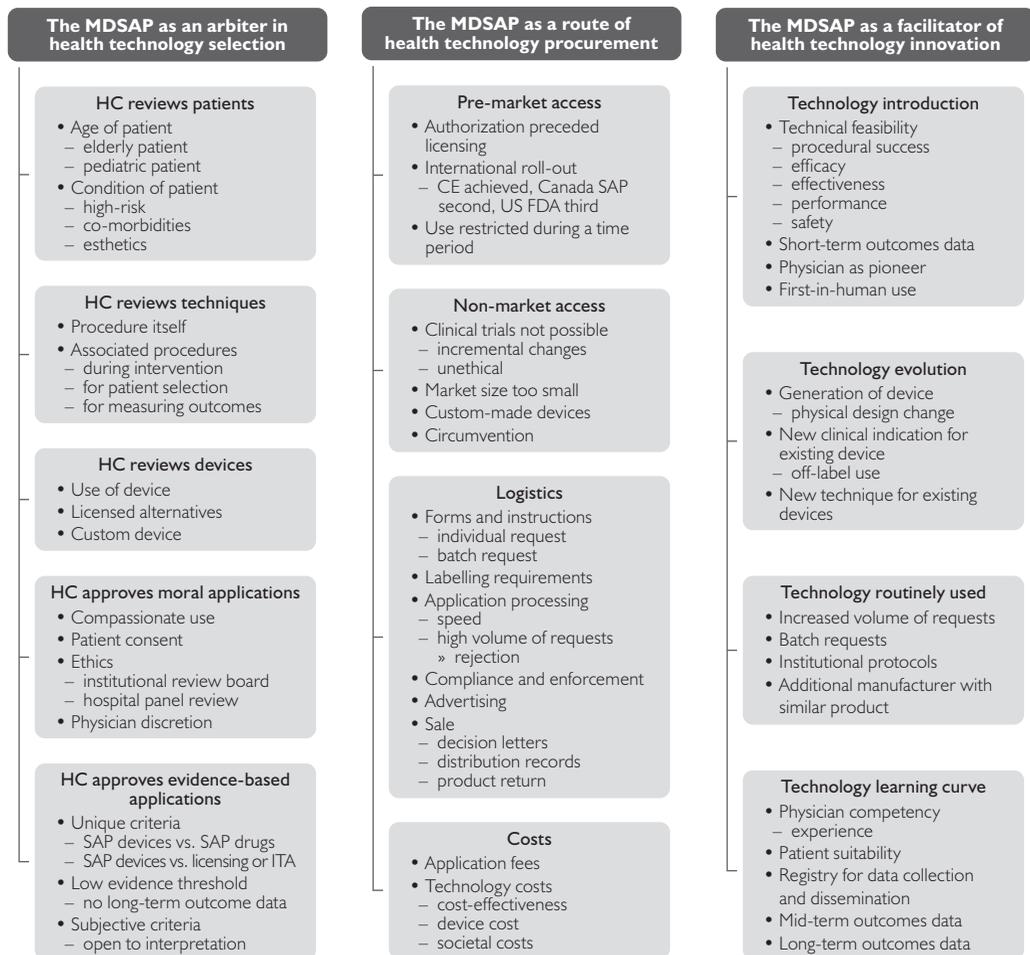
1.1 APPROVAL IS FOR PATIENTS AND CLINICAL INDICATIONS

The MDSAP provides approval for the patient as an individual, not patients in aggregate or at the population level, and is described as having “a single patient focus” (Health Canada 2007). “... all patients received approval to have surgery from Health Canada on the Special Access Program ...” (Pop et al. 2002). In addition, small batches of devices for multiple individuals may be approved on a case-by-case basis (Health Canada 2014).

Many authors indicated that patient eligibility was dependent upon the clinical indication (Amat-Santos et al. 2015; Basmadjian et al. 2016; Campelo-Parada et al. 2016; Chu et al. 2016; de Varennes et al. 2016; Gonzalez-Barlatay et al. 2017; Peters 2002; Rodés-Cabau et al. 2010; Sapp et al. 2013; Saw et al. 2015, 2017; Webb et al. 2006). Peters (2002) explained that MDSAP “provides approval for the use of silicone gel implants for the following patients: mastectomy, augmentation after failed saline implants (usually with ripples and

fold) and primary augmentation if a saline failure is strongly predicted. Health Canada has not approved the use of gel implants for general use.” More recently, de Varennes et al. (2016) reported that “These cases were not ‘run-of-the-mill’ AVR [aortic valve replacements]. Health Canada would not have authorized us to use a valve in that setting.”

FIGURE 1. Concept map derived through thematic synthesis of the literature



CE = European Conformity; FDA = Food and Drug Administration; HC = Health Canada; ITA = investigational trial access; MDSAP = Medical Devices SAP; SAP = Special Access Program.

1.2 APPROVAL IS FOR TECHNIQUES AND PROCEDURES

Regarding percutaneous aortic valve implantation, Webb et al. (2006) wrote, “The procedure was approved by the Therapeutic Products Directorate, Department of Health and Welfare, Ottawa, Canada, for compassionate clinical use ...”

Further examples include needle ablation (Sapp et al. 2013), left atrial appendage closure (Regueiro et al. 2017; Saw et al. 2015) and left atrial decompression (Amat-Santos et al. 2015). Some authors attributed approval of not only a procedure but also an entire program to the MDSAP. “In 2005, the Canadian TAVI [transcatheter aortic valve implantation]

program was approved by the Department of Health and Welfare (Ottawa, Ontario, Canada) for compassionate clinical use ..." (Rodés-Cabau et al. 2010).

1.3 APPROVAL IS FOR DEVICES

The MDSAP approves the use of unlicensed alternatives to licensed medical devices when they are perceived to be clinically superior (Almashham et al. 2008; Abraham et al. 2012; Bagur et al. 2016; Campelo-Parada et al. 2016; Humpl et al. 2010; Nietlispach et al. 2010; Raymond et al. 2001; Regueiro et al. 2017; Ricci et al. 2017; Saw et al. 2017). Peters' (2002) review of breast implants noted the availability of two types of implants: saline-filled (comprising 95% of implants), which were licensed, and gel-filled (5%), which, at the time, were unlicensed. Gel-filled implants were being used for "patients with exceptional circumstances, who received approval on compassionate grounds, because the quality of their final results would be more compromised with saline implants ... than with gel implants."

The uniqueness of the device (Is it sufficiently different from a licensed alternative?) was a consideration in approval. Minor variations in design and incremental improvements were considered insufficient for granting approval (Health Canada 2016).

The MDSAP also approves custom-made devices (Government of Canada 1998b; Health Canada 2016). Two examples are custom-made endovascular stents (Lioupis et al. 2012; Mewhort et al. 2011; Nietlispach et al. 2010) and a custom-made device for atrial septal defect closure (Gonzalez-Barlatay et al. 2017).

1.4 APPROVAL DEPENDS UPON MORAL JUDGMENTS

"Compassionate use" was noticeably absent in government documents, but in primary studies, justification for MDSAP approval often related to compassion (Cheung et al. 2010; Cheung et al. 2014). Ricci et al. (2017) stated that the MDSAP was intended to offer treatment "in a patient population that had no other therapeutic option."

The requirement for patient consent is found in the "Undertaking" section of the application form. However, Health Canada has recognized that it has no jurisdictional authority in this area, because patient consent is established in the physician-patient relationship, and regulated at the provincial/territorial level through colleges of medicine (Government of Canada 2007). Soon et al. (2011) wrote, "The prosthesis was approved for compassionate use by the department of Health and Welfare, Ottawa, Canada, in consenting patients declined for conventional reoperative surgery." Similarly, Gurvitch et al. (2010) wrote, "All patients were approved on a compassionate-use basis and gave written informed consent."

Institutional review was not a requirement for approval, but was mentioned as being sought in select cases (Basmadjian et al. 2016; Chu et al. 2017; Del Trigo et al. 2016a). Asch (2002) noted, "In cases in which it was deemed that filter removal had to be postponed beyond 12 weeks for a medical indication, specific approval from both the ethics department and the Health Protection Branch was sought and granted." The requirement for approval from all three parties was noted by Dahdah et al. (2007). "Given the investigational

status of the device used in this case report, approval was obtained from an institutional government-designated pediatric ethics committee and from the Canadian Special Access Programme of the Therapeutic Products Directorate, Health Canada. Parental written informed consent was obtained prior to the intervention.”

1.5 APPROVAL DEPENDS UPON EVIDENCE ADEQUACY

Approval depends upon satisfying minimum evidence requirements as defined by Health Canada. Its Special Access Unit, with scientific reviewers and medical experts in the Bureau, decides on authorization based on the medical rationale provided and other information available (Health Canada 2016). These evidence requirements are unique to the MDSAP because of their separate position (in Part 2) within the Medical Devices Regulations. A number of documents described this evidentiary uniqueness through comparisons with other programs.

Health Canada (2007) noted: “Separate regulatory provisions for drugs and devices have created inconsistencies between two programmes even though they have the same overarching intention, namely to provide emergency use access to products unavailable on the Canadian market.” Walker et al. (2014) concluded that many jurisdictions have “a lower evidentiary standard for devices compared to drugs.”

Two articles compared the denial of a request for AIDS drugs with the approval of requests for breast implants and argued that there was less evidence of benefit to breast implant recipients (cosmetic) than there was to AIDS drug recipients (life-saving) (Christie and Montaner 2006; Government of Canada 2006b).

Differences in evidence requirements for investigational testing, licensing and obtaining devices via special access were also raised. As indicated by Health Canada, “Medical devices authorized under Special Access do not undergo the same level of scrutiny required to obtain a medical device license or an authorization for investigational testing” (Health Canada 2016).

Evidence thresholds were seen as being open to interpretation. A report of the Standing Committee on Health captured this sentiment with a committee member’s question, “So I am wondering how you can determine that the risk is acceptable and therefore offer breast implants to all these women without having any long-term studies?” (Government of Canada 2005b).

