#### HEALTHCARE

# POLICY Politiques de Santé

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

# Volume 5 + Number 4

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Data Matters • Discussion and Debate • Research Papers Knowledge Translation, Linkage and Exchange



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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.

Healthcare Policy/Politiques de Santé 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 Healthcare Policy/Politiques de Santé 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.

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CATHERINE L. MAH, ASTRID GUTTMANN, ALLISON MCGEER, MURRAY KRAHN AND RAISA B. DEBER

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JANINE ARKINSON, ANNE HOLBROOK AND WOJCIECH WIERCIOCH Studies on public perceptions of interactions between physicians and the pharmaceutical industry have been inadequate internationally and non-existent in Canada. Research is urgently needed to help shape policies regarding potential conflicts of interest.

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A survey of Quebec GPs found that those who treat patients with moderate and transient mental disorders usually follow them on a continuous basis; only 25% who see patients with severe and persistent mental illness provide follow-up. Group practice models and shared-care initiatives should be encouraged to manage more complex mental health cases.

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CHRISTOPHER J. LONGO

Critical illness insurance offers both benefits and limitations in mitigating financially derived healthcare access inequities.

#### Research Papers

# e120 Living Environments for People with Moderate to Severe Acquired Brain

ANGELA COLANTONIO, DANA HOWSE, BONNIE KIRSH, TERESA CHIU, RACHEL ZULLA AND CHARISSA LEVY

The authors identify factors that enable or act as barriers to appropriate living environments for people living with ABI. While a standardized model of care for such

- a diverse population is not possible, lack of facilities, beds and trained staff and a poorly coordinated system have resulted in long wait lists for specialized residential settings.
- e139 Exploring Wait List Prioritization and Management Strategies for Publicly Funded Ambulatory Rehabilitation Services in Ontario, Canada: Further Evidence of Barriers to Access for People with Chronic Disease LAURA A. PASSALENT, MICHEL D. LANDRY AND CHERYL A. COTT The most frequently reported methods to manage wait lists for OT and PT included teaching self-management strategies (85.0%), implementing attendance policies (69.5%) and conducting wait list audits (67.3%). These findings suggest an increasing number of Ontarians are encountering barriers in access to needed care.
- e157 Anthropological Approach of Adherence Factors for Antihypertensive Drugs

  ALINE SARRADON-ECK, MARC EGROT, MARIE ANNE BLANC

  AND MURIELLE FAURE

  The authors describe and analyze patients' experience of antihypertensive drugs to
  explain the social and symbolic logics that shape individuals' medication practices.

  Prescription compliance does not depend solely on the patient's perception of
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JOEL LEXCHIN, NEIL ARYA ET SONAL SINGH

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critères d'Erickson, qui offrent un cadre pour la prise de décisions en matière de stratégies nationales de vaccination, afin d'évaluer si le programme coïncide ou non avec de solides politiques de santé publique.

# Questions de données

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Les exemptions à la vaccination avant l'entrée à l'école, qui peuvent être accordées selon des critères médicaux ou non, posent un certain nombre de défis éthiques et politiques. Les auteurs examinent la situation au Canada, où les lois de vaccination avant l'entrée à l'école sont plutôt rares.

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ROBIN L. URQUHART, GRACE M. JOHNSTON, SHAUNA M. MCVORRAN ET FRED I. BURGE

Dans le but de partager la recherche sur les soins en fin de vie et pour pallier aux inégalités dans la qualité des soins en Nouvelle-Écosse, les auteurs ont embauché un stagiaire en échange de connaissances pour rédiger un rapport de surveillance. Ils réfléchissent sur cette initiative et partagent leurs points de vue sur l'expérience en échange de connaissances.

# Rapports de recherche

- Étude de cas sur l'effet de substitution entre la durée de consultation chez 58 l'omnipraticien et les pratiques de prescription de médicament BRUNO VENTELOU, SOPHIE ROLLAND ET PIERRE VERGER Pour un cas de patient hypothétique souffrant de dépression légère, les omnipraticiens qui ont les plus hauts taux de consultation sont deux fois plus enclins à opter pour la pharmacothérapie que leurs collègues moins occupés, par rapport à la psychothérapie seulement ou à une combinaison des deux. Dans plus de 50 % des ordonnances, la décision médicale ne respecte pas les lignes directrices de la pratique clinique.
- 69 Perception du public sur l'interaction entre les médecins et l'industrie pharmaceutique : une revue systématique JANINE ARKINSON, ANNE HOLBROOK ET WOJCIECH WIERCIOCH À l'échelle internationale, la recherche sur la perception du public au sujet de

l'interaction entre les médecins et l'industrie pharmaceutique reste inadéquate, alors qu'elle est absente au Canada. Il y a un besoin urgent pour ce type de recherche afin d'aider à orienter les politiques au sujet des conflits d'intérêts.

Diens entre établissements de pratique clinique et omnipraticiens qui acceptent des patients présentant des troubles mentaux

MARIE-JOSÉE FLEURY, JEAN-MARIE BAMVITA, DENISE AUBÉ ET JACQUES TREMBLAY

Un sondage effectué auprès des omnipraticiens du Québec démontre que ceux qui reçoivent des patients présentant des troubles mentaux modérés ou transitoires assurent habituellement le suivi sur une base continue; à l'inverse, seulement un quart des omnipraticiens qui reçoivent des patients présentant des troubles mentaux sévères et persistants assurent le suivi. Les modèles de pratique de groupe et les initiatives de soins partagés devraient favoriser la gestion de cas plus complexes de troubles mentaux.

# Exclusivités en ligne

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e113 Accès équitable aux services de santé et remplacement de revenu dans les cas de cancer : l'assurance contre les maladies graves est-elle une aide ou une entrave?

CHRISTOPHER J. LONGO

L'assurance contre les maladies graves offre des avantages et des limites dans l'atténuation des inégalités d'accès financières face aux services de santé.

# Rapports de recherche

e120 Milieux de vie pour les personnes vivant avec une lésion cérébrale acquise modérée ou sévère

ANGELA COLANTONIO, DANA HOWSE, BONNIE KIRSH, TERESA CHIU, RACHEL ZULLA ET CHARISSA LEVY

Les auteurs repèrent les facteurs qui facilitent ou font obstacle à un milieu de vie adéquat pour les personnes vivant avec une LCA. Bien qu'un modèle standard de soins pour une telle population soit difficile à élaborer, le manque d'installations, de lits et de personnel formé, ainsi qu'un système peu coordonné, ont donné lieu à de longues listes d'attentes pour les places en résidences spécialisées.

e139 Examen des stratégies de priorisation et de gestion des listes d'attente pour les services ambulatoires de réadaptation subventionnés par les fonds publics en Ontario, Canada : données additionnelles sur les obstacles d'accessibilité pour les personnes souffrant d'une maladie chronique

LAURA A. PASSALENT, MICHEL D. LANDRY ET CHERYL A. COTT

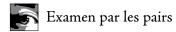
Les méthodes les plus souvent indiquées pour la gestion des listes d'attente pour les services d'ergothérapie et de physiothérapie comprennent, notamment, l'enseignement

des stratégies d'autogestion (85,0 %), la mise en place de politiques d'assiduité (69,5 %) et le contrôle des listes d'attente (67,3 %). Les résultats laissent croire qu'un nombre grandissant d'Ontariens se heurtent à des obstacles en matière d'accessibilité aux services dont ils ont besoin.

# e157 Approche antropologique des déterminatnts de l'observance dans le traitement de l'hypertension artérielle

ALINE SARRADON-ECK, MARC EGROT, MARIE ANNE BLANC ET MURIELLE FAURE

Les auteurs décrivent et analysent l'expérience des patients en matière de pharmacothérapie antihypertensive, afin de comprendre la logique sociale et symbolique des facteurs qui influent sur le comportement des individus face à la médication. L'adhésion au traitement ne dépend pas seulement des risques cardiovasculaires perçus par le patient, mais aussi de la façon dont il accepte pleinement le traitement et l'intègre à sa vie quotidienne.



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# The Buzz about the Upcoming G8 Summit and Global Health

8 WATCHERS HAVE BEEN SPECULATING ABOUT THE BLACKFLIES IN Muskoka for months, but it is mosquitoes that will feature in formal discussions at the upcoming Summit. As host of the G8, Prime Minister Stephen Harper has announced that he will ask his colleagues to focus on the extent to which countries have met previous G8 commitments (Office of the Prime Minister 2010). Among them was a pledge in 1998 to support the global "Roll Back Malaria" initiative, with the goal of significantly reducing the death rate from the disease by 2010.

Canada will also be championing a global agenda for improving maternal and child health at the Summit. With only five years left until the 2015 deadline, much progress still needs to be made to achieve the Millennium Development Goals (Secretary General to the United Nations 2010). One of those goals is to reduce the under-five mortality rate by two-thirds between 1990 and 2015. The United Nations reports that child mortality in developing countries fell from 99 deaths per 1,000 live births at the beginning of this period to 72 in 2008. With a goal of 33 deaths per 1,000 live births by 2015, there is still much to do.

Can it be done? Historical analysis by Hans Rosling (2009) from Sweden's Karolinska Institute demonstrates that significant progress is possible. Two hundred years ago, Sweden had an infant mortality rate that was about the same as Liberia has today. By 1888, the rate had fallen to about what Mozambique's is now. Sweden passed modern-day India's rate in 1920. Since then, rates have continued to improve. Today, however, Singapore's infant mortality rate is even better than Sweden's, reflecting more recent and rapid progress. In the last few years, several other countries have also outpaced the rate of improvement required to achieve the Millennium Development Goals, including Bangladesh, Egypt and Brazil. Unfortunately, some countries have failed to achieve progress over the same period, or even had setbacks.

How have Canadian children fared? At the beginning of the 20th century, about one in seven newborns died before their first birthday (Bourbeau et al. 1997). That is about the same as the rate in Angola today, according to UNICEF (2010). By 2007, Canada's infant mortality rate had fallen to 5.1 infant deaths per 1,000 live births, or one in 196 newborns (Statistics Canada 2010). This figure represents an average annual improvement of about 3%, although recent advances have been more modest

(1.4% on average between 1991 and 2007). All gains are welcome, but both figures represent rates of progress below the 4.3% required globally to achieve the Millennium Development Goals. With infant mortality in some parts of Canada more than four times higher than that in other areas, there may be opportunities to champion improvements at home as well as abroad.

Also looking back and looking forward, this issue brings to a close my first year as editor-in-chief of *Healthcare Policy/Politiques de santé*. I would like to thank all those who made it possible to publish the journal over the last year, in particular the authors, editors and Longwoods staff for their many contributions. Their collective support enabled progress on a key goal that the editorial team set for the year: further reducing the time between submission of a manuscript and a final decision on its inclusion in the journal. Median times fell at all stages of the process, from the first step (the median time between manuscript submission and selection of initial reviewers/rejection was 12–13 days in 2009) to the final step, receipt of revisions following review to decision on publication. The median time for the latter was 14 days in 2009, down from 28 days the year before.

In this issue, we also extend special thanks to the dozens of reviewers from around the world who provided expert advice to our authors and editors over the past year. Without their insights and thoughtful comments, producing a high-quality journal would not be possible. They also contributed to accelerating the overall publication process. The median time between a request for reviews and receipt of all reviews was 64 days in 2009, down from 68 days in the previous year.

Please help us to continue to make the journal an important source of new research and insights related to healthcare policy. We are continuing to build our database of reviewers and we welcome volunteers. If you are interested in taking part, please contact Ania Bogacka.

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Editor-in-chief

# Bourdonnements autour du Sommet du G8 et de la situation sanitaire mondiale

Discription de discussions officielles au cours du sommet. À titre d'hôte du G8, le premier ministre Stephen Harper a annoncé qu'il demandera à ses collègues de mesurer à quel point les pays ont tenu les engagements pris lors des sommets antérieurs (Cabinet du premier ministre 2010). Parmi ces engagements, il y a la promesse, faite en 1998, d'appuyer le plan d'action contre le paludisme dans le but de réduire notablement le taux de mortalité dû à la maladie, et ce, avant 2010.

Pendant le sommet, le Canada mettra également en vedette un programme mondial pour l'amélioration de la santé maternelle et infantile. À cinq ans seulement de l'échéance de 2015, il y a beaucoup à faire pour réaliser les objectifs du Millénaire pour le développement (secrétaire général des Nations Unies 2010). Un de ces objectifs est de réduire des deux tiers le taux de mortalité des enfants de moins de cinq ans, entre 1990 et 2015. Les Nations Unies indiquent que depuis le début de la période visée, la mortalité infantile dans les pays développés est passée de 99 décès pour 1000 naissances vivantes à 72 pour 1000, en 2008. L'objectif de 33 décès pour 1000 naissances vivantes en 2015 demandera donc encore beaucoup de travail.

Peut-on y arriver? Une analyse historique effectuée par Hans Rosling (2009), de l'Institut suédois Karolinska, démontre qu'il est possible d'accomplir des progrès notables. Il y a 200 ans, le taux de mortalité infantile en Suède était comparable à celui du Libéria actuel. En 1888, ce taux avait baissé pour atteindre l'équivalent de celui du

Mozambique aujourd'hui. En 1920, il équivalait à celui de l'Inde de nos jours. Depuis, le taux continue de décroître. Pourtant, le taux de mortalité infantile à Singapour est, de nos jours, encore meilleur que celui de la Suède, ce qui indique des progrès récents plus rapides. Au cours des dernières années, plusieurs pays ont pris une avance considérable face aux taux requis pour réaliser les objectifs du Millénaire pour le développement, notamment le Bangladesh, l'Égypte et le Brésil. Malheureusement, certains pays n'accomplissent aucun progrès, ou accusent même un retard en ce sens.

Quelle est la situation au Canada? Au début du XXe siècle, environ un enfant sur sept nouveaux-nés mourait avant d'atteindre l'âge d'un an (Bourbeau et al. 1997). C'est sensiblement le taux actuellement observé en Angola, selon l'UNICEF (2010). En 2007, le taux de mortalité infantile au Canada avait chuté à 5,1 décès pour 1000 naissances vivantes, soit un sur 196 nouveaux-nés (Statistique Canada 2010). Ces chiffres correspondent à une amélioration annuelle moyenne d'environ trois pour cent, bien que les progrès récents aient été plus modestes (1,4 pour cent en moyenne, entre 1991 et 2007). Toute amélioration est favorable, mais ces moyennes représentent une progression en deçà des 4,3 pour cent nécessaires à l'échelle de la planète pour atteindre les objectifs du Millénaire pour le développement. Dans certaines régions du Canada, la mortalité infantile est quatre fois plus élevée qu'ailleurs au pays; il y a donc lieu de faire valoir les initiatives d'amélioration au pays comme ailleurs dans le monde.

Maintenant, pour faire un retour sur le passé et jeter un regard vers l'avenir, ce numéro marque, pour moi, presque une année à titre de rédactrice en chef de *Politiques de santé/Healthcare Policy*. J'aimerais remercier tous ceux qui ont rendu possible la publication de cette revue au cours de l'année écoulée, en particulier les auteurs, les éditeurs et le personnel de Longwoods pour leurs nombreuses contributions. Leur appui collectif a permis de faire avancer un des principaux objectifs annuels établis par l'équipe de rédaction, soit de réduire davantage le temps entre la soumission d'un manuscrit et la décision finale de l'inclure dans la revue. Les temps médians ont été réduits partout dans le processus, de la première étape (le temps médian entre la soumission d'un manuscrit et le choix d'une première révision ou d'un refus était de 12 à 13 jours en 2009) à la dernière étape, c'est-à-dire la réception des révisions suite à la première décision de publier ou non. Le temps médian pour cette étape était de 14 jours en 2009, comparé à 28 jours l'année antérieure.

Dans le présent numéro, nous tenons également à remercier spécialement les douzaines de réviseurs du monde entier qui, au cours de l'année, ont offert leurs conseils avisés aux auteurs et aux éditeurs. Sans leur aide et leurs commentaires, il serait impossible de publier cette revue de grande qualité. Ils ont aussi contribué à accélérer l'ensemble du processus de publication. Le temps médian entre la demande de révisions et leurs réceptions était de 64 jours en 2009, comparé à 68 jours l'année antérieure.

Nous sollicitons votre aide pour continuer à faire de cette revue une source impor-

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tante de nouvelles recherches et de pistes pour les politiques de santé. Nous continuons à dresser notre liste de réviseurs; les volontaires sont donc bienvenus. Si vous êtes intéressés, veuillez communiquer avec Ania Bogacka.

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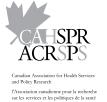


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# Tough on Crime? Pfizer and the CIHR

# Sévère à l'égard de la criminalité? Pfizer et les IRSC



by ROBERT G. EVANS

# **Abstract**

The appointment of Dr. Bernard Prigent, vice-president and medical director of Pfizer Canada, to the Governing Council of the Canadian Institutes of Health Research, outraged many Canadian health researchers. Pfizer has been a "habitual offender," persistently engaging in illegal and corrupt marketing practices, bribing physicians and suppressing adverse trial results. Since 2002 the company and its subsidiaries have been assessed \$3 billion in criminal convictions, civil penalties and jury awards. The \$2.3-billion settlement in September 2009 – a month before Dr. Prigent's appointment – set a new record for both criminal fines and total penalties. A link with Pfizer might well advance the commercialization of Canadian research – unhindered by law or morality. Is that now the only mandate, Dr. Beaudet?

# Résumé

La nomination du Dr Bernard Prigent, vice-président et directeur médical de Pfizer Canada, au conseil d'administration des Instituts de recherche en santé du Canada a indigné plusieurs chercheurs du milieu de la santé au Canada. Pfizer est un « récidi-

viste », souvent impliqué dans des pratiques commerciales illégales ou malhonnêtes, offrant des pots-de-vin aux médecins et discréditant les résultats d'essais jugés indésirables. Depuis 2002, le montant total des condamnations, des amendes administratives et des amendes prononcées par des jurys, imposées à la firme et à ses filiales, est évalué à 3 milliards de dollars. L'amende de 2,3 milliards de dollars, prononcée en septembre 2009, a établi un record tant pour les amendes au criminel que pour l'ensemble des sanctions pénales. Les liens avec Pfizer peuvent sans doute faire progresser la commercialisation de la recherche au Canada – sans les entraves de la loi ou de la morale. Est-ce donc là votre unique mandat, Docteur Beaudet?

N JANUARY 15 OF THIS YEAR, US FEDERAL PROSECUTORS IN BOSTON filed a complaint against Johnson & Johnson (J&J) and related companies, alleging violations of the federal *False Claims Act* and related legislation (Associated Press 2010). Allegedly, from 1999 through 2004, J&J made payments to Omnicare to induce increased prescribing of Risperdal to patients in nursing homes. Risperdal is J&J's brand of risperidone, a drug used in the treatment of schizophrenia.

The inducement was somewhat indirect. Omnicare is a pharmaceutical services provider, the largest in North America, that contracts with nursing homes and other facilities to provide drugs prescribed by patients' physicians. Omnicare's pharmacists dispense these drugs; they also provide oversight of patients' drug use and health condition. According to the complaint, Omnicare pharmacists review patients' charts at least monthly and make prescribing recommendations that physicians follow more than 80% of the time.

The ultimate objective of all prescription drug marketing is to determine what is written on the prescription pad. In this case, the chain of influence ran from drug company to dispensing contractor to pharmacist to physician. Over the period alleged, J&J sales through Omnicare rose from \$100 million to \$280 million. Risperdal made up more than one-third of these sales.

Omnicare's website stresses the company's mission to promote the health of seniors.

# Omnicare: The Prescription for Positive Outcomes

Omnicare is the nation's leading provider of pharmaceutical care for seniors. Each day, our pharmacists serve more than 1.4 million residents of skilled nursing, assisted living, and other healthcare facilities in 47 states and Canada. While doing this, we capture a tremendous amount of data. Omnicare combines this data with its proprietary outcomes algorithm technology, based on best practices in geriatric medicine, to identify and help treat diseases in the elderly.

We do all this, and much more, with one goal in mind: to help ensure the health of seniors in a cost-effective manner. (Omnicare 2010)

This noble language might suggest that Omnicare is "an eleemosynary outfit." Not so. It is a strictly for-profit corporation (OCR-N on the NYSE) like Johnson & Johnson (JNJ-N), with the mission – the one for which its executives are paid – of providing "enhanced shareholder value" – i.e., profit for its shareholders. For the hardeyed men and women of Wall Street, the rest is just public relations fluff. Payments from J&J to Omnicare to encourage pharmacists to promote the prescribing of Risperdal were a win—win strategy for both corporations.

For patients, perhaps not so much. Atypical antipsychotic drugs such as risperidone can have some quite nasty side effects; in particular, the US Food and Drug Administration requires manufacturers to include special labelling warning of an increased risk of death related to psychosis and behavioural problems in elderly patients with dementia.

Kickbacks in the nursing home pharmacy context are particularly nefarious because they can result in excessive prescribing of strong drugs to patients who have little or no control over the medical care they are receiving. ... Nursing home doctors should be able to rely on the integrity of the recommendations they receive from pharmacists, and those recommendations should not be a product of money that a drug company is paying to the pharmacy. (US Attorney Carmen Ortiz, quoted in Associated Press 2010).

In addition to the risks to patients, the other side of the coin of corporate gain was the cost to public and private payers. But these interests, like those of patients, were not represented when J&J implemented a strategy of, in effect, purchasing Omnicare's nursing home pharmacists to act as an extension of its own sales force.

The charges against J&J have not been proven in court, nor are they likely to be. Corporations prefer not to go to trial; rather, they negotiate a settlement that will permit them to continue denying wrong-doing while paying to make the charges go away. (Such settlements may, however, include a formal guilty plea on one or more criminal charges.) Omnicare, as it happens, settled related charges last November for a payment of \$98 million to the United States and state governments (Associated Press 2010); with that case settled, J&J will probably choose the same option. The only real issue in dispute will be the size of the penalties.

The amount of money involved in this case is in fact very small potatoes. J&J will probably pay a couple of hundred million in fines and civil penalties. The stakes were somewhat higher last September, when Pfizer and related companies settled a number of charges for a total of \$2.3 billion (O'Reilly and Capaccio 2009). This settlement

set a new record for a criminal fine – \$1.2 billion – plus civil penalties of \$1 billion. Subsidiary Pharmacia & Upjohn pleaded guilty to one count of a felony, misbranding of a pharmaceutical, and was assessed a forfeiture of \$100 million.

A number of fraudulent marketing practices were involved for a number of different Pfizer or subsidiary products. The criminal charges focused on the illegal promotion of several Pfizer brands – Bextra (valdecoxib, a pain medication, since removed from the market), Geodon (ziprasidone HCl, an atypical antipsychotic), Zyvox (linezolid, an antibiotic) and Lyrica (pregabalin, a seizure medication). These were promoted for "off-label" use, i.e., for uses other than those approved by the FDA.<sup>3</sup> But there were also kickbacks to physicians and the use of unverified and misleading marketing materials to promote the prescribing of several other Pfizer brands, including Viagra (sildenafil) and Lipitor (atorvastatin).

This was by no means Pfizer's first offence. In 2007, Pfizer subsidiary Pharmacia & Upjohn paid \$34 million and pleaded guilty to paying kickbacks for formulary placement of its drugs and entered into a Deferred Prosecution Agreement for offlabel distribution of Genotropin, its brand for the human growth hormone somatropin (US Department of Health & Human Services and US Department of Justice n.d.).

In 2004, Pfizer subsidiary Warner–Lambert pleaded guilty and paid more than \$430 million to resolve criminal charges and civil liability arising from its fraudulent marketing practices with respect to Neurontin, its brand for the drug gabapentin. Originally developed for the treatment of epilepsy, Neurontin was illegally promoted off-label for the treatment of various forms of neurological pain, and in particular for migraine.

In 2002, Pfizer and its subsidiaries Warner-Lambert and Parke-Davis paid \$49 million to resolve civil claims that it had failed to report best prices for its drug Lipitor as is required under the *Medicaid Drug Rebate Statute*.

As this is being written, gabapentin is back in the news. The CBC (2010) reports that

Pfizer has been ordered to pay \$142 million US in damages for fraudulently marketing gabapentin, an anti-seizure drug marketed under the name Neurontin. A federal jury in Boston ruled Thursday that Pfizer fraudulently marketed the drug and promoted it for unapproved uses.<sup>4</sup>

This case demonstrates one reason why drug companies often prefer to settle rather than go to trial. The CBC report continues:

Data revealed in a string of U.S. lawsuits indicates the drug was promoted by the drug company as a treatment for pain, migraines and bipolar disorder – even though it wasn't effective in treating these conditions and was actually

toxic in certain cases, according to the Therapeutics Initiative, an independent drug research group at the University of British Columbia.

The trials forced the company to release all of its studies on the drug, including the ones it kept hidden.

A new analysis of those unpublished trials by the Therapeutics Initiative suggests that gabapentin works for one out of every six or eight people who use it, at best. The review also concluded that one in eight people had an adverse reaction to the drug.

Dr. Tom Perry, quoted in the story, estimates that Neurontin sales in Canada are around \$300 million per year. Since the drug has been in use since the late 1990s, at least a billion dollars has been spent on an illegally promoted drug with few benefits and serious side effects.

In response to this record of persistent criminal behaviour, the September 2009 settlement included Pfizer's signing of an "integrity agreement" to be overseen by the US Department of Health & Human Services. In essence, while denying virtually all charges of wrong-doing, Pfizer accepted a form of trusteeship for a period of years, to try to prevent the company from doing in the future what it denied having done in the past.<sup>5</sup>

The integrity agreement, however, imposed the further requirement that Pfizer make public its cash payments to practitioners. On March 31, 2010, the *New York Times* reported that

Pfizer ... paid about \$20 million to 4,500 doctors and other medical professionals in the United States for consulting and speaking on its behalf in the last six months of 2009 ... [and] \$15.3 million to 250 academic medical centers and other research groups for clinical trials .... (Wilson 2010)

While most of the disclosures were required by the integrity agreement, "[c]ompany executives said they had long planned to be more transparent." The "skepticism [of] some outside experts" may have been reinforced by the fact that Pfizer's website (like those of Eli Lilly, Merck and GlaxoSmithKline) is "set up in ways that make it difficult to download and analyze the entire database" (Wilson 2010). It is also notable that the integrity agreement does not apply to payments made to physicians outside the United States – in Canada, for example – and accordingly, none of these were disclosed.

An integrity agreement was also imposed in the previous record settlement of health industry fraud charges, the \$1.7 billion paid by the Hospital Corporation of America (HCA) in 2003 (US Department of Justice 2003b). In this case, the charges involved "false claims arising from a variety of allegedly unlawful practices, including

cost report fraud and the payment of kickbacks to physicians" (US Department of Justice 2003a) as well as fraudulent billings of various types. But in the HCA case the Department of Justice also proceeded against a number of corporate executives. A corporation may treat both criminal and civil penalties as simply business expenses, to be weighed against the revenues earned from illegal behaviour. But human beings can be put in jail, and that is a whole other matter. Conceivably, convicting corporate executives of criminal behaviour and sentencing them to terms of imprisonment might be a more effective deterrent to the "repeat offender" behaviour demonstrated by Pfizer.

Unfortunately, while several HCA executives were indicted, the American courts threw out the charges against individuals. The corporation – i.e., its shareholders – incurred the financial penalties; the executives involved were presumed innocent. In the absence of such personal liability, both criminal and civil penalties appear to be, to Pfizer at least, a business expense worth incurring. You have to spend money to make money.