THEME #2: THE MDSAP AS A ROUTE OF HEALTH TECHNOLOGY PROCUREMENT

2.1 PRE-MARKET ACCESS

The MDSAP provided an early route for professionals to access unlicensed products which subsequently were licensed, e.g., the Thermablate™ endometrial ablation technology (Vilos and Edris 2007) and the product Bio-Alcamid™ (Ellis and Sardesai 2008). Both were first used through MDSAP before receiving regulatory approval. More recently, Health Canada has stated that although the SAP plays a role by providing access to products that have not yet obtained market authorization (Health Canada 2007), it is not intended as an “early market access” route for devices that are still in trials, still in development or awaiting licensure (Health Canada 2016). However, the rapid increase in the number of requests

to the MDSAP in recent years (see Section 2.3 below) may suggest its use as a mechanism for achieving early market access.

However, the MDSAP does appear to play a role in commercialization based on the sequential licensing of a device at an international level. The product may have been licensed in one jurisdiction and obtained via special access before receiving market approval in Canada or an additional jurisdiction. The Amplatzer Plug III (a CE-marked device) was accessed via MDSAP in Canada while under evaluation by the Food and Drug Administration in the US (Jilaihawi and Ibrahim 2010). A second example was the international roll-out of Thermablate, initially approved for sale by the State Drug Administration in China and also used to treat 54 women in Canada via the MDSAP before it received licensing. Approval for sale in Europe with CE marking followed (Yackel and Vilos 2004).

A variation of the pre-market access concept was the case of silicone gel implants, whereby the products were initially licensed, then withdrawn from the market and obtained only by SAP and later marketed again after additional studies had demonstrated the products were safe (Brown et al. 2005; Hall-Findlay 2011; Spear and Hedén 2007).

2.2 NON-MARKET ACCESS

Certain devices obtained through the MDSAP have never been licensed in Canada. Accumulating the clinical evidence needed for market approval is sometimes seen as an insurmountable barrier. For heart valves, Webb et al. (2010) explained, “It is unlikely that we will see rigorous testing of all potential combinations of available surgical and transcatheter valve types, frames configurations, and sizes.” Interventions to treat rare diseases are also difficult to evaluate through clinical trials, because of the small number of patients (Walker et al. 2014). Custom-made devices are also challenging to evaluate for efficacy because each device is designed specifically for one individual (Klepinski 2006; Lioupis et al. 2012).

Also, Canada represents a small potential market (e.g., the CE-labelled Innogenetics Inno-LIA HIV I/II Score, an unlicensed assay, can only be obtained through the SAP [Kadivar et al. 2013]).

2.3 LOGISTICS

The logistics of procurement were described in several papers, including Health Canada’s recently issued Guidance document (Health Canada 2016). Collectively, they provide information relevant to manufacturers, importers and healthcare professionals on topics such as: applicant qualifications, individual and batch requests, advertising, labelling, purchasing and sale, return of unused products, etc., within the context of the MDSAP.

The volume of SAP requests is also a logistics issue. In 2004, the Auditor General’s report stated: “In 2002, Health Canada received 5,000 requests through the Special Access Program, a 683 percent increase in the last four years. Since the staff who process requests through the Special Access Program are the same as those who conduct pre-market evaluations, time spent dealing with these requests is time taken away from working on pre-market

evaluations” (Government of Canada 2004). Health Canada (2016) similarly advised, “the Special Access Unit experiences a high volume of requests and follow-up communications,” and the Therapeutic Products Directorate’s annual performance reports drew attention to the application processing metrics of the MDSAP (Health Canada 2013; Health Canada 2014).

2.4 COSTS

The two relevant types of costs associated with the MDSAP are program costs and device costs. Devices being requested through MDSAP are exempt from application fees on the basis of the determination that “these devices have been exempted ... for public good reasons” (Government of Canada 1998a). It is not clear how institutions pay for them, but Health Canada has offered guidance on two matters: (1) devices do not have to be provided free of charge by the manufacturer and (2) cost savings of the device are not an adequate justification for granting access (Health Canada 2016). Only one study of cost-effectiveness of a device being acquired by SAP was found in the literature (Hancock-Howard et al. 2013).

Walker et al. (2014) discussed the cost of these devices to society from an ethical standpoint. “Potential cost burdens to society are difficult to predict as the funding implications of SAPs vary by location and program. Where health care payment systems are structured around evidence of safety, efficacy, and cost-effectiveness, SAPs have the potential to open the door to costly and unproven interventions, thereby subverting attempts to contain costs based on sound reasoning and evidence. Supplying unproven interventions entails opportunity costs; manufacturers may not develop alternative options and governments have less to spend on more effective interventions.”

THEME #3: THE MDSAP AS A FACILITATOR OF HEALTH TECHNOLOGY INNOVATION

3.1 TECHNOLOGY INTRODUCTION

The MDSAP enables access to emerging technologies (Government of Canada 2004; Health Canada and the Public Health Agency of Canada 2014; Health Canada 2016; Osten et al. 2010; Sinclair et al. 2013; Webb et al. 2006).

Several papers discussed technical feasibility, safety, procedural success rate, efficacy or short-term patient outcomes, all key information elements for technology uptake and diffusion (e.g., Chu et al. 2017; Helton et al. [2011] and Purdham et al. [2012] on cardiac valves; de Hemptinne et al. 2017; Saw et al. 2017). Health Canada has acknowledged the importance of publishing studies that report on such elements to communicate findings to the relevant clinical community (Health Canada 2016).

The MDSAP has also been used to facilitate first-in-man-use applications of devices for patients “who would otherwise have no clinical options” and were given “careful scrutiny” (Health Canada 2016). In 2005, during meetings of the Standing Committee on Health, the program was portrayed as providing access, with the healthcare professional described as the initiating force or the technology pioneer (Government of Canada 2005a, 2005b).

3.2 TECHNOLOGY EVOLUTION

The MDSAP provides access to evolving technologies (evolution of the device or of its use). In several papers, device evolution was phrased in the language of “generations,” such as the third-generation HeartWare HVAD (Rao et al. 2013), second-generation endometrial ablation technologies (Vilos and Edris 2007) or second-generation transcatheter aortic valve (Bagur et al. 2016) or in terms of improvement or evolution in time (Purdham et al. 2012; Stein and Stein 2014; Velasco-Sanchez et al. 2013). Device evolution was expressed in terms of novel techniques or additional clinical indications. For example, Osten et al. (2010) described how TAVI evolved from an antegrade transvenous transseptal approach to percutaneous retrograde transfemoral and antegrade transapical approaches. Occasionally, off-label use was reported as being intertwined with special access use: “The use of CSs [covered stents] in this study were obtained as an off-label application through a special-access government medical programmer [sic] (Kundu et al. 2011).” However, Health Canada distinguishes between the two and provides oversight of off-label use through the Investigational Testing provisions of Part 3 of the regulations (Health Canada 2016).

3.3 TECHNOLOGY ROUTINELY USED

The MDSAP can influence the path of a technology to routine use. In some cases, after the first MDSAP approval, requests for the device have accelerated, as its adoption became more widespread. TAVI was one of the most documented technologies accessed through the MDSAP in Canada, its use rising exponentially as it became well-established for treating select patients (Del Trigo et al. 2016b; Jilaihawi et al. 2012). Silicone breast implants experienced a large increase in use in Ontario between 2000 and 2005 as plastic surgeons gained confidence in their safety (Snell et al. 2008).

Health Canada’s position on the general use of devices obtained via SAP is that health-care facilities should not expect to obtain individual devices on an ongoing basis, and that SAP approval does not suggest that the device is appropriate or suitable for general use (Health Canada 2016). However, batch requests for devices routinely required in urgent, life-threatening circumstances are available on a case-by-case basis (Health Canada 2014).

3.4 TECHNOLOGY LEARNING CURVE

Many non-drug health technologies are associated with learning curves, of which an important component is appropriate patient selection (Zamorano et al. 2011). This is reported as being particularly true with MDSAP devices (Chu et al. 2017; Ricci et al. 2017; Soon et al. 2011; Wong et al. 2010). The MDSAP has advised that, where device training is required prior to use, the timing of training prior to submitting the SAP application should be considered (Health Canada 2016).

Once devices are accessed, there is limited monitoring (Government of Canada 2006a). To assist with the collection of outcomes data about specific new technologies, a number of registries have been created (Cribier and Zajarias 2008; Guerrero et al. 2015; Purdham et al. 2012).

Some papers referred to the MDSAP in terminology associated with research, such as the “Canadian special access trial” and “Canadian special access study” (Del Valle-Fernández et al. 2010; Hancock-Howard et al. 2013). Other research-oriented articles noted that the device was initially obtained via special access, and then became licensed. “During the initial portion of this study, the PED was only available through a Health Canada compassionate-use program (O’Kelly et al. 2013).”

Limitations

The limitations of this study include its reliance upon publicly available sources. There are two potential implications of this: (1) incompleteness of the medical devices identified and (2) over-representation of emerging technology and technology adoption themes, because of the nature of the research articles reviewed.

Discussion

The three global themes of technology selection, procurement and innovation determined through the scoping review suggest that the MDSAP is one mechanism of HTM in Canada. In most cases, medical devices adopted by health systems have received regulatory approval from Health Canada. However, based on the findings of the review, many enter the same systems each year through the MDSAP. Because HTM takes a life cycle approach, the MDSAP, therefore, becomes an important consideration.

Diffusion of innovations starts from individual use cases, where authorizations are granted on ethical grounds after assessment of safety, effectiveness and risk/benefit for *individuals*. While the MDSAP is not intended to be an early market access route for medical devices, it involuntarily plays that role. As additional authorized requests for the emerging technology continue to build the evidence base, a critical mass is reached that permits (or disqualifies) device licensing and marketing. This decision is now no longer made on the basis of optimal care for an *individual*, but on the ethical grounds of safety and effectiveness at the *population* level.

Thus, the special access program does not appear to be used to circumvent licensing and sale for general (population) use. The MDSAP allows an emerging or evolving technology to demonstrate that it has promise and gather support and momentum. Where evidence is limited, the healthcare professional bridges the evidence gap by providing the medical rationale to Health Canada on the application form. This enables ethically desired patient outcomes as well as product commercialization.

The findings from this scoping review suggest that the MDSAP may be an effective commercialization strategy for industry. By providing education and training in the use of new technologies to physician pioneers, industry has a commercialization route available for cases in which clinical trial data are difficult to obtain. Bates (2008) investigated similar programs in the pharmaceutical context, known in Europe as “named patient programmes,” and provided evidence that these programs were effective in increasing market share.