This point was illustrated in 1998, when the Canadian courts rejected a suit by Bristol-Myers Squibb to suppress a research report on the effectiveness of various forms of statins. CCOHTA (the Canadian Coordinating Office of Health Technology Assessment, now the Canadian Agency for Drugs and Technologies in Health) had found that statins were, indeed, effective in lowering blood levels of LDLs, but that no one variant had an advantage over others on the market. Bristol-Myers Squibb's pravastatin (branded as Pravachol) had the leading market share in Canada, and the company feared that this assessment might undercut its marketing. The company sought an injunction forbidding the report's release. This was denied. The company appealed the ruling. The appeal was denied.

But Bristol-Myers Squibb won by losing. The release of the report was delayed from December 1997 until May 1998, and a large part of CCOHTA's budget, and the time and focus of its staff, were diverted to litigation. As the *Journal of the American Medical Association* reported, "[t]he \$230,000 that CCOHTA spent on lawyers to defend the right to publish its report represents approximately the income from a single day of sales of Pravachol in Canada, but it amounts to 13% of CCOHTA's annual budget" ("Drug Firm Suit Fails to Halt Publication of Canadian Health Technology Report" 1998). The costs of (probably predictably) unsuccessful litigation were well worth incurring – as was the opprobrium of the research community. Memories are short.<sup>6</sup>

Nor are the financial penalties very significant compared to the size of the companies involved (see Table 1).

In eight years of repeated malfeasance, Pfizer has accumulated just under \$3 billion in fines and civil penalties, or only about a third of last year's net revenues. For J&J, a penalty of \$200–\$300 million would hardly count as pocket change.

But the world evolves. In January 2010 the FBI, operating in conjunction with authorities in the United Kingdom and Israel, executed a "sting" operation against a number of mostly small-time arms dealers who offered bribes to the "representatives"

of a fictitious African nation to secure equally fictitious contracts to supply arms and ammunition. This is an offence under the US Foreign Corrupt Practices Act (FCPA), and the charges are laid against the individuals who offer bribes or otherwise engage in corrupt practices as defined by American law. The FBI were careful to ensure that the victims of the sting were fully aware that their intended actions were illegal. Twenty-two executives were then arrested, all but one in Las Vegas (where else?).

**TABLE 1.** Sales and net revenues, based on 2009 annual reports of the world's 12 largest pharmaceutical firms (millions USD)

Company	Revenue	Net Income
Johnson & Johnson	61,897	12,266
Pfizer	50,009	8,635
Roche	45,304	7,860
GlaxoSmithKline	44,421	8,877
Novartis	44,267	8,454
Sanofi–Aventis	40,870	11,814
AstraZeneca	32,804	7,544
Abbott Laboratories	30,800	N/A
Merck	27,428	13,024
Bristol-Myers Squibb	TBA	TBA
Bayer Healthcare	22,297	2,365
Eli Lilly	21,836	4,328

Source: http://en.wikipedia.org/wiki/List\_of\_pharmaceutical\_companies. Retrieved April 9, 2010.

This operation was the first under a new *modus operandi* for the US Department of Justice, involving a "campaign-style" approach targeting industries identified as highly corrupt and then trying to bring simultaneous prosecutions against a large number of people in those industries. It also featured close transatlantic cooperation between the FBI and the City of London police (Henriques 2010).

What is of particular interest is that the next industry to be targeted using the Foreign Corrupt Practices Act was pharmaceuticals. On November 12, 2009, at the 10th Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum, Assistant Attorney General Larry Breuer (chief of the Department of Justice criminal division) cautioned that the level of government involvement in health systems outside the United States makes the environment ripe for bribery, corruption and FCPA violations. He indicated that the department's increased scrutiny of the pharmaceutical industry "will mean investigation and, if warranted, prosecution of corporations ... but also it will involve investigation and prosecution of senior executives" (Main Justice 2009). Will the international nature of the pharmaceutical industry enable such investigations to reach corrupt practices – and individuals – within the United States itself? (Could it reach into Canada?) Answers are probably some years away.

A commercial corporation, as a legal person, differs from natural persons - you

and me – in being wholly amoral. It is a social organization brilliantly designed for a single purpose – the pursuit of profit. The test of a corporate action is, will it tend to increase profits – or, more generally, the net worth of the corporation? The action may involve the breaking of laws, or threats to the health and well-being of patients or other natural persons. Looking at Pfizer's record, one thinks of the phrase "habitual criminal." But the corporation lacks the *mens rea*, the guilty mind, associated with criminality in the natural person. Amoral, purely legal persons recognize no moral restraints, so are no more capable of feeling guilt than a robot (Bakan 2004).

But "Corporations don't lie, steal, conceal, plunder, bribe and scheme. People do." The corporate form typically permits corporate executives to escape personal accountability. The key to discouraging corporate malfeasance in the pharmaceutical industry may therefore lie in reaching through the corporate veil to charge those natural persons whose decisions determine the behaviour of the corporation.

But there is no risk of that happening in Canada. In sharp contrast to the US Department of Justice, regulatory authorities in Canada are reminiscent of Monty Python's parrot.<sup>8</sup> To the contrary, and to the outrage of much of Canada's health research community, the vice-president and medical director of Pfizer Canada, Dr. Bernard Prigent, was on October 5, 2009, appointed to the Governing Council of the Canadian Institutes of Health Research (CIHR), the premier national institution for funding health research.

This extraordinary appointment raises very troubling questions about the motivations not only of the Canadian federal government, but also of Dr. Alain Beaudet, the president of CIHR. Dr. Beaudet is well aware (unlike, one suspects, most of Mr. Harper's Conservatives) of the difference between genuine pharmaceutical innovation and a marketing masquerade. Yet the appointment can only have been made on his recommendation, or at least with his blessing. What was he thinking when he decided to get into bed with Pfizer, and deliberately snubbed so many Canadian health researchers? Is it conceivable that Dr. Beaudet was simply unaware of Pfizer's record of persistent criminal behaviour and casual disregard for the health and well-being of patients? That would be a major failure of due diligence; the record is all in the public domain and readily available. Was he bowing to government pressure? Again, unlikely. People of integrity, under political pressure to betray the public trust, should and do resign.

The most plausible explanation may be that Dr. Beaudet shares the federal government's objective of promoting the increased commercialization of research in Canada – at whatever cost. He may see a closer relationship with Pfizer as a way to increase funding for drug research – perhaps even for the CIHR – and of currying favour with Ottawa. But while Dr. Beaudet undoubtedly recognizes a distinction between "commercialization" and drug pushing, Pfizer does not. Does Dr. Beaudet consider the company's history of criminal settlements, guilty pleas and convictions irrelevant to this appointment – or even a positive recommendation? If all that matters is increased

sales of drugs, regardless of their benefits, Pfizer is the one to call. Dr. Beaudet's CIHR, like Mr. Harper's federal government, may just hope to share the loot. 10

A closer relationship with Pfizer, and the drug industry generally, may indeed promote greater commercialization of Canadian research. If so, Pfizer and other shareholders will reap the benefits, as will those Canadian researchers who become their "out-house" (as opposed to in-house) research departments. Dr. Beaudet's political masters, apparently believing that an expanded drug industry is an end in itself regardless of the consequences for the health of Canadians or the costs of healthcare, will also be pleased. All economic activity – beneficial, harmful or just plain ineffectual – is included in the gross domestic product. Illegal and corrupt marketing practices, and the drugs they promote, all contribute to "economic growth" as well as drug company profit.

But Pfizer's track record inspires no confidence whatever that the health of Canadians will benefit in proportion, if at all, from any such growth. What is certain is that any benefits in health or wealth from this relationship will be paid for, and over-paid, by Canadian patients, insurers and taxpayers. Dr. Beaudet has allowed the commercialization mandate to override CIHR's responsibilities to Canadians. Pfizer is not an eleemosynary outfit.

# Acknowledgements

With thanks to Morris Barer and Steven Lewis.

#### NOTES

- 1. See also US Department of Justice, "United States Files Suit against Drug Manufacturer Johnson & Johnson." Retrieved April 9, 2010. <a href="http://www.justice.gov/usao/ma/Press%20">http://www.justice.gov/usao/ma/Press%20</a> Office%20-%20Press%20Release%20Files/Jan2010/JohnsonandJohnsonPR.html>.
- 2. "Around the headquarters in Rahway, New Jersey, there is so much high-minded talk about Merck's life saving mission that one might consider the company an eleemosynary outfit. But this mis-impression is never conveyed in conversation with [the president] who is as devout a disciple of the bottom line as ever there was." (Robertson 1976: 136)
- 3. Physicians may prescribe a drug for an off-label use, but the manufacturer may not legally promote it for such use.
- 4. The suit was brought by Kaiser Foundation Health Plan Inc. and Kaiser Foundation Hospitals, and was described in *Business Week* as a "civil racketeering trial." See www.businessweek.com/news/2010-03-23/pfizer-defends-epilepsy-drug-neurontin-at-fraud-trial-in-boston.html.
- 5. Having done no wrong, Pfizer presumably paid \$2.3 billion just to avoid the trouble of proving its innocence in court.
- 6. Coincidentally, the offices of CCOHTA in Ottawa were burgled during this dispute, and computer disks were stolen, but no suspects were ever identified.
- 7. Steven Lewis, obviously inspired by the National Rifle Association of the United States.

#### Tough on Crime? Pfizer and the CIHR

- 8. Perhaps if the federal government rather than the provinces had to pay for pharmaceuticals, they might be more energetic. But white-collar crime seems to be taken much less seriously in Canada. Recall that Conrad Black was tried, convicted and imprisoned in the United States for "obstruction of justice," removal of documents in blatant violation of a court order. The order was issued and the offence occurred in Canada; no charges were laid here.
- 9. Pfizer is no different from any other pharmaceutical firm, only larger and more egregious.
- 10. If that is the only objective, why not legalize (and tax) B.C. Bud? Because that would upset the Americans, who are armed and dangerous.

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# Gardasil® – The New HPV Vaccine: The Right Product, the Right Time? A Commentary

Gardasil® – le nouveau vaccin contre le PVH : s'agit-il du bon produit au bon moment? Commentaire



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# **Abstract**

The federal and provincial governments have undertaken a universal immunization program to protect school-aged girls against cervical cancer using the new human papillomavirus vaccine Gardasil®. While the vaccine appears to be effective and safe, there are a number of important unanswered questions regarding it and the effects of the immunization program. Here we briefly review key literature about the vaccine and then use the Erickson criteria, which offer an evidence basis for decision-making regarding national immunization strategies, to evaluate whether the program is congruent with sound public health policy. Our analysis of the national decision to recommend and fund a vaccination program using Gardasil® raises significant questions about the basis for this program.

# Résumé

Les gouvernements fédéral et provinciaux ont entrepris un programme de vaccination universelle, chez les filles d'âge scolaire, pour prévenir le cancer du col de l'utérus à l'aide du nouveau vaccin contre le papillomavirus humain, Gardasil®. Bien qu'il semble efficace et sécuritaire, il existe de nombreuses questions sans réponse quant au vaccin et aux effets du programme de vaccination. Nous examinons brièvement ici la principale littérature au sujet du vaccin et nous employons les critères d'Erickson, qui offrent un cadre pour la prise de décisions en matière de stratégies nationales de vaccination, afin d'évaluer si le programme coïncide ou non avec de solides politiques de santé publique. Notre analyse de la décision nationale visant à recommander et à financer un programme de vaccination utilisant le Gardasil® soulève des questions raisonnables quant aux fondements de ce programme.

designed to prevent cervical cancer, was licensed by Health Canada in July 2006. In February 2007, the National Advisory Committee on Immunization (NACI) recommended that girls aged 9–13 years (i.e., before the onset of sexual intercourse) and women aged 14–26, even if they have had previous Pap smear abnormalities or HPV infections, be immunized. The federal government followed with an announcement of a \$300-million allocation to provincially organized immunization programs. The immunization strategy has received the support of the Public Health Agency of Canada (PHAC), the Canadian Paediatric Society and the Society of Obstetricians and Gynaecologists (SOGC). The vaccine is now being provided free of charge to school-aged girls in all provinces and the Yukon Territory.

The Canadian Women's Health Network has advised caution about the program,

and a peer-reviewed paper in the CMAJ (Lippman et al. 2007) said that the decision may have been premature. Merck Frosst, the SOGC and the Chief Public Health Officer of Canada have each publicly defended the vaccine program against such criticisms. Was the decision to offer widespread provision of the vaccine sound public policy based on science – the best use of our resources to decrease morbidity and save lives?

# Decision-Making in Public Policy

Decision-making in public policy is challenging; scientific evidence of benefit and risk is only part of the equation. Exogenous factors such as crises and economic pressure, ideology and values, and stakeholders, including media and lobby groups, each necessarily play roles in determining health policy. But all these considerations need to be taken into account in a transparent and systematic manner from both the individual and societal perspectives before making a recommendation. Has this been done in the case of the HPV vaccine?

Erickson and colleagues were funded by the Canadian Institutes of Health Research and Health Canada's Subcommittee on Immunization of the Advisory Committee on Population Health to help enhance decision-making on vaccines and to develop more uniform and evidence-based decision-making in the context of a national immunization strategy. Through a modified Delphi process they defined 58 criteria under 13 broad categories including such factors as the burden of disease, vaccine characteristics, immunization strategy, cost-effectiveness, acceptability, feasibility and evaluability of the program, along with equity, ethical, legal and political considerations (Erickson et al. 2005).

PHAC organized a workshop on the HPV vaccine in 2006, explicitly using the Erickson criteria to evaluate the questions that a public health authority might raise when considering establishment of an HPV immunization program (PHAC 2006). The following year NACI concentrated on two elements of the Erickson criteria (burden of disease and vaccine characteristics) in making specific recommendations about using the vaccine (NACI 2007). The criteria have also been used in the decision-making of the Canadian Immunization Committee (CIC 2007).

We recognize that the federal nature of Canada means that the final shape of any vaccination program rests with provincial governments. However, their decisions will be based, at least in part, on what has transpired at the national level where the Erickson criteria were applied. Therefore, in this commentary we use 10 of the 13 Erickson criteria, including the two that were used by NACI, to revisit the national decision to recommend and fund a program to vaccinate school-aged girls with Gardasil®. The three criteria omitted – ethical and legal considerations and conformity of programs – are more appropriately evaluated in individual provincial-level programs.

Our paper is not a systematic review but rather is intended to stimulate debate about health policy. Therefore, we cite representative literature from well-argued commentaries that present important arguments about public health issues as well as original literature to illustrate our points. A more comprehensive evaluation of the material about cervical cancer and vaccination programs is beyond the scope of this article.

# Erickson Criteria for Decision-Making on Vaccines Burden of disease

Cervical cancer is the 11th most common cause of cancer in women, afflicting 1,350 Canadian women and killing 400 annually. Adding HPV vaccination prior to HPV exposure in girls to an ongoing secondary screening campaign (Pap smears) and the promotion of safe sexual practices is being advanced as a way to reduce the burden of disease from cervical cancer, especially in vulnerable groups of women (CIC 2007). These vulnerable groups include immigrant and Aboriginal women and the disabled, each of whom may miss Pap screening for reasons of culture, language, education, poverty and distance from healthcare facilities (NACI 2007). Previous work in the United States and Belgium has linked school vaccination rates to such factors as fathers' socio-economic status, lower educational level, single-parent families and race (Middleman 2004; Vandermeulen et al. 2008). There does not appear to have been any investigation to establish whether a school-based program of the type being instituted in Canada might miss people from the same demographic who currently have low cervical screening rates, questions related to one of the Erickson criteria. In a survey of Canadian street youth, almost 30% of girls had dropped out of school before grade 8, meaning that they would potentially miss being vaccinated (NACI 2007).

# Vaccine characteristics - evidence of potential benefit and harm

Gardasil® is effective in limiting pre-cancerous changes caused by HPV types 16 and 18, responsible for 70% of cervical cancers, and types 6 and 11, responsible for 90% of genital warts (Garland et al. 2007). The results from a recent systematic review (Rambout et al. 2007) show an overall Peto odds ratio of 0.14 (95% confidence interval 0.09–0.21) from combined per-protocol analyses for the reduction in high-grade cervical lesions caused by vaccine-type HPV strains compared to control groups.

So far the vaccine seems to be safe, with no increase in adverse events reported in the randomized trials done to date. As of the end of February 2009, PHAC had received 407 reports of adverse events following HPV immunization. The majority of these adverse events were not serious and are consistent with the results reported by clinical trials conducted prior to the approval of the vaccine, and can be expected with

the administration of any vaccine (PHAC 2009). In the United States, as of the end of 2008, there were 12,424 reports of adverse events following immunization (AEFIs). Seven hundred and seventy-two reports (6.2% of all reports) described serious AEFIs, including 32 reports of death. Disproportional reporting of syncope and venous thromboembolic events were noted with data mining methods (Slade et al. 2009). These findings must be interpreted against the limitations (possible underreporting) of a passive reporting system. Both CIC and NACI have accepted the vaccine as safe, and neither recommended a post-marketing surveillance campaign. In the absence of long-term data about the vaccine's safety, that acceptance seems premature.

# Research questions and ability to evaluate

At the time of the decision to fund the vaccine, fewer than 1,200 girls under 16 had been studied (Merck now says this is 3,000), and then for an average of only three-and-a-half years. In the age group 9–15, the group being targeted in Canada, the vaccine is immunogenic in the short term but long-term efficacy has not been established (Gostin and DeAngelis 2007). The lack of efficacy data in this age group has also been noted by CIC (2007) and NACI (2007), but both agencies have assumed that immunogenicity will translate into clinical efficacy. Neither recommended any specific research program to validate this assumption. CIC did recommend linking a registry of HPV vaccine coverage with a registry of cervical cancer, as well as a national HPV sentinel surveillance system, but no action has been taken at the national level.

What will be the proper frequency for cervical screening for women vaccinated before adolescence? This question, which has not been answered, is important because the overwhelming majority of lesions with mildly abnormal cytology or histology are not related to either of the types that Gardasil® protects against. Raffle (2007), writing in the *BMJ*, points out that this finding means that screening in this cohort will yield a very high ratio of trivial findings relative to significant ones, where intervention has positive results. If HPV screening replaces Pap smears in vaccinated women, then this concern will be alleviated; but NACI did not deal with this issue, and CIC said only that there is a "need to define the role of HPV testing." Therefore, we cannot be sure what type of screening program will be available in the future.

A reduction in the HPV types 16 and 18 could lead to an epidemiological shift of HPV disease as one or more of the 15 other high-risk oncogenic strains moves to fill the ecological niche (Sawaya and Smith-McCune 2007). As with the other two questions posed above, there is no indication that this issue is being considered in any future research agenda.

# Immunization strategy

The goals of any potential mass vaccination program need to be clearly articulated. CIC has stated that its goal is "to decrease the morbidity and mortality of cervical cancer, its precursors and other HPV-related cancers in women in Canada" through a combination of primary (vaccination) and secondary (screening) programs. If this is to be achieved through the eradication of HPV types 16 and 18 from the general population (the elimination of cancer caused by these types), then should boys also be vaccinated? However, Gardasil® is only now being tested in men, and the results of this trial are not yet available. If a reduction in the burden of harm from cervical cancer is the goal, then we need to know about the duration of immunity following a complete schedule of immunization. This question has not been resolved but has important implications. Lifelong immunity would result in a 61% reduction in the incidence of cervical squamous cell carcinoma, whereas 30-year immunity would reduce this to 6% (Van de Velde et al. 2007).

# Feasibility and acceptability of the program

The success of a vaccination program aimed at school-aged girls will depend on the attitudes of clinicians and parents. Eighty-five per cent to 90% of Canadian family physicians, obstetricians/gynaecologists and paediatricians plan to recommend the vaccine (Duval et al. 2007), but only 70%–75% of parents of girls aged 8–18 indicated that they planned to get their children vaccinated (Ogilvie et al. 2007). The CIC's goal is to achieve a vaccination rate of 80% within two years of the commencement of the program and 90% after five years (CIC 2007). In practice, there has been significant variability in vaccination rates in school programs, ranging from 49% in Ontario to 87% in Quebec (Canadian Press 2009).

#### Cost-effectiveness

Is Gardasil® the most cost-effective measure for public health? The NACI strategy of immunizing every Canadian female aged 9–26 would involve vaccinating over 5 million females at a cost of \$2 billion today for the vaccine alone. Table 1 summarizes the results of the three Canadian cost-effectiveness studies that have been undertaken so far (BC Cancer Agency 2006; Brisson et al. 2007; Marra n.d.). The cost per quality-adjusted life-year (QALY) varies substantially, depending on the underlying assumptions that go into the model; particularly important is how long immunity will last. Two of the models assume an uptake of at least 80% (BC Cancer Agency 2006; Marra n.d.), a rate that has not been universally achieved in Canadian provinces to

date. Furthermore, the study from the British Columbia Cancer Agency (2006), using a vaccine cost of \$300 and assuming the need for one booster at \$100, concluded that over a 26-year period the cost of the vaccine greatly outweighs that of avoiding treatment of HPV-related disease in the province (\$373.6 million versus \$54 million).

TABLE 1. Results of Canadian cost-effectiveness studies

Study	BC Cancer Agency (2006)	Brisson et al. (2007)	Marra (n.d.)
Assumptions	12-year-old girls vaccinated     Protection against HPV 6/11/16/18     80% uptake     Efficacy 100%     Booster shot required at 10 years     Cost per course \$300 + \$100 (booster)	12-year-old girls vaccinated     Protection against HPV 6/11/16/18     Efficacy 95%     Lifetime immunity/30 years/30 years with booster     Cost per course \$400 + \$167 (booster)	<ul> <li>Grade 6 &amp; 9 girls vaccinated (grade 9 catchup)</li> <li>Protection against HPV 16/18</li> <li>Vaccine compliance grade 6: 85% &amp; grade 9: 80%</li> <li>Efficacy 100%</li> <li>Lifetime immunity/10 years</li> <li>Cost per dose \$134.95 + \$12.66 administration (total, 3 doses)</li> </ul>
Cost per quality- adjusted life-year (QALY)	• \$45,000–\$60,000 (2002 US dollars)	\$20,512 (lifetime)     \$64,584 (30 years)     \$36,981 (30 years with booster)     (2005 Canadian dollars)	\$25,417 (lifetime)     \$113,078 (10 years)     (Canadian dollars, year not stated)

# Equity

A key question is the public health outcome of a vaccination program versus the investment of an equivalent amount of money in outreach programs, such as more vigorous promotion of Pap smears and condom use, targeted to high-risk groups. Consistent condom use can reduce the risk of cervical and vulvovaginal HPV infection (Winer et al. 2006). A meta-analysis has shown that 54% of patients with invasive cervical cancer had inadequate screening histories, and 41.5% had never been screened (Spence et al. 2007). These groups of women are extremely difficult, but not impossible, to reach. In the mid-1990s, Australia instituted a program involving funded positions for women's health educators, provider education and public campaigns designed to increase cervical screening rates among Indigenous women living in the Northern Territory (Binns and Condon 2006). The screening rate subsequently improved, although in most areas Indigenous participation remained lower than national levels. In one part of the Northern Territory, however, it was considerably higher. In a US study, the use of health advisers and a nurse practitioner to perform

the screening increased the rates of breast and cervical cancer screening in low-income women, especially those in greatest need (Margolis et al. 1998).

### Political considerations

Before the federal and Ontario governments made favourable decisions about the vaccine, former advisers to both governments registered as lobbyists to work for Merck through the public relations firm Hill and Knowlton. Part of their brief was "Proposed policy decision to support a childhood immunization program for HPV and funding related thereto." The SOGC received a \$1.5-million grant from Merck (Page 2007). These revelations could raise questions about the role that Merck and its lobbyists played in the entire process.

# Conclusion

A summary of the arguments for and against current Canadian policy appears in Table 2.

TABLE 2. Summary of arguments for and against current Canadian policy

	Positives	Negatives
Numbers	More than 25,000 people in trials, larger than for most vaccines     Immunogenicity high in younger ages	Few females under 16 studied
Clinical effects	Effective against strains causing both genital warts and cancer     Appears to be highly efficacious if administered before exposure to the virus     Adverse effects thus far are minimal	Vaccine is immunogenic in the short term in the 9–15 age group but long-term efficacy not established Doesn't cover 30% of oncological strains, unknown potential for oncological shift
Cost-effectiveness	Savings in future?     Cost per QALY gained within acceptable range but dependent on assumptions made in model	Uncertainties about benefits Is the price of the vaccine excessive? Study done for BC Cancer Agency analysis shows vaccination program is much more costly than treatment of HPV at current vaccine price Will use of the vaccine reduce frequency of Pap smears? Will there be a need for boosters? Will high-risk populations be immunized?
Endorsement	Canadian Immunization Committee, Canadian Paediatric Society, National Advisory Committee on Immunization, Public Health Agency of Canada, Society of Obstetricians and Gynaecologists of Canada     Many other countries have approved Gardasil®	Questions about possible conflicts- of-interest in decisions made by government and Society of Obstetricians and Gynaecologists of Canada

Our analysis of the national decision to recommend and fund a vaccination program using Gardasil® raises significant questions about the basis for this program. Many of the questions that we have posed, such as the ability to reach marginalized groups with the vaccine, could either be answered, or strategies to deal with the unanswered questions could be developed, relatively quickly. We are not alone in identifying gaps in the knowledge base and the need for additional research. Indeed, many of the points that we make were also raised by NACI and CIC. These questions could potentially have been investigated during an ongoing vaccination program, but the fact that they were not incorporated into the funding announced by the government, or clearly articulated by PHAC, suggests to us that they may continue to be relatively ignored while the focus is still primarily on vaccination rates.

Some may believe that we are holding this vaccine to a higher standard than is typically applied to other new vaccines. In response, we note that this vaccine is different from others, such as the ones for meningitis that have been recently introduced. Diseases such as meningitis can be rapidly fatal, and a quick response to decrease their incidence is justifiable without long-term studies. In this case, we do not believe that there is the need to rush to make decisions. What is the crisis that precludes wait-

Just because we have a vaccine does not mean that we should rush to implement a program of universal immunization without thinking through the policy implications. ing for better policy to be developed? In asking this question, we do not mean to minimize the pain and suffering that women endure when they have abnormal Pap smears, anogenital warts and, even worse, cervical cancer. However, the fact is that over 90% of women

clear HPV infections within two years, and while the vaccine will reduce the prevalence of HPV infections, herd immunity will require several generations (Canadian Agency for Drugs and Technologies in Health 2007). Just because we have a vaccine does not mean that we should rush to implement a program of universal immunization without thinking through the policy implications. Failure to adhere to a rigorous process for recommending a massive vaccination campaign may severely damage the public image of the healthcare system.

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# Compulsory School-Entry Vaccination Laws and Exemptions: Who Is Opting Out in Ontario and Why Does It Matter?

Lois et exemptions en matière de vaccination obligatoire avant l'entrée à l'école : qui choisit d'être exclut en Ontario et pourquoi cela a-t-il de l'importance?



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## **Abstract**

School-entry vaccination regulations are a policy instrument that has been widely used in some jurisdictions as a mechanism to ensure high immunization coverage rates. Exemptions to school-entry vaccination, which can be allowed on medical or non-medical grounds, present a number of ethical and policy challenges. In this paper, we consider the situation in Canada, where school-entry vaccination laws are rare. We present newly available aggregate-level registry data from Ontario comparing the use of medical and non-medical immunization exemptions to school-entry vaccination and the implications for population health.

## Résumé

La réglementation en matière de vaccination avant l'entrée à l'école est une politique qui a été largement utilisée par certains gouvernements afin d'assurer un taux élevé de couverture vaccinale. Les exemptions à la vaccination avant l'entrée à l'école, qui peuvent être accordées selon des critères médicaux ou non, posent un certain nombre de défis éthiques et politiques. Dans cet article, nous examinons la situation au Canada, où les lois de vaccination avant l'entrée à l'école sont plutôt rares. Nous présentons de nouveaux ensembles de données provenant de l'inscription en Ontario, en comparant l'utilisation des exemptions à la vaccination avant l'entrée à l'école (de nature médicale ou non) ainsi que les répercussions sur la santé de la population.