The review identified a number of evidence gaps and, in turn, areas for future research. They include investigating the magnitude and level of significance of the MDSAP in Canada.

To what extent does it shape the healthcare landscape – in which medical specialties or for which diseases? What is the health economic impact? It might be useful to take a different methodological approach (cf. a scoping review, such as this) to this, utilizing surveys and interviews of clinicians and industry representatives to get a deeper understanding of the SAP processes. Of note, in the area of custom-made devices, very little information is currently publicly available. Concept maps stratified by stakeholder groups should also be developed. The special access program is a unique federal route with a different mandate than the standard licensing route. Are the unique circumstances, opportunities and risks surrounding special access devices sufficiently understood at the provincial and territorial level? At the institutional level? And, as Bryan et al. (2014) implore, are they optimally managed?

Conclusion

This paper provides the first scoping review and analysis of publicly available information pertaining to the Canadian Medical Devices Special Access Programme. Because this route appears to be a preferred one for the early introduction of innovative and rapidly evolving medical devices, it is important to understand it in the context of developing a pan-Canadian HTM approach. Such an approach would require the review of devices along their life cycles, and not just at the entry phase. The MDSAP may provide a means of early study of such devices, with subsequent studies being conducted as the device evolves (e.g., to second and third generations) or the understanding of its characteristics and functionalities become more evident. The MDSAP may provide the opportunity to generate evidence on early use, and permit the modification of policy regarding its continued utilization.

Acknowledgements

We gratefully acknowledge the contributions provided by the subject matter experts during the consultative exercise in Stage 6. However, this paper does not claim to represent any reviewer's position. Responsibility for the content and conclusions of this study resides with the authors. We are also grateful to Leigh-Ann Topfer and Lynn Lacombe-Robinson for support with the literature searches.

Correspondence may be directed to: Roland K. Maier, School of Public Health, University of Alberta, 3021, Research Transition Facility, 8308-114 Street NW, Edmonton, AB T6G 2V2; tel.: 780-802-6892; fax: 780-248-1546; e-mail: rkmaier@ualberta.ca.

References

- Abraham, R.J., A.J. Illyas, T. Marotta, P. Casey, B. Vair and R. Berry. 2012. "Endovascular Exclusion of a Splenic Artery Aneurysm Using a Pipeline Embolization Device." *Journal of Vascular and Interventional Radiology* 23(1): 131–35. doi:10.1016/j.jvir.2011.09.015.
- Almashham, Y., N. Dahdah and J. Miro. 2008. "Use of Radiofrequency then Stent Implantation for Recanalization of Complete Aorta Coarctation." *Pediatric Cardiology* 29(1): 207–09. doi:10.1007/s00246-007-9090-2.

The Medical Devices Special Access Program in Canada: A Scoping Study

- Amat-Santos, I.J., S. Bergeron, M. Bernier, R. Allende, H.B. Ribeiro, M. Urena et al. 2015. "Left Atrial Decompression through Unidirectional Left-to-Right Interatrial Shunt for the Treatment of Left Heart Failure: First-In-Man Experience With the V-Wave Device." *EuroIntervention* 10(9): 1127–31. doi:10.4244/EIJY14M05_07.
- Anderson, S., P. Allen, S. Peckham and N. Goodwin. 2008. "Asking the Right Questions: Scoping Studies in the Commissioning of Research on the Organisation and Delivery of Health Services." *Health Research Policy and Systems* 6(1): 7. doi:10.1186/1478-4505-6-7.
- Arksey, H. and L. O'Malley. 2005. "Scoping Studies: Towards a Methodological Framework." *International Journal of Social Research Methodology* 8(1): 19–32. doi:10.1080/1364557032000119616.
- Asch, M.R. 2002. "Initial Experience in Humans with a New Retrievable Inferior Vena Cava Filter." *Radiology* 225(3): 835–44. doi:10.1148/radiol.2252011825.
- Attride-Stirling, J. 2001. "Thematic Networks: An Analytic Tool for Qualitative Research." *Qualitative Research* 1(3): 385–405.
- Bagur, R., P.J. Teefy, B. Kiaii, D. Diamantouros and M.W. Chu. 2016. "First North American Experience with the Transfemoral ACURATE-neo™ Self-Expanding Transcatheter Aortic Bioprosthesis." *Catherization and Cardiovascular Interventions* 90: 130–38.
- Basmadjian, L., A. Basmadjian, L.-M. Stevens, F.-P. Mongeon, R. Cartier, N. Poirier and I. El Hamamsy. 2016. "Early Results of Extra-Aortic Annuloplasty Ring Implantation on Aortic Annular Dimensions." *Journal of Thoracic and Cardiovascular Surgery* 151(5): 1280–85.e1.
- Bates, A.K. 2008. "Implementing a Pre-Launch Named Patient Programme: Evidence of Increased Market Share." *Journal of Medical Marketing: Device, Diagnostic and Pharmaceutical Marketing* 8(4): 319–24. doi:10.1057/jmm.2008.25.
- Brown, M.H., R. Shenker and S.A. Silver. 2005. "Cohesive Silicone Gel Breast Implants in Aesthetic and Reconstructive Breast Surgery." *Plastic and Reconstructive Surgery* 116(3): 768–79. doi:10.1097/01.prs.0000176259.66948.e7.
- Bryan, S., C. Mitton and C. Donaldson. 2014. "Breaking the Addiction to Technology Adoption." *Health Economics* 23(4): 379–83. doi:10.1002/hec.3034.
- CADTH. 2017. *CADTH 2017–2018 Annual Business Plan*. Retrieved December 10, 2017. <<https://www.cadth.ca/sites/default/files/pdf>>.
- Campelo-Parada, F., A. Regueiro, E. Dumont, R. DeLarochelière, J.-M. Paradis, S. Mhammedi et al. 2016. "Embolic Protection in Patients Undergoing Transaortic Transcatheter Aortic Valve Replacement: Initial Experience with the TriGuard HDH Embolic Deflection Device." *Journal of Cardiac Surgery* 31: 617–22.
- Cheung, A., J.K.F. Hon, J. Ye and J. Webb. 2010. "Combined Off-Pump Transapical Transcatheter Aortic Valve Implantation and Minimally Invasive Direct Coronary Artery Bypass." *Journal of Cardiac Surgery* 25(6): 660–62. doi:10.1111/j.1540-8191.2010.01081.x.
- Cheung, A., J. Webb, S. Verhey, R. Moss, R. Boone, J. Leipsic et al. 2014. "Short-Term Results of Transapical Transcatheter Mitral Valve Implantation for Mitral Regurgitation." *Journal of the American College of Cardiology* 64(17): 1814–19. doi:10.1016/j.jacc.2014.06/1208.
- Christie, T.K.S. and J.S.G. Montaner. 2006. "The Perverted Irony of Health Canada's Special Access Programme." *Canadian Medical Association Journal* 174(12): 1746.
- Chu, M.W., R. Bagur, P. Diamantouros, P.J. Teefy and B. Kiaii. 2016. "Early Clinical Outcomes with a Novel Self-Expanding Aortic Bioprosthesis in Patients at Higher Risk for Coronary Obstruction: First North American Experience with the ACURATE-AT System." *Canadian Journal of Cardiology* 32(10) (Suppl.1), S237.
- Chu, M.W., R. Bagur, K.L. Losenno, P.M. Jones, P. Diamantouros, P. Teefy et al. 2017. "Early Clinical Outcomes of a Novel Self-Expanding Transapical Transcatheter Aortic Valve Bioprosthesis." *Journal of Thoracic and Cardiovascular Surgery* 153(4): 810–18.
- Cribier, A. and A. Zajarias. 2008. "Transcatheter Aortic Valve Replacement: The Future is Here!" *Revista Española de Cardiología* 61(11): 1123–25.