MMUNIZATION HAS BEEN CALLED ONE OF THE GREATEST PUBLIC HEALTH achievements of the last century (US Department of Health and Human Services 2000). In addition to the protection afforded by a vaccine to an individual, non-immune persons in a community can be protected from person-to-person disease transmission if a threshold proportion of immune persons exists, referred to as "herd" immunity (Fine 2004; Orenstein et al. 2004).

Governments and public health officials have long used schools as an effective community setting in which to implement collective vaccination policies. School-based policies are generally of two types: regulatory instruments (e.g., school-entry vaccination laws) and mechanisms for service delivery (i.e., immunizations administered in the school setting.) In jurisdictions such as the United States, state-level compulsory

vaccination laws are widely used and have been demonstrated to be highly effective towards achieving high coverage rates for routine universal childhood immunizations (Hinman et al. 2002; Hodge and Gostin 2001).

# Vaccination Exemptions: Ethical and Policy Challenges

From ethical and policy standpoints, compulsory vaccination laws require that the state make provisions for those who do not consent to immunization (Gostin 2000). Individuals are usually afforded the opportunity to opt out on medical or non-medical grounds, also referred to as an "exemption." Exemptions, however, can entail a number of policy challenges. First, exemptions (in sufficient number) can compromise herd immunity (Colgrove 2006: 4). Second, it has been argued that exemptions are inherently inequitable: exempted individuals avoid personal risks while maintaining collective benefits (Salmon et al. 2006). Non-medical exemptions are sometimes labelled "religious," "moral," "conscientious" or "philosophical," indicating policy trade-offs prioritizing personal values. Third, and less often emphasized, are the individual consequences of exemptions. Even in highly immunized populations, modelled measles risk (Salmon et al. 1999) and case-control-based pertussis risk (Glanz et al. 2009) have been demonstrated to be substantially higher among unvaccinated than vaccinated children. While undervaccination owing to late or missed immunizations is a significant problem (Guttmann et al. 2006), children who have received no vaccinations, particularly related to non-medical exemptions, are also of concern.

Unvaccinated children are significantly different from their undervaccinated counterparts. Unvaccinated children are more likely to have good primary care (Guttmann et al. 2006), to be male, white, of higher socio-economic status and clustered geographically (Smith et al. 2004), increasing personal and population disease transmission risk through local susceptibility. For example, children exempted for religious and philosophical reasons have been demonstrated to be 35 times more likely than vaccinated children to contract measles, in addition to increasing community risk by upwards of 30% (Salmon et al. 1999).

Given the range of issues related to exemptions recently recapitulated in the United States (Omer et al. 2009), we wanted to examine the current situation for Canada. Our analysis focused on Ontario, one of only two provinces with a compulsory school-entry vaccination law.

# Data and Methods

We reviewed federal and provincial legislation on compulsory vaccination, including school-entry laws (Canadian Legal Information Institute database, http://www.canlii.org). We then examined exemptions in Ontario, using data from the Immunization

Registry Information System (IRIS). IRIS contains electronic immunization records for school-aged children in Ontario based on unvalidated retrospective parental report. While parental recall is one of the least accurate methods of immunization information collection (Bolton et al. 1998), it is likely that parents use written immunization records (the province provides standard "yellow cards" through health units and providers for individuals to maintain themselves), provider records or both to supplement their recall.

Data are maintained separately by each of Ontario's 36 public health units and aggregated periodically by the Ontario Ministry of Health and Long-Term Care (2006). IRIS has acknowledged limitations, including a lack of formal protocols for recording non-compulsory vaccines, incompatibility between health units, an inability to assess coverage rates in real time and a reliance on demographic information collected by boards of education and participating private schools for denominator values used in immunization coverage reports (Association of Public Health Epidemiologists in Ontario 2009). Prior to 2004, data were available only on total exemptions. More detailed aggregate information was recently provided to the researcher for the 2004/2005 and 2005/2006 school years (including registered day nurseries). This encompassed medical and non-medical exemptions across 16 birth-year cohorts for three sets of vaccines: diphtheria—pertussis—tetanus, polio and measles—mumps—rubella (MMR).

We compared (a) medical and non-medical exemptions and (b) birth cohorts. For the birth cohort comparison, we grouped children (1) born in 1997 and earlier and (2) born in 1998 and after. Nineteen ninety-eight was chosen as the dividing year for two reasons. First, "up-to-date" standards for immunization coverage are typically assessed at age 7 (Haimes et al. 2005; PHAC 2006). This grouping was intended to accommodate children with lapsed immunizations but "caught up" by age 7. Second, a widely publicized paper in *The Lancet* in 1998 (Wakefield et al. 1998) alleged a link between MMR vaccination and autism. The paper was compellingly refuted (National Advisory Committee on Immunization 2006: 233), and after a partial retraction by some of the study authors (Murch et al. 2004), it has since been fully retracted by the journal (Editors of *The Lancet* 2010). It has been argued that the events surrounding the paper "triggered a collapse in [public] confidence" in MMR vaccine (Horton 2004: 747). High non-medical exemptions for younger children, particularly for MMR, might provide an indication of public vaccination perceptions related to that era.

# The Limited Scope of School-Entry Regulation in Canada

Compulsory immunization laws of any kind are rare in Canada, limited mainly to federal authority for health protection (e.g., armed forces). It is up to each province/territory to determine which immunizations will be included in routine schedules, to

decide which immunizations will be publicly paid for and to organize how immunizations will be delivered. Provincial/territorial (P/T) programs are informed by national-level expert advice but are not enforced through any legislative mechanism, even in the presence of the new National Immunization Strategy (NIS 2003). Evidence of immunization against specific vaccine-preventable diseases is compulsory at school entry in only two provinces: Ontario (1990) and New Brunswick (1997). In other provinces, immunization enforcement is a matter of local or school authority.

## Limited and out-of-date regulation

Canadian school-entry vaccination laws are both limited and outdated. Only six vaccines are compulsory in Ontario and New Brunswick: diphtheria, tetanus, polio, measles, mumps and rubella. In contrast, the Ontario publicly funded routine immunization schedule includes five additional immunizations prior to school age (not including annual influenza): pertussis, *Haemophilus influenzae* type b (Hib), varicella, meningococcal group C conjugate and pneumococcal conjugate; New Brunswick also includes hepatitis B vaccine in infancy (PHAC 2009). New Brunswick also includes hepatitis B vaccine in infancy (PHAC 2008).

The rapid expansion of P/T immunization programs in the last five years, related to federal funding for the NIS, has contributed, in part, to this disparity. Even so, school-entry regulations are disproportionately out of date. Routine Hib immunization, for example, has been part of all P/T schedules since 1992 and has been administered routinely in all jurisdictions using a combination vaccine (pertussis, polio, tetanus, diphtheria and Hib) since 1998 (Health Canada 1999; PHAC 2006). Hib is not compulsory in either Ontario or New Brunswick, although both provinces have recently amended their regulations (in 2007 and 2006, respectively).

# Exemptions

Exemptions to school-entry vaccination are easily obtained and allowable on medical and non-medical grounds. In Ontario, non-medical exemptions were formerly available only on religious grounds (original 1982 legislation); prompted by anti-vaccination lobby efforts, an amendment was added in 1984 allowing objections of conscience (Arnup 1992), and this is reflected in the current law (1990). Medical exemptions require a physician's statement attesting to prior immunity or contraindication; non-medical exemptions may be obtained simply with a parental affidavit, signed before a commissioner. This is concerning, given that higher non-medical exemption rates have been documented in jurisdictions where administrative procedures are comparatively easy (Rota et al. 2001; Salmon et al. 2005).

# Who is opting out in Ontario?

In Ontario, we found that the overall immunization exemption rate is low: less than 2%. This is comparable to or slightly lower than other estimates in the literature based on data from public health (Toronto 2009) and physician billing (Guttmann et al. 2006) sources, respectively. Such figures represent approximately 35,000 to 40,500 students in any given school year. Of these, approximately 23,000 to 24,500 students have been exempted for non-medical reasons. Non-medical exemptions exceeded medical exemptions for all required vaccines. While older children had slightly higher overall exemption rates, younger children were much more frequently exempted for non-medical reasons.

TABLE 1. Exemptions to compulsory school-entry vaccination in Ontario

Antigen group	School year	Total exemptions		Exemptions for children born in 1998 and onward (%)		Exemptions for children born in 1997 and prior (%)	
		Total exemption rate across all birth cohorts (exempted/ enrolled; %)	Ratio of non- medical to medical exemptions	Total exemption rate, born 1998 and onward (exempted/ enrolled; %)	Ratio of non- medical to medical exemptions	Total exemption rate, born 1997 and prior (exempted/ enrolled; %)	Ratio of non- medical to medical exemptions
Diphtheria- Pertussis- Tetanus	2004/2005	(37,624/2,515,360) 1.50%	1.68	(7,612/632,599) 1.20%	4.32	(30,012/1,882,761) 1.59%	1.38
	2005/2006	(36,186/2,241,677)	1.75	(7,801/598,429) 1.30%	4.31	(28,385/1,638,664) 1.73%	1.43
Polio	2004/2005	(36,840/2,511,499) 1.47%	1.81	(7,715/663,753) 1.16%	4.23	(29,125/1,877,746) 1.55%	1.50
	2005/2006	(35,356/2,436,623) 1.45%	1.95	(5,429/498,749) 1.09%	5.33	(29,927/I,937,874) I.54%	1.64
Measles- Mumps- Rubella (MMR)	2004/2005	(40,501/2,514,378) 1.61%	1.51	(7,546/632,845) 1.19%	4.81	(32,954/I,881,533) I.75%	1.22
	2005/2006	(38,490/2,436,600) 1.58%	1.61	(7,726/653,733) 1.18%	4.77	(30,764/I,782,867) I.73%	1.29
				Mean ratio	4.63	Mean ratio	1.41
				Mean ratio, 2004/2005	4.45	Mean ratio, 2004/2005	1.37
				Mean ratio, 2005/2006	4.80	Mean ratio, 2005/2006	1.45

Source: Ontario Ministry of Health and Long-Term Care. 2008 (August 18). *Immunization Exemptions 2004/05 and 2005/06*. [Unpublished.] Toronto: Author.

# Do Exemptions Matter in Canada? Policy Directions

This was a preliminary look at the nature of exemptions to school-entry vaccination laws in the Canadian setting, with a descriptive examination of Ontario exemptions based upon newly available aggregate data. In the presence of a limited scope of compulsory immunization laws in Canada, the overall exemption rate is low. Non-medical exemptions exceed medical exemptions, however, and younger children appear to have been more frequently exempted for non-medical reasons.

The ability to link these data with individual-level characteristics is not yet possible and reflects continuing gaps in public health reporting (Manuel 2006) and the evolving state of immunization information systems (Toronto 2009). Longitudinal individual-level data, models or both, collated with geographic distribution of exemptions, will be important to ascertain discrete estimates of personal and population risk related to opting out in Ontario. Nonetheless, the preliminary findings presented here are of public health and policy concern.

First, in the presence of continuing underimmunization with regard to national childhood coverage targets (Frescura 2007), increased propensity towards non-medical exemptions in communities constitutes another barrier to achieving the levels of immunization coverage required to prevent disease transmission. Our findings corroborate other studies demonstrating an increasing rate of specifically non-medical exemptions claimed by parents on behalf of their children (Salmon et al. 2005). Given that children with non-medical exemptions tend to be geographically clustered (Salmon et al. 1999; Calandrillo 2004; Omer et al. 2009), such findings present potential risks for transmission of disease and consequently, an impact on population health. As recently as 2005, for example, a large outbreak of rubella (over 300 cases) occurred in a religious community in Ontario opposed to immunization, including 10 cases in pregnant women with the associated risk of congenital rubella syndrome in their newborns (National Advisory Committee on Immunization 2006: 299).

Second, we reflect upon the notion that even in the presence of limited state intervention into individual behaviour, the finding that younger children (born in 1998 and after) appear to have been exempted much more frequently for non-medical reasons suggests that, consistent with trends such as for MMR vaccination in the United Kingdom, Canadian parents too may be increasingly weighing perceived personal risk over personal and population benefit when it comes to making decisions about immunization for their children. Accordingly, effective and accurate communication of vaccination risk has been a dominant concern among immunization advocates.

Finally, a detailed examination of the ethical and legal issues related to nonmedical exemptions in Canada is beyond the scope of this paper, but a few issues are presented here for future consideration. Compulsory immunization policies present

tensions and trade-offs between individual rights and liberties and societal goals. Nonmedical exemptions are one way of dealing with these trade-offs. Different jurisdictions have interpreted these trade-offs differently, however, and a rethinking of this policy issue is perhaps warranted in Canada. In the United Kingdom, for example, in the wake of significant decreases in childhood MMR vaccination coverage, the issue of compulsory vaccination was revisited and not recommended by certain analysts (Salmon et al. 2006). In contrast, in the United States, where compulsory schoolentry immunization laws exist in all states, non-medical exemptions are not uniform; many states do not allow philosophical/conscientious exemptions, and this approach has not been found to be unconstitutional (Calandrillo 2004). It has been argued that compulsory immunization laws "demonstrate a public commitment to vaccination" (Salmon et al. 2005). If policy makers were to update (and potentially extend) compulsory school-entry vaccination laws in Canada, such developments should be incumbent upon a more in-depth policy discussion regarding a national responsibility to ensure a reliable supply of safe and effective vaccines for collective immunization programs (Verweij and Dawson 2004; Salmon et al. 2006).