- Dahdah, N., R. Ibrahim and L. Cannon. 2007. "First Recanalization of a Coronary Artery Chronic Total Obstruction in an 11-Year-Old Child with Kawasaki Disease Sequelae using the CROSSER Catheter." *Pediatric Cardiology* 28(5): 389–93. doi:10.1007/s00246-006-0083-3.
- Davis, K., N. Drey and D. Gould. 2009. "What are Scoping Studies? A Review of the Nursing Literature." *International Journal of Nursing Studies* 46(10): 1386–400. doi:10.1016/j.ijnurstu.2009.02.010.
- de Hemptinne, Q., E.M. Horlick, M.D. Osten, X. Millan, V.-X. Tadros, M. Pighi et al. 2017. "Initial Clinical Experience with the GORE® CARDIOFORM ASD Occluder for Transcatheter Atrial Septal Defect Closure." *Catheterization and Cardiovascular Interventions* 90: 495–503.
- de Varennes, B., K. Lachapelle, R. Cecere, I. Szczepkowski and J. Buithieu. 2016. "North American Single-Center Experience with a Sutureless Aortic Bioprosthesis." *Journal of Thoracic and Cardiovascular Surgery* 151(3): 735–42. doi:10.1016/j.jtcvs.2015.10.064.
- Del Trigo, M., S. Bergeron, M. Bernier, I.J. Amat-Santos, R. Puri, F. Campelo-Parada et al. 2016a. "Unidirectional Left-to-Right Interatrial Shunting for Treatment of Patients with Heart Failure with Reduced Ejection Fraction: A Safety and Proof-of-Principle Cohort Study." *Lancet* 387: 1290–96.
- Del Trigo, M., A. Dahou, J.G. Webb, D. Dvir, R. Puri, O.A. Altisent et al. 2016b. "Self-Expanding Portico Valve Versus Balloon-expandable SAPIEN XT Valve in Patients With Small Aortic Annuli: Comparison of Hemodynamic Performance." *Revista Española de Cardiología (English Edition)* 69: 501–08. doi:10.1016/j.rec.2015.08.019.
- Del Valle-Fernández, R., C.A. Martínez and C.E. Ruiz. 2010. "Transcatheter Aortic Valve Implantation." *Cardiology Clinics* 28(1): 155–68. doi:10.1016/j.ccl.2009.09.002.
- Ellis, D. and M.G. Sardesai. 2008. "Bio-Alcamid: An Alternative to Fat Transfer." *Facial Plastic Surgery Clinics of North America* 16(4): 429–33. doi:10.1016/j.fsc.2008.05.002.
- Gale, N.K., G. Heath, E. Cameron, S. Rashid and S. Redwood. 2013. "Using the Framework Method for the Analysis of Qualitative Data in Multi-Disciplinary Health Research." *BMC Medical Research Methodology* 13(1): 117.
- Gibson, S. and T. Lemmens. 2015. "The Promise and Peril of Adapting the Regulatory System to the Pharmacogenomic Context." *McGill Journal of Law and Health* 8(2): S145–S230.
- Gonzalez-Barlatay, F., A. Fournier, M.-J. Raboission and N. Dahdah. 2017. "Atrial Septal Defect Closure with Occlutech® ASD Fenestrated Device in a Child with Severe Pulmonary Hypertension." *Pediatric Cardiology* 38: 202–05.
- Government of Canada. 1985. *Food and Drugs Act (R.S.C. 1985. c. F-27)*. Retrieved January 31, 2017. <<http://laws-lois.justice.gc.ca/eng/acts/F-27/index.html>>.
- Government of Canada. 1998a. *Canada Gazette Part I*. Vol. 132, No. 24. Ottawa, ON. Retrieved January 28, 2017. <<http://publications.gc.ca/gazette/archives/p1/1998/1998-06-13/pdf/g1-13224.pdf>>.
- Government of Canada. 1998b. *Medical Devices Regulations (Consolidation) SOR/98-282*. Retrieved September 2, 2016. <<http://laws-lois.justice.gc.ca/PDF/SOR-98-282.pdf>>.
- Government of Canada. 2004. *March 2004 Report of the Auditor General of Canada: Chapter 2 – Health Canada Regulation of Medical Devices*. Retrieved September 4, 2016. <<http://www.oag-bvg.gc.ca/internet/docs/20040302ce.pdf>>.
- Government of Canada. 2005a. *38th Parliament, 1st Session, Number 045, Standing Committee on Health, Evidence, Thursday, June 2, 2005*. Retrieved January 31, 2017. <<http://www.parl.gc.ca/content/hoc/Committee/381/HESA/Evidence/EV1900397/HESA EV45-E.PDF>>.
- Government of Canada. 2005b. *38th Parliament, 1st Session, Number 051, Standing Committee on Health, Evidence, Thursday, October 27, 2005*. Retrieved September 4, 2016. <<http://www.parl.gc.ca/content/hoc/Committee/381/HESA/Evidence/EV2067614/HESA EV51-E.PDF>>.
- Government of Canada. 2006a. *39th Parliament, 1st Session, Number 028, Standing Committee on Health, Evidence, Tuesday, November 21, 2006*. Retrieved January 31, 2017. <<http://www.parl.gc.ca/content/hoc/Committee/391/HESA/Evidence/EV2528861/HESA EV28-E.PDF>>.
- Government of Canada. 2006b. *House of Commons Debates, Official Report, Thursday, November 9, 2006*. Retrieved September 4, 2016. <<http://www.parl.gc.ca/content/hoc/House/391/Debates/080/HAN080-E.PDF>>.

The Medical Devices Special Access Program in Canada: A Scoping Study

- Government of Canada. 2007. *39th Parliament, 1st Session, Number 036, Standing Committee on Health, Evidence, February 5, 2007*. Retrieved September 4, 2016. <http://www.parl.gc.ca/content/hoc/Committee/391/HESA/Evidence/EV2663348/HESA_EV36-E.PDF>.
- Guerrero, M., V.S. Mahadevan, P. Martinez-Clark, J. Rodes-Cabau, D. Ciaburriet, A. Greenbaum et al. 2015. "Transcatheter Mitral Valve Replacement with Balloon Expandable Valves in Native Mitral Valve Disease Due to Severe Mitral Annular Calcification: Results from the First Global Registry." *Journal of the American College of Cardiology* 66(15) (Suppl.): B291–92.
- Gurvitch, R., D.A. Wood, E.L. Tay, J. Leipsic, J. Ye, S.V. Lichtenstein et al. 2010. "Transcatheter Aortic Valve Implantation: Durability of Clinical and Hemodynamic Outcomes beyond 3 Years in a Large Patient Cohort." *Circulation* 122(13): 1319–27. doi:10.1161/circulationaha.110.948877.
- Hall-Findlay, E.J. 2011. "Breast Implant Complication Review: Double Capsules and Late Seromas." *Plastic and Reconstructive Surgery* 127(1): 56–66. doi:10.1097/prs.0b013e3181fad34d.
- Hancock-Howard, R.L., C.M. Feindel, J. Rodes-Cabau, J.G. Webb, A.K. Thompson and K. Banz. 2013. "Cost Effectiveness of Transcatheter Aortic Valve Replacement Compared to Medical Management in Inoperable Patients with Severe Aortic Stenosis: Canadian Analysis based on the PARTNER Trial Cohort B findings." *Journal of Medical Economics* 16(4): 566–74. doi:10.3111/13696998.2013.770747.
- Health Canada. 2006. *Guidance for Industry: Keyword Index to Assist Manufacturers in Verifying the Class of Medical Devices*. Retrieved September 2, 2016. <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/keyword_motscles2-eng.pdf>.
- Health Canada. 2007. *Special Access Programme Issue Identification Paper*. Retrieved September 2, 2016. <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/acces/sap_pas_ident-eng.pdf>.
- Health Canada. 2013. *Medical Devices Bureau Annual Performance Report Fiscal Year 2012–13: April 1, 2012 through March 31, 2013*. Ottawa, ON: Therapeutic Products Directorate.
- Health Canada. 2014. *Medical Devices Bureau Annual Performance Report: April 1, 2013 through March 31, 2014*. Ottawa, ON: Therapeutic Products Directorate.
- Health Canada. 2016. *Guidance for Health Care Professionals on Special Access and Custom-Made Medical Devices*. Retrieved September 2, 2016. <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/acces/sap-md-dg-as-im-ld-eng.pdf>.
- Health Canada and the Public Health Agency of Canada. 2014. *Evaluation of the Medical Devices Program 1999–2000 to 2011–2012*. Retrieved September 4, 2016. <http://www.hc-sc.gc.ca/ahc-asc/alt_formats/pdf/performance/eval/medical_devices-materiels_medicieux-eng.pdf>.
- Helton, T.J., S.R. Kapadia and E.M. Tuzcu. 2011. "Clinical Trial Experience with Transcatheter Aortic Valve Insertion." *International Journal of Cardiovascular Imaging* 27(8): 1143–54. doi:10.1007/s10554-011-9825-2.
- Humpl, T., S. Furness, C. Gruenwald, C. Hyslop and G. van Arsdell. 2010. "The Berlin Heart EXCOR Pediatrics—the Sickkids Experience 2004–2008." *Artificial Organs* 34(12): 1082–86. doi:10.1111/j.1525-1594.2009.00990.x.
- Jilaihawi, H., T. Chakravarty, R.E. Weiss, G.P. Fontana, J. Forrester and R.R. Makkar. 2012. "Meta-Analysis of Complications in Aortic Valve Replacement: Comparison of Medtronic-Corevalve, Edwards-Sapien and Surgical Aortic Valve Replacement in 8,536 Patients." *Catheterization and Cardiovascular Interventions* 80(1): 128–38. doi:10.1002/ccd.23368.
- Jilaihawi, H. and R. Ibrahim. 2010. "Complex Transcatheter Paravalvular Leak Repair." *Catheterization and Cardiovascular Interventions* 76(2): 194–97. doi:10.1002/ccd.22476.
- Kadivar, K., L. Malloch, Y. Adonsou-Hoyi, D. Ng, S. Lavoie, K. Pulido et al. 2013. "Would CLSI M53-A have helped in the Diagnosis of HIV in Canada? Results of the Performance of Canadian Laboratories Participating in a Recent NLHRS Proficiency Testing Panel Containing HIV-1 Antigen Positive (Antibody Negative) and HIV-2 Samples." *Journal of Clinical Virology* 58(1): 303–05. doi:10.1016/j.jcv.2013.04.009.
- Klepinski, R.J. 2006. "Old Customs, Ancient Lore: The Development of Custom Device Law through Neglect." *Food and Drug Law Journal* 61: 237–49.