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# Perspectives of an Interdisciplinary Research Team to Engage Practice: Lessons from a Knowledge Exchange Trainee Experience

Points de vue d'une équipe multidisciplinaire de recherche sur la participation à la pratique : leçons tirées de l'expérience d'un stagiaire en échange de connaissances



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## **Abstract**

End-of-life (EOL) care is an area of health services that will ultimately affect us all. To share the knowledge emerging from EOL research and to address inequities in the quality of EOL care in Nova Scotia, a knowledge exchange (KE) trainee was hired to translate research and surveillance into a Surveillance Report. The purpose of this paper is to reflect upon this initiative and share the research team's perspectives on their KE experiences. We describe four key competencies of the KE trainee selected, and discuss lessons learned from this KE trainee experience, to expand our understanding of KE.

## Résumé

Le soins en fin de vie est un aspect des services de santé qui nous affectera tous un jour. Afin de partager les connaissances issues d'une recherche sur les soins en fin de vie et pour pallier aux inégalités dans la qualité des soins en fin de vie en Nouvelle-Écosse, un stagiaire en échange de connaissances a été embauché pour transposer la recherche dans un rapport de surveillance. L'objectif de cet article est de réfléchir sur cette initiative et de partager les points de vue de l'équipe de recherche sur leur expérience en échange de connaissances. Nous décrivons quatre compétences principales du stagiaire et nous discutons des leçons tirées de son expérience, afin de diffuser notre compréhension sur l'échange de connaissances.

Dalhousie University in Halifax, Nova Scotia, received an Interdisciplinary Capacity Enhancement (ICE) grant from the Canadian Institutes of Health Research to establish ongoing surveillance and monitoring of end-of-life (EOL) care, with a systematic focus on vulnerable populations (Johnston et al. 2006).

EOL care is an area of health services that will ultimately affect us all. A 1995 Senate report (Special Senate Committee 1995) stated that EOL care is "characterized by uneven access to services, and disruptive, ineffective care leading to substandard outcomes." A 10-year follow-up found little change in care provision (Carstairs 2005). In Nova Scotia, only 21% are completely satisfied with EOL services (Cancer Care Nova Scotia 2003). That the number of persons dying of terminal chronic disease will

increase steeply (Saint-Jacques et al. 2002) makes these reports more unsettling. To share the knowledge emerging from Nova Scotia—based EOL research and to address inequities in the quality of EOL care in the province, NELS recruited a knowledge exchange (KE) trainee [SM] to translate research and surveillance knowledge emerging from the NELS/ICE team into a Surveillance Report. Given their limited understanding of and experiences with KE, NELS/ICE researchers decided to employ a dedicated individual to develop the report in cooperation with NELS members and other stakeholders in the EOL care community. The purpose of this paper is to reflect upon this initiative and share the research team's perspectives on their efforts (e.g., hiring a KE trainee) towards making research findings more relevant to decisionand policy makers in Nova Scotia.

## The KE Initiative

Employing individuals in dedicated KE roles (knowledge brokers are one example) may be one way to help researchers and decision-makers communicate their needs and abilities, and advocate for the use of evidence in healthcare (CHSRF 2003; Thompson et al. 2006; Dobbins et al. 2009; Ward et al. 2009). Havelock and colleagues (1971; Havelock 1986) introduced the concept of such "linkers" as individuals who connect the knowledge producers and users by transferring knowledge and communicating users' needs and feedback. The primary role of this KE trainee was to draft the first Surveillance Report by seeking out, acquiring, evaluating and synthesizing the most current available research and other data generated by NELS/ICE team members. The report was meant to translate evidence to inform policy and decision-making and, as such, the trainee was expected to engage stakeholders meaningfully in its development process to ensure an accurate, locally relevant and useful end product. Therefore, to acquire data and contextual information and to share knowledge, the role involved working with NELS/ICE team members; managers of palliative care programs and the provincial cancer agency responsible for advising on cancer care services; policy makers in government (e.g., Department of Health, Health Canada and Vital Statistics); and staff of other agencies/organizations involved in EOL research and care delivery. The KE trainee was expected to evaluate the information received to document an overview of research and surveillance progress and needs, and help identify recommendations for further research development in the Nova Scotia context. Figure 1 presents the research team's vision for the Surveillance Report in relation to its contributors and audiences.

The KE trainee was hired for a four-month period from mid-April to mid-August 2007. Although she had a master's degree in health services administration, she had little previous experience in EOL care or KE theory and practice. While the Surveillance Report is ultimately intended for external audiences, gathering and

evaluating evidence – and placing that evidence in the local context – required the KE trainee to maintain ongoing communication within the NELS/ICE team, particularly the principal investigators [GJ, FB], to ensure that the report was an accurate and comprehensive representation of current knowledge and practices. She also connected with others, primarily via e-mail, to verify data and specific details. The report development process was largely iterative and involved cycles of comment, feedback and revision within the NELS/ICE team.

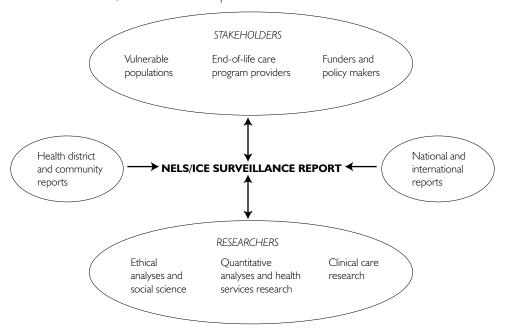


FIGURE 1. The NELS/ICE Surveillance Report in relation to its contributors and audiences

Source: Adapted from End of Life Care in Nova Scotia: Surveillance Report (Network for End of Life Studies 2008).

In addition, there were two formal in-person rounds of consultation to collect feedback from NELS/ICE team members and others associated with EOL care and planning for the province (e.g., policy makers, clinicians, program planners and data managers). An initial consultation meeting was held to gain participants' ideas and visions for the report, an understanding of the data elements or indicators that they desired and the directions they felt the team should take. This meeting set the framework for the report. A similar feedback meeting was later convened to discuss an early draft of the report. Subsequently, as the report progressed in development, drafts were sent to specific reviewers (including clinicians, program managers and policy makers) for their feedback and perspectives.

To maximize a report's usability, a number of factors should be considered. First, authors need to maximize the user-friendliness and relevancy of their messages (Feldman et al. 2001). Reports should be presented in such a way that the information is easily understood without losing its essence. Accordingly, the KE trainee was responsible for incorporating a succinct, attractive and easy-to-read layout and design. As well, data had to be transferred in an easily accessible and "digestible" format and translated into the local context in order to ensure its relevancy to those individuals actually in a position to effect change (Feldman et al. 2001).

A second factor that must be considered is that decision-makers are more likely to use research findings when they are involved early in the KE process (Beyer and Trice 1982). The two formal rounds of consultation and feedback were early in the report process and included decision-makers from various programs and organizations. Additionally, throughout the planning, gathering and drafting stages of the report, the KE trainee worked with managers of provincial palliative care programs and services, as well as staff at local and provincial agencies involved in care delivery for persons nearing EOL. Such involvement promotes awareness of research findings, encourages buy-in to the need for this type of information and supports a collaborative working environment. Additionally, for some people, participation in the planning and feedback stages may promote feelings of ownership over the report, thereby increasing the likelihood they will attend to and use the information upon its release/dissemination (Wathen et al. 2008).

A third factor that increased the complexity of this particular task was the focus on "interdisciplinary research." The NELS/ICE researchers are grounded in three distinctly different disciplines (Figure 2). The KE trainee's supervisor [GJ] has prior experience in "town—gown" partnership formation (Johnston et al. 1998) and interprofessional education development (Johnston and Banks 2000; Johnston et al. 2003). The report's intent was to facilitate research synthesis and generate evidence that permits informed dialogue on appropriate changes/actions that decision- and policy makers may consider to improve care, rather than explicitly improve care. That is, research and surveillance are viewed as intermediary steps towards improving services. Along the continuum of use, the report was meant to increase "enlightening" use of evidence by providing a deeper understanding of the complexity of the problems and the consequences of action, and facilitating the establishment of realistic and achievable goals and benchmarks (Innvaer et al. 2002). An understanding of these three factors was integral to drafting a usable Surveillance Report.

The KE trainee tracked her tasks on a daily basis to determine the primary functions of this KE role. Additionally, she recorded her thoughts and viewpoints on particular tasks to gather contextual data on her work and on KE approaches in the local context. This documentation allowed us to delineate more clearly the core competencies of the KE trainee, reflect upon practices and rethink and improve ongoing KE activities.

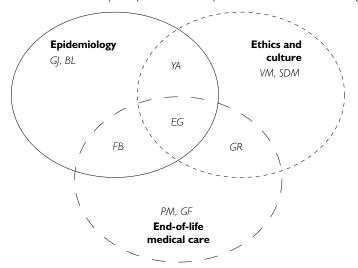


FIGURE 2. Interdisciplinary context of key NELS/ICE research investigators

# Results of the KE Experience

The first Surveillance Report (Network for End of Life Studies 2008) is a synthesis of the most current available data in Nova Scotia surrounding EOL care research and surveillance, with particular emphasis on vulnerable populations. (This report can be downloaded from http://www.nels.dal.ca.) The report identifies issues that require cross-sector dialogue, highlights key findings at a level that is comprehensible to most audiences and presents an overview of a vulnerable population's historical barriers in access to care.

The majority of the KE trainee's time was spent on three broad categories: researching and writing (63%), connecting with people via e-mail and meetings (19%) and directly organizing and responding to feedback (9%). In connecting with people, e-mail use accounted for 63% of this time, and primarily related to the subject matter of the report. The daily journal indicated that the KE trainee was surprised and sometimes frustrated by the amount of time spent using e-mail.

One of the KE trainee's functions was to organize the feedback collected via the two rounds of consultation and respond accordingly (e.g., perform further research, communicate issues to NELS/ICE team members, integrate suggestions into the report, etc). Regarding this, perhaps the most startling feature was the volume of suggestions, comments and critique. While some comments pertained to grammatical and style issues, the vast majority addressed issues the team had not previously considered. Consequently, the KE trainee had to add additional sections ("How is this report different?"), clarify some major issues (e.g., race, ethnicity, language and culture), reframe the layout to feature particular content (e.g., recommendations), omit portions considered irrelevant for decision- and policy makers and extensively revise sections. Overall,

the team regarded the quality of the feedback as exceptional and highly valuable to the report's development, but this added to the KE trainee's workload.

One issue that repeatedly arose during the consultation and feedback processes was how to deal with differing perspectives, for example, defining and naming ethnic origin. Some team members felt that certain terms were unacceptable (e.g., minority, Aboriginal), while others argued the words were standard terminology. The KE trainee worked with the principal investigators either to find a "middle ground" or to state the concern explicitly in the report ("Aboriginal" was kept, with a caveat noting that this was a Statistics Canada term; a better and widely accepted term did not exist).

Prior to recruiting the trainee, the supervisor identified four main competencies (combination of skills, abilities and knowledge [Welton 2007]) required to perform the KE activities related to this role. These attributes were strengths of the KE trainee recruited. While these competencies are necessary, the supervisor later realized that each one contains a "flip side" that is also requisite, and that ideally can be mastered through team KE development processes (Table 1). For example, while the KE role required the ability to work independently and with minimal direction, it also required that the trainee continually operate as a team player, interacting on an interpersonal level and readily adapting to emerging ideas and pursuits. A person skilled in KE should have the ability and comfort level to simultaneously operate from both dimensions of the identified competencies.

# Lessons Learned

# KE trainee perspective

Perhaps the most important lesson learned is that the KE process is not simply the synthesis, dissemination and application of research findings to enhance usability for end users; rather, KE is a complicated, ongoing and highly repetitious process that requires the active participation of both researchers and end users. Reflection on this KE trainee process will contribute to the development of future KE activities.

While not surprising, a second but related lesson is that the iterative nature of the KE process makes it labour intensive. Anyone undertaking a project of this type must be aware of the enormous amount of time and patience required to work successfully and properly with a team of individuals with different backgrounds and priorities, and with limited time to contribute to the process. This view was echoed by the KE trainee's supervisor, who reported that she underestimated the extent of the work and time required to create the report, in the approach described, both in terms of planning/writing and resolving interpersonal conflicts among those drafting the report. While the KE trainee was successful in drafting a complete report within the four months, another year of editing and proofreading was required before all stakeholder issues were fully resolved and the 86-page report was released. Concurrent with this editing,

the NELS/ICE team contracted out a "Listening to Stakeholders" consultative process and report, further enhancing the KE process.

Accordingly, there is a definite need within research teams and organizations to recognize the significance of dedicating resources to KE positions. As KE activities grow in importance, it is difficult for researchers and decision-makers to devote the time and energy required to learn the nuances of effective and efficient KE. A designated and dedicated KE specialist can spend time to connect with interested individuals from a variety of professional backgrounds, cultivate useful and trusting working relationships and use those connections to transfer relevant knowledge across disciplines. If this person begins as a trainee, KE expertise needs to be readily available.

TABLE 1. Competencies required for success in knowledge exchange (KE) activities

KE dimensions	Identification of need	Required KE competencies
Focused vs. "Big Picture"	Recognized initially	Focused and organized to produce attractive product within set time; developed a clear, concise and simple finished product
	Learned through process	Values and has a desire to understand context; incorporates an understanding of the context and interrelationships within work environment and products
Independent vs. Team Player	Recognized initially	Self-directed; worked well on own with minimal direction to achieve predefined goal of preparing draft report in set time period
	Learned through process	Interacts with team and others on an interpersonal level Accepts direction from team leader and adapts to emerging team vision; invites critique of work; revises efficiently in response to critique Shares ownership of work; readily provides documentation and drafts of work to team members
Flow vs. Precision	Recognized initially	Wrote in an easy-to-read style that was logical and clear
	Learned through process	Checks accuracy of details; pays attention to precision in terminology and subtleties of language
"High Tech" vs. "Low Tech"	Recognized initially	Skilled in computer technologies including Internet and database searches, PowerPoint slide production and advanced word-processing features (e.g., table of contents, footnotes, track changes, headers/footers, etc.)
	Learned through process	Uses "lower tech" processes and trains others to use     "high tech"; values non-technological rigour and wisdom

# Supervisor perspective

Despite being experienced researchers in epidemiological, health services and clinical studies, NELS/ICE team members had limited experience with supporting and car-

rying out KE activities. Accordingly, one of the main lessons was the need for applied generic KE tools and supports, and established research team writing processes and methods, especially if a trainee rather than an experienced KE specialist is recruited. This need is critical given the embryonic stage of KE development. Generic KE tools and supports include KE job descriptions and hiring tips; descriptions of KE responsibilities and expectations; "to do" checklists (CHSRF 2006) and timelines; self/team evaluation and reflection tools (CHSRF n.d.); and expertise/mentors. While the sharing of tools such as job and role (responsibility and expectation) descriptions for KE personnel may appear straightforward, these tools were not available at the research team's institutions during the hiring process, yet would have assisted a research team with limited KE experience.

The NELS/ICE team has committed to developing capacity and building infrastructure. However, a tension exists between selecting trainees who will develop skills through involvement in the KE and research team processes (requiring additional time and effort) versus hiring experienced individuals (requiring additional funds). This tension is a reality in the current health research environment and will remain as the KE field evolves because skilled KE personnel are in short supply. While it is vital to increase capacity, researchers will have to consider the advantages and disadvantages of training their own KE personnel versus maximizing project efficiency by contracting or directly hiring KE experts.

Finally, a report in itself is inadequate at translating findings in a meaningful way for most people. The research team has become keenly aware of the message of Lavis and colleagues (2003) that interactive engagement may be most effective at transferring research knowledge. Accordingly, it is vital that researchers meet with decision-makers one-on-one or in small groups, discover their interests and begin to understand how to build bridges between their needs and interests and what the research team has learned and has the capacity to provide. In the end, developing relationships by working with people over time, and in mutually beneficial ways, is key to effective KE. One tool that has proven valuable for the NELS/ICE team is regular work-in-progress sessions, which allow the researchers to maintain engagement with stakeholders while concurrently providing stakeholders the opportunity to learn about EOL research and contribute their tacit knowledge and experience during the research development and analysis phases.

# Summary

A goal of the NELS/ICE research team is to build a surveillance system with KE processes to enable development of policies and interventions for comprehensive community-based care. Though there was no formal evaluation to explore the extent to which decision-makers actually used or referred to the report in their subsequent

work, the addition of a dedicated KE trainee facilitated the selection of knowledge and its adaptation to the local context, and actively supported relationship-building between researchers and end users. Given the lessons learned, as the NELS/ICE team progresses with its research and surveillance agendas, researchers will be encouraged to meet directly with stakeholders to cultivate these relationships and undertake KE responsibilities (e.g., act as their own "linkers") rather than employing an outside individual, unfamiliar with the research team, to adopt the KE role. As researchers develop their KE skills, their credibility may make them ideal choices as "linkers" between their work and the decision-making communities (Lavis et al. 2003). Certainly, this reflection on incorporating a KE trainee has provided insight for further development of our KE activities. We hope our experiences will be useful for other research teams embarking on integrated and expanded KE endeavours.

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# A Case Study on the Substitution Effect between the Length of GP Consultation and Drug Prescribing Practices

Étude de cas sur l'effet de substitution entre la durée de consultation chez l'omnipraticien et les pratiques de prescription de médicament



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## A Case Study on the Substitution Effect between the Length of GP Consultation and Drug Prescribing Practices

## Abstract

The relationship between the length of GP consultation in primary care and drug prescribing practices is still a subject for debate. Patients' morbidity, generating both very long consultation times and large volumes of prescriptions, may mask an underlying substitution among GPs regarding the length of time they offer to patients versus the alternative of prescribing pharmaceuticals. We propose to pursue the debate by analyzing the results of a case vignette, submitted to 1,900 GPs, in which patient morbidity is controlled for by definition. In this case – a hypothetical patient suffering from mild depression – we observe the choice between three types of treatment strategy: psychotherapy, drug therapy and a combination of the two. We observe that the GPs with the highest consultation rates were twice as likely to adopt the drug therapy option as their counterparts with lower rates of consultation. Moreover, for more than 50% of drug prescriptions, the medical decisions contradict clinical practice guidelines.

## Résumé

La relation entre la durée de consultation dans les soins primaires et les pratiques de prescription est un sujet qui suscite encore des débats. La morbidité des patients, qui donne lieu à de longues consultations et à de grandes quantités de prescriptions, peut dissimuler un effet de substitution chez les omnipraticiens entre temps consacré aux patients et prescription de produits pharmaceutiques. Nous proposons de poursuivre le débat en analysant les résultats d'une vignette, présentée à 1900 omnipraticiens, dans lequel la morbidité du patient est, par définition, contrôlée. Dans ce cas (un patient hypothétique souffrant de dépression légère), nous étudions le choix entre trois types de stratégies pour le traitement : la psychothérapie, la pharmacothérapie et une combinaison des deux. Nous observons que les omnipraticiens ayant les plus hauts taux de consultation sont deux fois plus enclins à opter pour la pharmacothérapie que leurs pairs qui ont de plus bas taux de consultation. De plus, dans plus de 50 % des cas de prescription, la décision médicale ne respecte pas les lignes directrices de la pratique clinique.

ANY STUDIES HAVE SOUGHT TO DEMONSTRATE A CORRELATION between the length of physicians' consultation and the number of prescriptions written; for example, a 1972 study highlighted that 52% of GPs declared that they would prescribe less medicine if they had more time available during consultations (Dunnel and Cartwright 1972). Several subsequent studies have confirmed a negative relationship between the length of consultations and the number of pills prescribed: in general, prescribing pharmaceutical products is seen as an

opportunity for "substitution," enabling the doctor to save time with regard to patient education or psychological support (Dugdale et al. 1999; Freeman et al. 2002; Garnier and Marinacci 2001). Other results demonstrate the opposite effect: the longer the consultation, the more prescriptions are written (Amar and Pereira 2005; Heaney et al. 2002). Finally, other studies find no significant relationship between the length of a consultation and prescriptions written (Deveugele et al. 2002; Ridsdale et al. 1989).

These studies do not distinguish among the patients' illnesses, thereby potentially skewing the findings. Patients who suffer from serious pathologies require both long consultation times and numerous prescriptions. However, some doctors see chronic patients who simply need to renew prescriptions: then the consultation time is short, but the number of prescriptions per visit is high. Such heterogeneity in practice can suggest a correlation between the length of consultation and number of prescriptions, one that falsely blurs a fundamentally negative relationship based on the substitution of consultation time vis-à-vis prescription of medicines.

In our study protocol, the problem of heterogeneity does not arise because our starting point is a single, homogenous "clinical case" presented as a case vignette: all doctors in the survey were faced with the same hypothetically depressed patient. This approach could be compared to the methodology of the "standardized patient," used to measure variations in medical practice (people trained to portray patient roles during consultation; see, for example, Hutchison et al. 1998; Beaulieu et al. 2003). Case vignettes and case studies are a relatively cost-effective means of surveying many physicians, although the case submitted necessarily remains hypothetical. The analyses presented in this paper are based on this approach, with the aim of clearly documenting the relationship between the doctors' patient turnover rate and the number of prescriptions written as a treatment option.

# Methods

To create the sample, 4,592 independent GPs from five French regions with varying medical densities were contacted first by mail and then by telephone: a professional interviewer asked the physicians to participate, requested their consent and conducted the survey using a computer-assisted telephone interview (CATI). The questionnaire was previously pilot-tested with 20 GPs to check its clarity, length and face validity.

The initial random sampling was stratified by sex, age (under 45, 45 to 53 and 53 or over) and the type of area (rural, suburban and urban). Of the initial 4,592 GPs, 31.6% (n=1,453) refused to participate in the study. These physicians did not differ from the participants with respect to sex (p=0.22) or type of practice area (p=0.84), but they were older (p=0.001). In addition, 16.2% (n=744) were unreachable (because they were dead, retired, sick, had moved, or because the investigator had the incorrect telephone number) and 10.8% (n=494) were either moving or retiring in under six

## A Case Study on the Substitution Effect between the Length of GP Consultation and Drug Prescribing Practices

months or practised exclusively in a specific type of treatment (acupuncture, homeopathy, etc.), making them ineligible. Eventually, 1,901 doctors participated in the survey. As the sample structure could not be considered significantly different from the actual population structure of French GPs according to the three stratification criteria cited above, the representativeness of the sample was confirmed (p-value of the test of difference in proportion = 0.84).

The questionnaire covered the general working conditions of these 1,901 GPs. The variables relate to the doctors' socio-demographic data (age, sex, city and region of activity, etc.) or to their activity (billing sector, work in a group practice, participation in PPE [professional practices evaluation] or CME [continuing medical education]). A measure of GPs' sensitivity to the risks of polypharmacy was included. It was built by scoring physicians' level of agreement to five polypharmacy risk-reduction actions (see Figure 1): if GPs agreed with at least three propositions, we considered that they were sensitive to the risk of polypharmacy. Other objective information concerning the doctors' activity was provided through a matching process with the files of the Assurance maladie (French social security service), which in France registers all consultations made by every GP for a given period (month or year). These files enabled us to calculate the average length of consultation based on the total duration of activity declared by the doctor, divided by the number of procedures.<sup>2</sup> In this way we obtained an average figure indicating rhythm of practice, not based on any single day but rather based on activity over a continuing period (as a style of practice). By projecting these figures as weekly data, we obtained a regular consultation pattern for a physician's typical week.

FIGURE 1. Polypharmacy survey questions

In reducing risks of polypharmacy for patients over the age of 65, what is your level of agreement with the following items?					
I – Take more time to Very strongly agree		n medicinal interactions Strongly disagree			
2 – Follow up patients Very strongly agree	0 ,	Strongly disagree	Very strongly disagree		
3 – Organize prescribe Very strongly agree	U	,	Very strongly disagree		
4 — Give priority to non-drug treatment when it is possible  Very strongly agree Strongly disagree Very strongly disagree					
5 – Check prescriptions made by other physicians to these patients Very strongly agree Strongly agree Strongly disagree Very strongly disagree					

The questionnaire also included the following specific case vignette:

A known patient suffering for the first time from mild and temporary depression with no suicidal tendencies requests a consultation. What type of treatment do you provide? (several answers possible)

The doctor could choose from several possibilities: provide or prescribe psychotherapy, prescribe chemotherapy or prescribe phytotherapy (herbal medicine, such as St. John's wort in the case of depression). This vignette was constructed with the help of members of the Haute autorité de santé (HAS, the French national authority for health), because the final objective of the study was to examine the determinants of recourse to phytotherapy (recently reimbursed by the French social security system). We nevertheless felt that it was relatively more interesting to observe the "upstream" choices between resorting to drugs (including phytotherapy) and psychotherapy exclusively. We divided the doctors' answers into three categories: (1) doctors opting exclusively for the prescription of drugs, (2) doctors opting exclusively for non-drug treatment (psychotherapy) and (3) doctors suggesting a combination of drugs and non-drug options.

We intended to highlight the factors associated with these choices of treatment in the clinical case presented, a patient suffering from mild depression. We performed a multinomial logistical regression in which the dependent variable represented the three modalities – 1,2,3 – described above (multinomial methods allow taking into account the choice between the three options simultaneously). Two alternatives – "exclusive choice of drug treatment" and "choice of combining drug and non-drug treatment" – were compared to the reference "exclusive choice of non-drug treatment." Because the number of variables included in the model was not important (about 15), we performed a stepwise backward calculation with a 10% exit threshold, allowing us to add back variables if they later appeared to be significant. The analyses were performed using the SAS V9 software.

## Results

Two hundred and twenty-five doctors (i.e., 12.28% of the sample) opted for the purely pharmaceutical solution, 410 (22.38%) chose to provide or prescribe psychotherapy without any drug and 1,197 (65.34%) preferred to combine psychotherapy and drugs. Of those opting for a purely pharmaceutical solution, 133 (59.11%) chose chemotherapy rather than herbal therapy. Table 1 presents the results of the multinomial analysis between option 1 (exclusively drugs) and option 2 (psychotherapy). The regression analysis between option 2 (psychotherapy) and option 3 (combination of a drug and psychotherapy) is presented in Table 2.

## A Case Study on the Substitution Effect between the Length of GP Consultation and Drug Prescribing Practices

TABLE 1. Characteristics associated with the exclusive prescription of drug compared to the exclusive prescription of non-drug treatment\*

Variable	Category	Simple logistic regression		Multiple logistic regression	
		OR [95% CI]	P	OR [95% CI]	P
Type of practice area	Urban Suburban Rural	   1.18 [0.76–1.84]   1.63 [1.11–2.39]	0.46 0.01	   1.19 [0.74–1.90]   1.61 [1.06–2.44]	0.48 0.02
Region	Loire Lower Normandy Burgundy Brittany PACA	1 2.80 [1.50–5.23] 1.72 [0.95–3.11] 2.50 [1.50–4.18] 1.97 [1.19–3.27]	0.00 0.07 0.00 0.01	I 2.57 [1.35–4.88] 1.65 [0.90–3.03] 2.40 [1.42–4.06] 2.05 [1.20–0.50]	0.00 0.11 0.00 0.01
Participation in CME	Yes No	l 2.33 [1.39–3.92]	0.00	   1.91 [1.11–3.29]	0.02
Mean frequency of visits of drug representatives (weekly) (between 0 and 30)		1.14 [1.10–1.19]	0.00	1.13 [1.09–1.18]	0.00
Sensitivity to the risks linked to polypharmacy	Yes No	l 2.85 [1.45–5.62]	0.00	l 2.66 [1.31–5.39]	0.01
Rate of GPs who wish to reduce their work time		1.01 [1.00–1.02]	0.14	1.01 [1.00–1.02]	0.03
Average length of consultation	> 30 min < 30 min	l 2.27 [1.46–3.53]	0.00	l 2.04 [1.29–3.22]	0.00

<sup>\*</sup> The other variables tested were: sex; age; marital status; sector of practice; work in group practice; response modality; participation in PPE; share of patients with universal health coverage; share of patients over 60; use of an active information source such as a guidelines, medical journals, pharmaceutical laboratory or HAS websites, practice of "soft" medicine and use of a computer to prepare prescriptions.