- Kundu, S., M. Modabber, J.M. You, P. Tam, G. Nagai and R. Ting. 2011. "Use of PTFE Stent Grafts for Hemodialysis-Related Central Venous Occlusions: Intermediate-Term Results." *Cardiovascular and Interventional Radiology* 34(5): 949–57. doi:10.1007/s00270-010-0019-4.
- Levac, D., H. Colquhoun and K.K. O'Brien. 2010. "Scoping Studies: Advancing the Methodology." *Implementation Science* 5(1): 1–9. doi:10.1186/1748-5908-5-69.
- Lioupis, C., M.M. Corriveau, K.S. MacKenzie, D.I. Obrand, O.K. Steinmetz and C.Z. Abraham. 2012. "Treatment of Aortic Arch Aneurysms with a Modular Transfemoral Multibranched Stent Graft: Initial Experience." *European Journal of Vascular and Endovascular Surgery* 43(5): 525–32. doi:10.1016/j.ejvs.2012.01.031.
- Mays, N., C. Pope and J. Popay. 2005. "Systematically Reviewing Qualitative and Quantitative Evidence to Inform Management and Policy-Making in the Health Field." *Journal of Health Services Research and Policy* 10(Suppl. 1): 6–20.
- McAllister, P. and J. Jeswiet. 2003. "Medical Device Regulation for Manufacturers." *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine* 217(6): 459–67.
- Mewhort, H.E., J.J. Appoo, G.L. Sumner, E. Herget and J. Wong. 2011. "Alternative Surgical Approach to Repair of the Ascending Aorta." *Annals of Thoracic Surgery* 92(3): 1108–10. doi:10.1016/j.athoracsur.2011.01.092.
- Nietlispach, F., J. Leipsic, N. Wijesinghe, J.G. Webb and R.G. Carer. 2010. "First-in-Man use of a Tapered Endovascular Stent Graft for Treatment of Aneurysm after Coarctation Repair." *Catheterization and Cardiovascular Interventions* 76(7): 1035–40. doi:10.1002/ccd.22594.
- O'Kelly, C.J., J. Spears, M. Chow, J. Wong, M. Boulton, A. Weill et al. 2013. "Canadian Experience with the Pipeline Embolization Device for Repair of Unruptured Intracranial Aneurysms." *American Journal of Neuroradiology* 34(2): 381–87. doi:10.3174/ajnr.a3224.
- Osten, M.D., C. Feindel, M. Greutmann, K. Chamberlain, M. Meineri, B. Rubin et al. 2010. "Transcatheter Aortic Valve Implantation for High Risk Patients with Severe Aortic Stenosis Using the Edwards Sapien Balloon-Expandable Bioprosthesis: A Single Centre Study with Immediate and Medium-Term Outcomes." *Catheterization and Cardiovascular Interventions* 75(4): 475–85. doi:10.1002/ccd.22291.
- Peters, W. 2002. "The Evolution of Breast Implants." *Canadian Journal of Plastic Surgery* 10(5): 223–36.
- Pop, M., Y. Payette and M. Mansour. 2002. "Ultrasound Biomicroscopy of the Artisan Phakic Intraocular Lens in Hyperopic Eyes." *Journal of Cataract and Refractive Surgery* 28(10): 1799–803.
- Purdham, D.M., M.K. Natarajan, D.T. Ko, E.A. Chen, C. Feindel and K. Kingsbury. 2012. "Baseline Characteristics and In-Hospital Outcomes of TAVI in Ontario: Data from the Cardiac Care Network of Ontario (CCN) TAVI Registry." *Canadian Journal of Cardiology* 28(5): S158.
- Rao, V., J.F. Legare, R. Mac Arthur, J. Bashir, D. Freed, A. Cheung et al. 2013. "Multicenter Canadian Experience with the HeartWare HVAD." *Journal of Heart and Lung Transplantation* 32(4): S12.
- Raymond, J., F. Guilbert and D. Roy. 2001. "Neck-Bridge Device for Endovascular Treatment of Wide-Neck Bifurcation Aneurysms: Initial Experience 1." *Radiology* 221(2): 318–26. doi:10.1148/radiol.2212010474
- Regueiro, A., M. Bernier, G. O'Hara, K. O'Connor, J.-M. Paradis, J. Beaudoin et al. 2017. "Left Atrial Appendage Closure Initial Experience with the Ultraseal Device." *Catheterization and Cardiovascular Interventions* 90: 817–23.
- Ricci, D.R., J. de Vries and R. Blanc. 2017. "Role of Preliminary Registry Data in Development of a Clinical Trial of An Innovative Device: A Small But Integral Piece of a Health Policy Initiative." *Journal of Market Access & Health Policy* 5(1): 1283106.
- Rodés-Cabau, J., E. Dumont, D. Doyle and J. Lemieux. 2010a. "Transcatheter Valve-in-Valve Implantation for the Treatment of Stentless Aortic Valve Dysfunction." *Journal of Thoracic and Cardiovascular Surgery* 140(1): 246–48. doi:10.1002/ccd.22168.
- Saldana, J. 2012. *The Coding Manual for Qualitative Researchers* (2nd ed.). Thousand Oaks, CA: Sage Publishers.
- Sapp, J.L., C. Beeckler, R. Pike, R. Parkash, C.J. Gray, K. Zeppenfeld et al. 2013. "Initial Human Feasibility of Infusion Needle Catheter Ablation for Refractory Ventricular Tachycardia." *Circulation* 128(21): 2289–95. doi:10.1161/circulationaha.113.003423.

The Medical Devices Special Access Program in Canada: A Scoping Study

- Saw, J., P. Fahmy, P. DeJong, M. Lempereur, R. Spencer, M. Tsang et al. 2015. "Cardiac CT Angiography for Device Surveillance after Endovascular Left Atrial Appendage Closure." *European Heart Journal-Cardiovascular Imaging* 16(11): 1198–206. doi:10.1093/ehjci/jev067.
- Saw, J., P. Fahmy, L. Azzalini, J.-F. Marquis, B. Hibbert, C. Morillo et al. 2017. "Early Canadian Multicenter Experience with WATCHMAN for Percutaneous Left Atrial Appendage Closure." *Journal of Cardiovascular Physiology* 28: 396–401.
- Sinclair, A, X. Xie and M. McGregor. 2013. "Surgical Aortic Valve Replacement with the ATS Enable® Sutureless Aortic Valve for Aortic Stenosis." Montreal, QC: Technology Assessment Unit (TAU) of the McGill University Health Centre (MUHC). Report no. 71. 27p.
- Snell, L., N. Baxter and J.L. Semple. 2008. "A Survey of Attitudes of Ontario Plastic Surgeons Leading up to the Return of Silicone Implants." *Plastic and Reconstructive Surgery* 122(5): 148e–49e.
- Soon, J.L., J. Ye, S.V. Lichtenstein, D. Wood, J.G. Webb and A. Cheung. 2011. "Transapical Transcatheter Aortic Valve Implantation in the Presence of a Mitral Prosthesis." *Journal of the American College of Cardiology* 58(7): 715–21. doi:10.1016/j.jacc.2011.04.023.
- Spear, S.L. and P. Hedén. 2007. "Allergan's Silicone Gel Breast Implants." *Expert Review of Medical Devices* 4(5): 699–708. doi:10.1586/174334440.4.5.699.
- Stafinski, T., R. Deber, M. Rhainds, J. Martin, T. Noseworthy, S. Bryan and D. Menon. 2017. "Decision-Making on New Non-Drug Health Technologies (NDTs) by Hospitals and Health Authorities in Canada." Manuscript submitted for publication.
- Stein, R. and R. Stein. 2014. "Surgical Correction of Presbyopia: A Focus on New Techniques." *Ophthalmology Rounds* 10(6): 1–8.
- Thomas, J. and A. Harden. 2008. "Methods for the Thematic Synthesis of Qualitative Research in Systematic Reviews." *BMC Medical Research Methodology* 8(1): 1. doi:10.1186/1471-2288/8/45.
- Varvasovszky, Z. and R. Brugha. 2000. "A Stakeholder Analysis." *Health Policy and Planning* 15(3): 338–45.
- Velasco-Sanchez, D., A. Tzikas, R. Ibrahim and J. Miró. 2013. "Transcatheter Closure of Perimembranous Ventricular Septal Defects." *Catheterization and Cardiovascular Interventions* 82(3): 474–79. doi:10.1002/ccd.24361.
- Vilos, G.A. and F. Edris. 2007. "Second-Generation Endometrial Ablation Technologies: The Hot Liquid Balloons." *Best Practice and Research Clinical Obstetrics and Gynaecology* 21(6): 947–67. doi:10.1016/j.bpobgyn.2007.03.022.
- Walker, M. J., W.A. Rogers and V. Entwistle. 2014. "Ethical Justifications for Access to Unapproved Medical Interventions: An Argument for (Limited) Patient Obligations." *American Journal of Bioethics* 14(11): 3–15. doi:10.1080/15265161.2014.957416.
- Webb, J.G., M. Chandavimol, C.R. Thompson, D.R. Ricci, R.G. Carere, B.I. Munt et al. 2006. "Percutaneous Aortic Valve Implantation Retrograde from the Femoral Artery." *Circulation* 113(6): 842–50. doi:10.1161/circulationaha.105.582882.
- Webb, J.G., D.A. Wood, J. Ye, R. Gurvitch, J. Masson, J. Rodés-Cabau et al. 2010. "Transcatheter Valve-in-Valve Implantation for Failed Bioprosthetic Heart Valves." *Circulation* 121(16): 1848–57. doi:10.1161/circulationaha.109.924613.
- Welp, M., A. de la Vega-Leinert, S. Stoll-Kleemann and C.C. Jaeger. 2006. "Science-Based Stakeholder Dialogues: Theories and Tools." *Global Environmental Change* 16(2): 170–81. doi:10.1016/j.gloenvcha.2005.12.002.
- Wong, D.R., J. Ye, A. Cheung, J.G. Webb, R.G. Carere and S.V. Lichtenstein. 2010. "Technical Considerations to Avoid Pitfalls during Transapical Aortic Valve Implantation." *Journal of Thoracic and Cardiovascular Surgery* 140(1): 196–202. doi:10.1016/j.jtcvs.2009.07.081.
- Yackel, D.B. and G.A. Vilos. 2004. "Thermablate EAS: A New Endometrial Ablation System." *Gynecological Surgery* 1(2): 129–32. doi:10.1007/s10397-004-0011-6.
- Zamorano, J.L., L.P. Badano, C. Bruce, K. Chan, A. Gonçalves, R.T. Hahn et al. 2011. "EAE/ASE Recommendations for the Use of Echocardiography in New Transcatheter Interventions for Valvular Heart Disease." *Journal of the American Society of Echocardiography* 24(9): 937–65. doi:10.1016/j.echo.2011.07.003.

HEALTHCARE

POLICY

Politiques de Santé

Special Issues Free for the Reader

Approaches to Accountability

“... this set of papers raises important issues around the theme of accountability. First, it shows that accountability is still in its infancy – not because providers or organizations do not want to be accountable or that governing bodies do not want to make them accountable, but because identifying the right targets and establishing the right mechanisms to account for the utilization of healthcare resources is a complex task.” – Guest Editor Jean-Louis Denis

Going for the Gold

“MCHP (among other centres) has shown that privacy concerns are not the issue; nor is it anything to do with the potential power of the analytical results. Perhaps it is this very power, though, that is at the root of the lack of progress.” – Guest Editor Michael Wolfson

Primary Healthcare Information System

“This special issue of *Healthcare Policy/Politiques de Santé* gives readers important new information on what can be done with existing PHC data sources and the requirements for additional data sources and systems to support health system management and policy development.” – Guest Editor Greg Webster

Regional Training Centres

“Canadian Health Services Research Foundation (CHSRF) and the Canadian Institutes of Health Research (CIHR) took on the basic blueprinting task when they envisioned the RTCs as a new approach to increasing capacity in applied health and nursing services research in Canada.” – Guest Editor Pat Martens

HealthcarePolicy.net

Understanding Patient Referral Wait Times for Specialty Care in Ontario: A Retrospective Chart Audit

Comprendre le temps d'attente pour les patients
recommandés auprès des soins spécialisés en Ontario :
audit rétrospectif des dossiers



CLARE LIDDY, MD, MSc, CCFP, FCFP
Clinician Investigator

*C.T. Lamont Primary Health Care Research Centre
Bruyère Research Institute
Ottawa, ON*

NIKHAT NAWAR, MSc
*Medical Student, Department of Medicine
University of Ottawa
Ottawa, ON*

ISABELLA MOROZ, PhD
*Research Associate
C.T. Lamont Primary Health Care Research Centre
Bruyère Research Institute
Ottawa, ON*

SHELAGH MCRAE, MD, CCFP, FCFP
*Family Practitioner
Gore Bay, ON*

CHRISTOPHER RUSSELL, BHSc
*Medical Student, Department of Medicine
University of Ottawa
Ottawa, ON*

ARIANA MIHAN
BSc Candidate, Research Assistant

*C.T. Lamont Primary Health Care Research Centre
Bruyère Research Institute
Ottawa, ON*

FANNY MCKELLIPS, DEC
*Research Assistant
C.T. Lamont Primary Health Care Research Centre
Bruyère Research Institute
Ottawa, ON*

DEREK MCLELLAN, MD
*Family Medicine Resident, Department of Family Medicine
University of Ottawa
Ottawa, ON*

LOIS CROWE, BA
*Research Manager
C.T. Lamont Primary Health Care Research Centre
Bruyère Research Institute
Ottawa, ON*

AMIR AFKHAM, BENG

Senior Project Manager – Enabling Technologies
The Champlain Local Health Integration Network
Ottawa, ON

ERIN KEELY, MD, FRCPC

Chief, Division of Endocrinology/Metabolism
The Ottawa Hospital
Ottawa, ON

Abstract

Context: When examining wait times for specialist care, the duration between a patient's referral and specialist visit (wait time one) is poorly understood.

Objectives: To calculate wait time one in primary care clinics across Ontario using chart audit.

Methods: We conducted a retrospective chart audit at five Ontario-based primary care clinics in 2014–2015.

Results: We analyzed 461 referrals. Median wait time one for non-urgent and urgent referrals was 79 and 49 days, respectively. Gastroenterology, obstetrics/gynecology, and ear, nose and throat received the most referrals. Wait times were longest for dermatology (112 days) and shortest for general surgery (32 days).

Conclusion: Wait times vary substantially by referral urgency and specialty type in Ontario. Calculating wait time from primary care clinics directly offers new perspectives on wait time one and enables clinics to target improvement efforts to best meet patient needs. Our findings will be relevant to providers and policy makers interested in implementing strategies to reduce wait times.

Résumé

Contexte : Dans l'examen du temps d'attente pour l'accès au spécialiste, la durée entre la recommandation du patient et la consultation auprès du spécialiste (temps d'attente « un ») est bien peu connue.

Objectifs : Calculer le temps d'attente « un » dans des cliniques de soins primaires en Ontario au moyen d'un audit des dossiers.

Méthode : Nous avons mené un audit rétrospectif des dossiers dans cinq cliniques de soins primaires établies en Ontario, en 2014–2015.

Résultats : Nous avons analysé 461 recommandations. Le temps d'attente « un » médian pour les recommandations non urgentes et urgentes était de 79 et 49 jours, respectivement. Les spécialités qui ont reçu le plus de recommandations étaient la gastroentérologie, l'obstétrique/gynécologie et l'oto-rhino-laryngologie. Les temps d'attente étaient plus longs pour la dermatologie (112 jours) et plus courts pour la chirurgie générale (32 jours).

Conclusion : Les temps d'attente varient considérablement en fonction de l'urgence de la recommandation et du type de spécialité, en Ontario. Le calcul du temps d'attente à partir des cliniques de soins primaires offre de nouveaux points de vue sur le temps d'attente « un » et permet aux cliniques de cibler leurs efforts d'amélioration afin de mieux répondre aux besoins des patients. Nos résultats sont pertinents pour les prestataires de soins et les responsables de politiques qui s'intéressent à la mise en place de stratégies pour réduire les temps d'attente.

LONG WAIT TIMES AND POOR ACCESS TO SPECIALIST CARE ARE A MAJOR PROBLEM facing the Canadian healthcare system. According to a recent international Commonwealth Fund Survey, Canada continues to perform below the international average for timely access to patient care, with Canadians in all provinces reporting the longest wait times for specialists among the 11 countries included. The study found that more than half of Canadians (56%) waited longer than four weeks to see a specialist, compared with the international average of 36% (CIHI 2017). In studies of patient experience, 18–21% of Canadians reported that their lives have been affected by the wait to see a specialist (Harrington et al. 2014; Sanmartin et al. 2006), with many patients reportedly experiencing stress, pain, a greater reliance on over-the-counter medications and challenges with work and maintaining the same level of income (Harrington et al. 2014). These factors can be further exacerbated by barriers to communication between providers, which reduce coordination of care and can cause delays in treatment or assessment. A 2011 report by the Royal College of Physicians and Surgeons of Canada identified a lack of effective communication between general practitioners and specialists as a major factor hindering intraprofessional relationships (Little 2011).

Evaluation of wait times in Ontario has mostly focused on the time between when a patient visits a specialist and when they receive the treatment/testing prescribed by the specialist, a metric referred to as wait time two (MOHLTC 2008). However, patient engagement in the healthcare system begins well before the specialist visit. The total time that a patient has to wait to receive treatment for a condition can be seen as the cumulative delay between several chronological steps: (1) the patient's decision to consult a primary care provider (PCP), (2) the appointment with the PCP, (3) the PCP sending a referral letter to a specialist, (4) the appointment with the specialist and (5) any further tests and/or treatment. The time between steps three and four (i.e., from the PCP's referral request to the specialist appointment) is called wait time one, and has received considerably less study than wait time two. In fact, despite significant progress in measuring and reporting wait times for treatments, there are currently no mechanisms in place to measure or report on the length of wait times to see specialists at the provincial level in Ontario. This is due, in part, to the challenges associated with measuring wait time one, which is affected by factors such as the financial costs of monitoring wait times given the high volume of patients waiting to see specialists; the incomparability of reporting standards given differences in workflows, processing times and record-keeping among clinics; and triage based on the urgency of patients' conditions (Petch and Dhalla 2013).

Most studies of wait time have been conducted from a specialist perspective in which referrals to a particular specialty were analyzed for patients with a specific clinical diagnosis (Armstrong et al. 2008; Barua and Fathers 2014), or else relied on physician or patient surveys (Petch and Dhalla 2013; Steven 2011). While these studies provide some perspective on wait times in Canada, they suffer from a number of methodological limitations, including low participation rates, a focus on a limited range of specialty groups, use of monetary incentives and a reliance on surveys answered

after the fact and hence subject to possible recall bias. Studies adopting a primary care perspective have relied principally on health administrative data, which offer large samples but face such limitations as low data quality, interpretation errors and inaccuracies. Chart audits, while more labor-intensive, offer a more accurate method for measuring elements of care quality (Green et al. 2012; Hogg et al. 2010), as they draw on data points not available in health administrative data, including physicians' notes and correspondence between providers.

In this study, we sought to (1) test the feasibility of calculating wait time one from the primary care perspective through a retrospective chart audit and (2) calculate wait time one from a sample of primary care practices in Ontario. The results of this study are highly relevant for provincial policy makers in their efforts to address the problem of excessive wait times for specialist care, and for other researchers studying wait times.

Methods

Study design and setting

We conducted a retrospective chart audit using a convenience sample of five primary care clinics in Ontario. Four were large academic family health teams located in a large urban area, and one was a rural clinic in the northern part of the province.

Sources of data and variable specification

Data were collected from two sources: referral letters that PCPs sent to specialists and the clinic's electronic medical records (EMRs).

REFERRAL LETTER DATA

Data elements extracted from the referral letter included: the date the referral was made, the specialty type, the reason for the referral, if the referral was urgent and if the referral was for a procedure. It was not always possible to capture the date the referral was made versus the date the referral was faxed to the specialist. Where possible, both dates were captured and the date the referral was made was used for the wait time one calculation. The urgency of the referral was ascertained based on the presence of select key words (e.g., priority, urgent, ASAP). Cases where urgency was suspected but not overtly indicated were classified as "unsure." Referrals for medical procedures, such as a colonoscopy or a colposcopy, were captured as procedural referrals.

EMR DATA

Data collected from the EMR included the date the patient saw the specialist, patient gender, patient year of birth and patient postal code (first three digits). We also identified instances of communication between specialists and PCPs at two time points: after the referral was sent and after their patient saw the specialist.

Data were abstracted and uploaded to the secure web-based collaboration space hosted by the Winchester District Memorial Hospital for the Champlain region and facilitated by

the Champlain Local Health Integration Network. All data were stored on secure servers at the Winchester District Memorial Hospital.

Sampling description

We took a systematic sample of 100 referrals from each clinic. Each clinic was asked to extract one month's worth of referrals from a period between September 2014 and November 2014. This total number of referrals in a particular month was then divided by 100 to obtain the sampling interval integer. If a clinic did not have a total of 100 referrals in one month, the time period was extended in order to obtain the desired 100 referrals from each clinic. It should be noted that the ease of pulling referrals varied among the clinics depending on their referral tracking processes and EMR capabilities. For this reason, the final sample of referrals generated by all clinics spanned a period from January 2014 to February 2015. The sampling for each clinic started by randomly selecting the first referral from the list, and then every k^{th} referral in the frame, where k was the sampling interval calculated as follows: $k = N/100$, where N was the total number of referrals per study frame for each clinic.

All referrals made to any specialty during the study time period were eligible for inclusion. Any non-urgent referrals for electronic consultation through the Champlain BASE™ eConsult service were excluded, as they have been received within seven days (Liddy et al. 2013).

Quality control

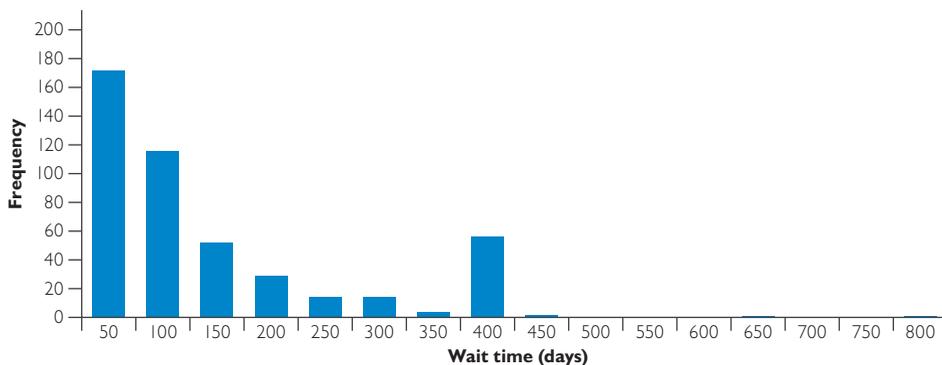
Medical students performed the chart abstraction. Standardized training was provided by the principal investigator and a medical resident who had experience in reviewing charts. Training was delivered in a single session roughly one hour in length, during which the sampling method, data collection form and capturing dates for wait time one calculation were explained. The students were encouraged to contact the research team with any specific questions while performing chart abstractions. On average, completing the chart abstraction process for 100 charts took three to five days depending on the complexity of the data collection (e.g., ability to extract referrals in a given month using paper, EMR or mixed methods) and student/clinic availability. To ensure consistency and quality of the data collected, members of the research team routinely monitored the data collection process and responded quickly to any questions that arose during the chart abstraction phase. Chart abstractors were also provided with a detailed written support material, which was based on those used in another major study of primary care practices in Ontario (Liddy et al. 2011).

Analysis

Wait time one was defined as the time (in days) between when the referral was requested by the PCP and when the patient saw the specialist. Because wait times do not typically follow

a normal distribution (Figure 1), medians and interquartile ranges (IQRs) were calculated. We tabulated counts and proportions as appropriate as part of the descriptive analysis of patient and referral information. In cases where there was no record of the patient having been seen by the specialist during the one-year follow-up period, we assumed a wait time of 365 days. This cut-off was selected to ensure a full year of chart abstraction was completed from the date the referral was initiated. EMRs at some participating clinics included data on specialist visits occurring outside of our 365-day window. These data were also collected where available and used in place of our 365-day assumption. All data analysis was completed in Microsoft Excel.

FIGURE 1. Distribution of wait times ($n = 461$ cases)



Results

A total of 501 charts were abstracted across five clinics. Forty referrals were excluded for the following reasons: (1) the patient declined the specialist appointment, (2) the patients’ symptoms resolved before the specialist appointment and the appointment was no longer needed, (3) the specialist rejected/redirected the referral or (4) the referral was to the Ontario Telemedicine Network (OTN) telederm program or OTN consultation through the OTN (OTN 2017).

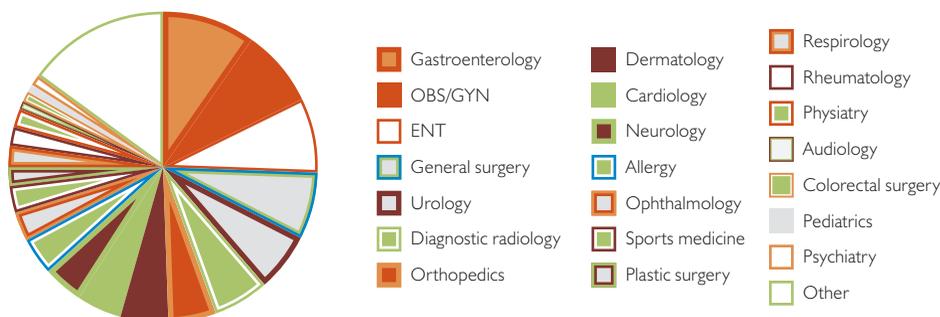
A total of 461 cases (92%) were therefore included in the final analysis. Of these, slightly more were completed on behalf of female patients (57%) and for adult patients (58%), and nearly one-third (31%) were for a procedure (Table 1). The proportion of referrals that were for a procedure varied across the five sites, with clinics five and three reporting higher rates of referrals for a procedure (41% and 38% of referrals were for a procedure, respectively) compared to clinic two, which had the lowest rate of 19% referrals for a procedure. The urgency of referral varied across sites, with clinic two reporting the highest proportion of urgent referrals (17%) compared to other clinics, all of which were under 10%.

Figure 2 illustrates the specialty distribution for all referrals submitted by the participating clinics. The most common specialty groups were gastroenterology (10%), obstetrics/gynecology (OBS/GYN) (8%), ear, nose and throat (ENT) (8%), general surgery (7%) and urology (6%).

TABLE 1. Characteristics of referrals

Characteristic	Clinic 1 (n = 97)	Clinic 2 (n = 89)	Clinic 3 (n = 86)	Clinic 4 (n = 98)	Clinic 5 (n = 91)	Total (N = 461)
Urgent, n (%)						
No	82 (85)	69 (78)	85 (99)	47 (48)	85 (93)	368 (80)
Unsure	8 (8)	5 (6)	0 (0)	44 (45)	0 (0)	57 (12)
Yes	7 (7)	15 (17)	1 (1)	7 (7)	6 (7)	36 (8)
Patient gender, n (%)						
Female	50 (52)	45 (51)	53 (62)	66 (67)	51 (56)	265 (57)
Male	47 (48)	44 (49)	33 (38)	32 (33)	40 (42)	196 (43)
Patient age, n (%)						
Child (0–18)	6 (6)	7 (8)	6 (7)	6 (6)	0 (0)	25 (5)
Adult (19–64)	52 (54)	48 (54)	39 (45)	59 (60)	71 (78)	269 (58)
Senior (65+)	39 (40)	34 (38)	41 (48)	33 (34)	20 (22)	167 (36)
Procedure, n (%)						
No	60 (62)	62 (70)	46 (53)	49 (50)	54 (59)	271 (59)
Unsure	11 (11)	10 (11)	8 (9)	20 (20)	0 (0)	49 (11)
Yes	26 (27)	17 (19)	32 (37)	29 (30)	37 (41)	141 (31)

FIGURE 2. Distribution of all referrals (n = 461) by specialty



ENT = ear, nose and throat; OBS/GYN = obstetrics/gynecology.

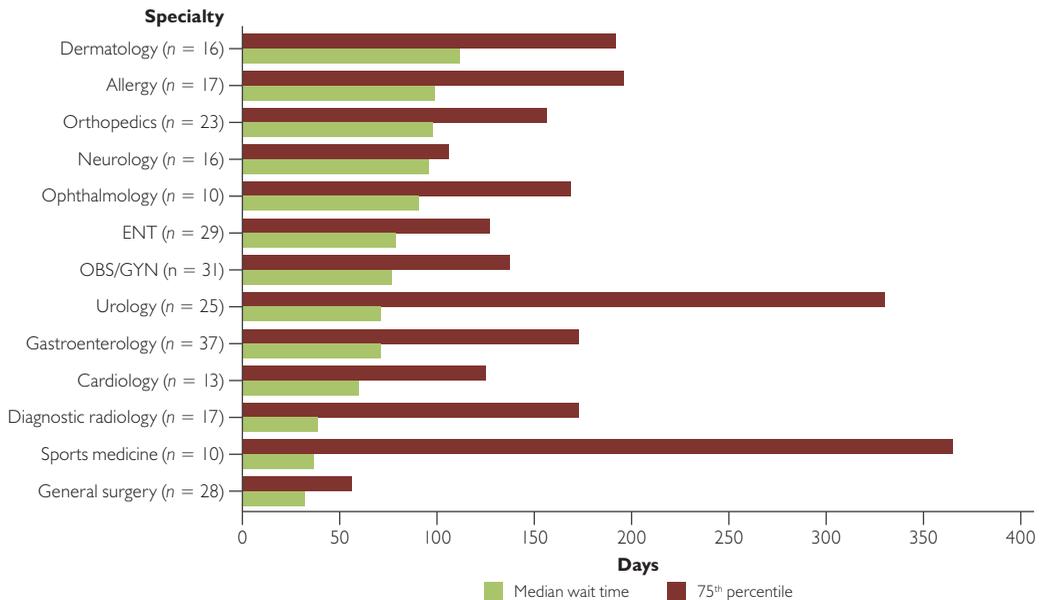
Wait time 1

In 11% of referrals (49/461), there was no indication the patient had seen the specialist after one year. For these cases, we assumed a wait time of 365 days. In an additional 2% of referrals (10/461), wait times of greater than 365 days were identified through EMR data (Figure 1). The median wait time across all five clinics for all non-urgent referrals was 79 days (IQR: 35–173). Urgent referrals had a median wait time of 49 days (IQR: 18.75–77.75), while for cases where urgency was unclear, the median wait time was 57 days (IQR: 24–111).

Clinic four had the shortest median wait time overall at 50 days (IQR: 24–172.5) and for non-urgent cases at 49 days (IQR: 24.5–261.5), while clinic two had the longest median wait time overall at 91 days (IQR: 48–222) and non-urgent at 105 days (IQR: 62–245).

In general, median wait times varied substantially among the different specialty groups. Figure 3 shows that among those specialty groups that received at least 10 non-urgent referrals, dermatology had the longest median wait times for all non-urgent referrals (112 days), followed by allergy (99 days), orthopedics (98 days) and neurology (96 days). General surgery had the shortest median wait times for non-urgent referrals (32 days), followed by sports medicine and diagnostic radiology (37 and 39 days, respectively).

FIGURE 3. Median wait time one in days from date referral is made until the date patient sees specialist for non-urgent referrals ($n = 368$), for the most popular specialty types with more than 10 referrals



ENT = ear, nose and throat; OBS/GYN = obstetrics/gynecology.

PCP-specialist communication

Communication between PCPs and specialists were examined at two time points: immediately after referral was made and after the referral visit took place. The specialist’s office corresponded with the PCP clinic after the patient was initially referred in 22% of referrals (98/461), and followed up with the PCP clinic after the patient’s visit in 79% of cases (366/461), often via a consult letter.

Discussion

We demonstrated that a retrospective chart audit is a feasible, reproducible method for assessing wait time one from the primary care perspective. The median wait time was 79 days for non-urgent referrals and 49 days for urgent referrals. Wait times varied substantially between

clinics, specialty groups and levels of urgency. Some specialties exhibited higher demand than others (e.g., gastroenterology, OBS/GYN), as evidenced by a greater number of referrals from all participating clinics. The majority of communication between PCPs and specialists took place after the patient visited the specialist, where the specialist often sent a consult letter back to the PCP informing them of the details of the appointment, as opposed to before the patient visit, such as a letter informing the PCP of the appointment date. Only a quarter of specialists communicated with PCPs after the initial referral appointment was made.

Few studies have been conducted in Canada exploring wait time one from the PCP perspective. An Ontario-based study linking family physicians' EMR data to healthcare administrative databases found that the length of wait time varied between specialty groups (Jaakkimainen et al. 2014), with gastroenterology demonstrating the longest wait time among non-surgical specialties (76 days) and cardiology the shortest (39 days). Another Ontario study using similar methods reported a median wait time of 53 days (Thind et al. 2012), while a study in Alberta found a median wait time of 61 days (Thanh et al. 2013). While these studies report shorter wait times than found in our analysis, they rely on administrative data to assess wait times, which are limited in the detail of a clinical encounter and do not capture information such as urgency and reason for referral.

The success of our methodology supports previous research, which found chart audits to be effective at assessing elements of performance and identifying areas for improvement (Gregory et al. 2008). Audit and feedback programs are frequently employed as quality improvement and educational interventions to professional practice, and often lead to moderate but potentially important improvements in care quality. The effectiveness of such programs is determined by the practice's baseline performance and the manner in which feedback is provided (Ivers et al. 2012). Our own experience supports this finding: we conducted knowledge exchange activities with participating practices following the study's completion, leading in some cases to changes in workflow. For example, median wait times in one clinic were virtually identical for urgent (78 days) and non-urgent cases (75 days), an issue that the clinic was unaware of and has now taken steps to remedy.

Finally, our findings suggest that the majority of PCPs received feedback from the specialist after the patient's visit, but few received an acknowledgement after initially sending the referral. This would likely cause the PCP to be unsure if the specialist received the referral and how long the patient can expect to wait for treatment. However, it is important to note that this estimate was based on correspondence explicitly recorded in the EMR, and does not rule out the possibility of unrecorded exchanges. In either case, this points to the importance of better communication from the specialist's office immediately after the referral was made and the need for PCPs to follow up with the specialist's office to verify if a consultation has occurred.

Our study has several limitations. The small sample size means that the number of referrals per specialty group is quite small. This makes our results more volatile and sensitive to extreme values, as evidenced by the considerable gap between the median and 75th percentile wait times seen in some specialties (e.g., sports medicine, urology). Future studies employing larger

sample sizes are warranted. Improvements in EMR technology could allow measurement data to be collected automatically, reducing the workload inherent in a chart audit and allowing for larger data sets to be collected in a more efficient way. For instance, all provinces across Canada are collecting wait time data for patients with priority conditions (e.g., cancer), and recently an indicator for specialist care wait time has been added (CIHI 2016). The referral data came from only a few clinics in Ontario, which limits the study's generalizability. We did not capture whether practitioners at any one clinic specialized in specific services (e.g., biopsies), which could have influenced the number of referrals submitted to a particular specialty group. Our calculation of wait time one varied based on data availability, with the date the referral was faxed to the specialist occasionally standing in for the date the referral was requested when the latter was not available. Furthermore, we were unable to account for patient-level factors that may have extended wait times (e.g., rescheduling of appointments, lack of availability). Wait times may have also been subject to over- and underestimation in some cases. Overestimation of wait times may have stemmed from instances where specialists' consultation letters were not sent or were misfiled. Conversely, instances where the patient had no recorded visit with a specialist were noted as having wait times of one year, though the actual wait time may have been longer. Future chart audits should examine the EMR for more than one year to see when exactly the patient was seen by the specialist. Another limitation of the chart audit is the reliance solely on the recorded information. Any information that was not explicitly recorded was assumed to not have occurred. For instance, referral urgency was determined based on the presence of various key words denoting urgency (e.g., ASAP, priority, urgent), which may not have been used in every case. Lastly, anecdotal evidence suggests that for certain specialties where it is practically impossible for a patient to get in via referral, family doctors stop referring.

Conclusion

Our study successfully demonstrated the feasibility of calculating wait time one from a primary care perspective using a chart audit. Using this method, we found median wait time one in participating clinics was 79 days for non-urgent referrals and 49 days for urgent referrals. We also demonstrated substantial variance in wait times for referrals to different specialty groups. Our findings suggest a need for new strategies to improve wait times for specialist care, such as the eConsult service. Furthermore, clinics can use chart audits to assess their own wait times, allowing them to target the specialties where the need for improvement is greatest.

Further research should examine whether wait times vary based on other factors (e.g., socio-economic status), as well as the economic impact of longer wait time one from the patient and payer perspectives.

Correspondence may be directed to: Clare Liddy, C.T. Lamont Primary Health Care Research Centre, Bruyère Research Institute, 43 Bruyère St. Annex E, Room 106, Ottawa, ON K1N 5C8; tel.: 613-562-6262 ext. 2928; fax: 613-562-6734; e-mail: cliddy@bruyere.org.

References

- Armstrong, D., A.N. Barkun, Y. Chen, S. Daniels, R. Hollingworth, R.H. Hunt et al. 2008. "Specialist Gastroenterology Care in Canada: The Practice Audit in Gastroenterology (PAGE) Wait Times Program." *Canadian Journal of Gastroenterology and Hepatology* 22(2): 155–60.
- Barua, B. and F. Fathers. 2014. *Waiting Your Turn: Wait Times for Health Care in Canada, 2014 Report*. Vancouver, BC: Fraser Institute.
- Canadian Institute for Health Information (CIHI). 2016. *Wait Times for Priority Procedures in Canada, 2016*. Ottawa, ON: Author. Retrieved December 13, 2017. <https://secure.cihi.ca/free_products/wait_time_report2016_en.pdf>.
- Canadian Institute for Health Information (CIHI). 2017. *How Canada Compares: Results from the Commonwealth Fund's 2016 International Health Policy Survey of Adults in 11 Countries*. Ottawa, ON: Author.
- Green, M.E., W. Hogg, C. Savage, S. Johnston, G. Russell, R.L. Jaakkimainen et al. 2012. "Methods for Measurement of Clinical Outcomes and Quality of Care in Primary Care Practices." *BMC Health Services Research* 12: 214. doi:10.1186/1472-6963-12-214.
- Gregory, B., C. Van Horn and V. Kaprielian. 2008. "Steps to a Chart Audit for Quality." *Family Practice Management* 15(7): A3–A8.
- Harrington, D.W., K. Wilson and M.W. Rosenberg. 2014. "Waiting for a Specialist Consultation for a New Condition in Ontario: Impacts on Patients' Lives." *Healthcare Policy* 9(4): 90.
- Hogg, W., E. Gyorfi-Dyke, S. Johnston, S. Dahrouge, C. Liddy, G. Russell et al. 2010. "Chart Audits in Practice-Based Primary Care Research: A User Guide." *Canadian Family Physician* 56(5): 495–96.
- Ivers, N., G. Jamtvedt, S. Flottorp, J.M. Young, J. Odgaard-Jensen, S.D. French et al. 2012. "Physician Feedback: Effects on Professional Practice and Healthcare Outcomes." *Cochrane Database of Systematic Reviews* 6: CD000259. doi:10.1002/14651858.CD000259.pub3.
- Jaakkimainen, L., R. Glazier, J. Barnsley, E. Salkeld, H. Lu and K. Tu. 2014. "See the Specialist: Patient and Provider Characteristics of Wait Times from Primary to Specialty Care." *BMC Family Practice* 15: 16. doi:10.1186/1471-2296-15-16.
- Liddy, C., W. Hogg, G. Russell, G. Wells, C.D. Armstrong, A. Akbari et al. 2011. "Improved Delivery of Cardiovascular Care (IDOCC) through Outreach Facilitation: Study Protocol and Implementation Details of a Cluster Randomized Controlled Trial in Primary Care." *Implementation Science* 6: 110. doi:10.1186/1748-5908-6-110.
- Liddy, C., M.S. Rowan, A. Afkham, J. Maranger and E. Keely. 2013. "Building Access to Specialist Care through E-Consultation." *Open Medicine* 7(1): e1–e8.
- Little, L. 2011. *System Issues, Policies and Practices Affecting Physician Intraprofessionalism*. Ottawa, ON: Royal College of Physicians and Surgeons of Canada.
- Ontario Ministry of Health and Long-Term Care (MOHLTC). 2008. *Ontario Wait Times Strategy*. Toronto, ON: Author. Retrieved March 9, 2017. <<http://www.health.gov.on.ca/en/public/programs/waittimes/strategy.aspx>>.
- Ontario Telehealth Network (OTN). 2017. Retrieved March 9, 2017. <<https://otnhub.ca/>>.
- Petch, J. and I. Dhalla. 2013. "Why Doesn't Ontario Report Complete Data on Wait Times?" Retrieved March 9, 2017. <<http://healthydebate.ca/2013/01/topic/wait-times-access-to-care/wait-1-vs-wait-2>>.
- Sanmartin, C., F. Pierre and S. Tremblay. 2006. "Waiting for Care in Canada: Findings from the Health Services Access Survey." *Healthcare Policy* 2(2): 43.
- Steven, L. 2011. "The Fraser Institute Wait Time Reports: Madness in the Method, but Method in the Madness." *Longwoods Essays*. Retrieved March 9, 2017. <<http://www.longwoods.com/content/22719>>.
- Thanh, N.X., M. Wanke and L. McGeachy. 2013. "Wait Time from Primary to Specialty Care: A Trend Analysis from Edmonton, Canada." *Healthcare Policy* 8(4): 35–44.
- Thind, A., M. Stewart, D. Manuel, T. Freeman, A. Terry, V. Chevendra et al. 2012. "What Are Wait Times to See a Specialist? An Analysis of 26,942 Referrals in Southwestern Ontario." *Healthcare Policy* 8(1): 80.



Longwoods Publishing Corporation | better care

Longwoods publishes healthcare research, reports, reviews, commentaries and news from and for academics, scientists, clinicians, policy makers, administrators and pundits.



Longwoods.com/subscribe