As seen in Table 1, the probability of prescribing drugs exclusively varied significantly according to the size of the town (p=0.02 for rural district) and region where the practice was located (p=0.01, but depending on regions), and was significantly higher among doctors not participating in CME (p=0.02), those with a high frequency of receiving medical representatives (p<.01), those less sensitive to the risks linked to polypharmacy among elderly people (p=0.01), those who wish to reduce their work time (p=0.03) and those who demonstrate short consultation length (p<.01).

Table 2 (the other face of the multinomial regression model) analyzed the choice between a mix of pharmaceutical and psychotherapeutic treatment vis-à-vis psychotherapy only. In the multiple regression model, the predictors of this choice are exclusively centred on drug issues: only high frequency of receiving pharmaceutical sale representatives and sensitivity to the risks of polypharmacy among elderly people remain significant (p<.01 and p=0.01, respectively). Consultation length was not significant in these cases.

**TABLE 2.** Characteristics associated with mixed prescription of drug and non-drug treatment compared to the exclusive prescription of non-drug treatment

Variable	Category	Simple logistic regression		Multiple logistic regression	
		OR [95% CI]	P	OR [95% CI]	P
Type of practice area	Urban Suburban Rural	0.87 [0.64–1.19] 0.94 [0.71–1.25]	0.38 0.69	0.94 [0.69–1.29] 0.96 [0.72–1.29]	0.71 0.40
Region	Loire Lower Normandy Burgundy Brittany PACA	1 1.07 [0.70–1.65] 0.81 [0.56–1.18] 0.84 [0.60–1.16] 1.18 [0.87–1.60]	0.75 0.27 0.28 0.28	   1.05 [0.68–1.63]   0.77 [0.52–1.12]   0.80 [0.57–1.12]   1.05 [0.76–1.45]	0.82 0.17 0.19 0.75
Participation in CME	Yes No	I I.67 [1.10–2.51]	0.02	I I.46 [0.96–2.23]	0.08
Mean frequency of visits of drug representatives (weekly) (between 0 and 30)		1.10 [1.06–1.13]	0.00	1.09 [1.06–1.13]	0.00
Sensitivity to the risks linked to polypharmacy	Yes No	I I.37 [0.77–2.43]	0.00	I I.29 [0.72–2.32]	0.01
Rate of GPs who wish to reduce their work time		1.00 [0.99–1.01]	0.85	1.00 [0.99–1.01]	0.79
Average length of consultation	> 30 min < 30 min	I I.18 [0.91–1.53]	0.21	I I.II [0.85–1.45]	0.45

## Discussion

The independent variables selected by the stepwise calculation were expected: the independence in relation to the pharmaceutical industry (low number of pharmaceutical sales representatives) and the attitude to the risk of polypharmacy are predictors of a low rate of recourse to drug treatment. This finding tends to validate the approach adopted, in particular the quality and sincerity of the doctors' answers to the clinical case put to them.

The length of consultation influenced the choice of strategy adopted by the GPs. Doctors with a lower average length of consultation also favoured prescription of drugs; there is therefore a negative correlation between the length of consultation and prescription. GPs with a lower average length of consultation may attempt to shorten the patient's visit: writing a prescription can be seen as a means of bringing the consultation to a close and inviting the patient to leave (Thomas 1978). In the case of doctors providing psychological treatment themselves in the non-drug option, a substitution can be envisaged between the therapeutic listening performed by the doctor to treat

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depression and recourse to a pharmacopoeia, enabling the doctor to save time in seeing the patient. (Indeed, among doctors who opt for an exclusively non-drug choice, 67.8% claim to provide psychotherapy themselves; furthermore, even in the case of psychotherapy provided by a colleague – a psychiatrist or psychologist – it is difficult to imagine that referral to a specialist is possible without an explanation of the reasons for

Another independent variable mirrors this result significantly: the more doctors wish to reduce their workload, the more they opt exclusively for drug prescription. the referral.) Another independent variable mirrors this result significantly: the more doctors wish to reduce their workload, the more they opt exclusively for drug prescription. In the second part of the regression – the comparison between a combination

of drug and psychotherapy vis-à-vis exclusive psychotherapy – there is no significant relationship between the length of consultation and the choice of prescription (p=0.45)(Table 2). This finding confirms the "time-saving" interpretation (substitution effect). The pressure of a high rhythm of consultation has no effect on the choice of modalities in which the doctor must, in all cases, devote psychological listening time to the patient.

Our findings of a negative correlation between the length of consultation and prescription are similar to those presented in the studies by Wilson (1985) and Davidson et al. (1994). The first paper suggests that if doctors engaged in longer consultations, they might reduce the number of drugs prescribed as well as improve the quality of the treatment provided. In the second, the over-prescribers are shown to be doctors with a heavy workload. Our study differs from that of Wilson insofar as the activity data supplied by the French social security office enabled us to obtain more reliable results (which are not simply declarative) concerning the length of consultations.

The strength of our study lies in the construction of the questionnaire: as the situation is identical for all the doctors surveyed, the biases caused by patient heterogeneity are removed. Nevertheless, it remains to be seen whether the negative correlation between the length of consultation and prescriptions written can be generalized for all pathologies, or whether the correlation is seen only in cases of treatment in the field of mental health, where the choice between therapeutic listening time and drug treatment is most clear cut.

Finally, we had the opportunity to examine the doctors' choices from the point of view of quality of care. The clinical case presented, i.e., a mild and temporary depression, does not correspond to the indications for drug chemotherapy as first-line treatment (ANAES 2002). However, this was the approach most often adopted by physicians who chose the drug-only option (of the 225 GPs who opted for a purely

pharmaceutical solution, 133 chose chemotherapy). If we disregard the doctors who opted for herbal therapy, which is a practice more consistent with ANAES guidelines, the average length of consultation variable is still significant at p=0.01 (and becomes non-significant for herbal prescriptions). Therefore, if public authorities wish to improve medical practice and curb certain reimbursements resulting from excessive drug prescription, they should pay more attention to the work time of self-employed

... if public authorities wish to improve medical practice and curb certain reimbursements resulting from excessive drug prescription, they should pay more attention to the work time of selfemployed GPs. GPs. We are conscious that controlling the work time of GPs, as an input for healthcare quality, could be difficult (see, for example, Wilson and Childs 2006 for a Cochrane review on interventions to change consultation times in general practice). But policy considerations, such as better

distribution of doctors across the territory (avoiding excessive workloads for doctors in underpopulated areas) or the adoption of payment schemes unrelated to the number of procedures, might affect the length of consultation: GPs less subject to time pressure would be more inclined to adopt different therapeutic strategies. Another policy option might aim to modify prescribing patterns directly, through education and druguse documentation, to counterbalance probable biases in information provided by pharmaceutical sales representatives (Lexchin 1997).

## Conclusion

We were able to interview independent GPs in five regions of France concerning the prescription strategy they adopt in the (hypothetical) case of a depressive patient. Among the characteristics of GPs who exclusively prefer to prescribe a drug instead of psychotherapy, we note that the role of length of consultation is decisive: the shorter the average consultation, the more doctors are likely to prescribe pharmaceutical treatment, which in this case does not conform to recommended practice.

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#### NOTES

- <sup>1</sup> But GPs who practised these types of medicine in a non-exclusive manner were included.
- <sup>2</sup> Specifically: the variable *length of consultation* in minutes was calculated by dividing the duration of activity declared by the doctor through the telephone questionnaire (total time worked as an independent doctor minus the time devoted to administrative tasks, medical training, speaking with medical representatives, etc.) by the number of procedures during the given period (a month or a year; to ensure that we eliminated seasonality in the date of the interview, we selected a year as the reference period, even if at the end of the study we projected the results into weekly data). The calculation also takes into account a constant transport time for all house calls of 10–20 minutes, with the precise value depending on whether the GP was located in an urban or a rural area. Consultations undertaken outside the scope of reimbursed healthcare are not considered, e.g., telephone or free consultations (less than 1% of the activity).

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# Public Perceptions of Physician– Pharmaceutical Industry Interactions: A Systematic Review

Perception du public sur l'interaction entre les médecins et l'industrie pharmaceutique : une revue systématique



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# **Abstract**

*Background*: Interactions between physicians and the pharmaceutical industry have led to concerns about conflict of interest (COI), resulting in COI guidelines that suggest a threshold beyond which interactions may be considered unacceptable. Guidelines

have also outlined the importance of public opinion on the topic. Consequently, we conducted a systematic review to determine the Canadian public's opinions of physician—pharmaceutical industry interactions.

Methods: A systematic review of the standard health sciences literature as well as grey literature was conducted and a number of experts were contacted. Pre-determined eligibility criteria were used to identify appropriate studies. Meta-analysis of the study findings was not possible owing to the variety of methods of reporting outcomes, the types of interactions studied and the diversity of populations studied.

Results: No studies on Canadian opinions were identified. Ten international studies (n=13,637), seven with patient groups and three with public citizens, were identified that examined opinions on aspects of awareness, acceptability, disclosure and perceived effects of physician—pharmaceutical industry interactions. Heterogeneity was observed in the awareness, acceptability and perceived effects of physician—pharmaceutical industry interactions; however, there appeared to be greater acceptability and fewer perceived effects with smaller, less costly interactions that directly benefit patients or a medical practice. Desire for disclosure of these interactions was consistent across studies. Interpretation: Research on the public's perception of physician—pharmaceutical industry interactions has been inadequate internationally and non-existent in Canada, and is urgently needed to help shape policies regarding potential conflict of interest.

# Résumé

Contexte : L'interaction entre les médecins et l'industrie pharmaceutique est source de préoccupation quant à la possibilité de conflits d'intérêts, ce qui a mené à des lignes directrices proposant un seuil au-delà duquel l'interaction pourrait être considérée inacceptable. Les lignes directrices font également voir l'importance de l'opinion publique sur le sujet. Nous avons donc mené une revue systématique pour déterminer quelle est l'opinion du public canadien sur l'interaction entre les médecins et l'industrie pharmaceutique.

Méthodologie : Nous avons procédé à une revue systématique de la littérature scientifique et grise, et nous avons communiqué avec des spécialistes. Les études ont été choisies selon des critères d'admissibilité prédéterminés. Il a été impossible de procéder à une méta-analyse des conclusions des études étant donné la variété de méthodes pour la présentation des résultats, les types d'interaction considérés et la diversité des populations étudiées.

Résultats: Nous n'avons trouvé aucune étude sur l'opinion des Canadiens. Nous avons repéré dix études internationales (N=13 637), dont sept portant sur des groupes de patients et trois sur des populations de citoyens, qui examinaient l'opinion au sujet de la prise de conscience, de l'acceptabilité, de la divulgation et des effets perçus en matière d'interaction entre les médecins et l'industrie pharmaceutique. Nous avons observé une

hétérogénéité pour ce qui est de la prise de conscience, de l'acceptabilité et des effets perçus; cependant, il semble qu'il y a une plus grande acceptabilité et moins d'effets perçus pour ce qui est des interactions plus petites et moins coûteuses qui présentent un avantage direct pour les patients ou pour un cabinet médical. La divulgation de ces interactions est un souhait qui s'observe de façon constante dans toutes les études. Interprétation: À l'échelle internationale, la recherche sur la perception du public au sujet de l'interaction entre les médecins et l'industrie pharmaceutique reste inadéquate, alors qu'elle est absente au Canada. Il y a un besoin urgent pour ce type de recherche afin d'aider à orienter les politiques au sujet des conflits d'intérêts.

NTERACTIONS BETWEEN PHYSICIANS AND THE PHARMACEUTICAL INDUSTRY are frequently documented and debated within the medical literature (Moynihan L 2003; Higgins 2007; Blumenthal 2004; Lambert 2005). A recent study revealed that 94% of physicians have some form of interaction with the pharmaceutical industry (Moynihan 2003). In addition to the more common interactions such as pharmaceutical detailing, the exchange of drug samples and industry-sponsored meals, physicians are regularly solicited to participate in industry-funded research and attend industry-funded continuing medical education (CME). Furthermore, select groups of physicians are asked to lead industry-funded research, sit on advisory boards and deliver industry-developed presentations (Campbell et al. 2007; Ross et al. 2008; Kaiser Family Foundation 2002; Holmer 2001). While these interactions have resulted in important clinical benefits, such as the advancement of valuable treatments (Stossel 2005), a number of highly publicized adverse events have also occurred (Psaty and Kronmal 2008; Kondro 2004; Olivieri 2003). The effects of physician–pharmaceutical industry interactions on physician behaviour have been reviewed and suggest an impact on prescribing practices, professional behaviour and attitude towards interactions with the pharmaceutical industry (Wazana 2000). Consequently, the potential for negative effects has led to concerns from physicians, academics and regulatory boards regarding conflict of interest (COI), where COI is broadly defined as conditions that cause a physician's primary interest – patient welfare – to be adversely influenced by secondary powers (Holmes et al. 2004).

As a result of these frequent interactions, a number of regulatory and advisory bodies have issued COI guidelines suggesting a threshold beyond which physician—pharmaceutical industry interactions are considered unacceptable (CADTH 2006a; Canada's Research-Based Pharmaceutical Companies 2007; CMA 2007; RCPSC 2005; CFPC 2006). Professional colleges such as the Royal College of Physicians and Surgeons of Canada have included statements in their COI guidelines that suggest physicians reflect on what the public would think of a physician—pharmaceutical

industry interaction when they are unsure whether it is appropriate (RCPSC 2005). The RCPSC believes that this is important because, according to its guidelines, "when physicians are seen or perceived to be in conflict of interest there is an inevitable erosion of public trust which is fundamental to our patients and society" (RCPSC 2005).

A number of previously published papers have articulated the same concerns, arguing that any physician-pharmaceutical industry interaction that leads the public to believe physicians are biased in their prescribing practices will affect the credibility of these physicians. Although the resulting biases may be unintentional, such public opinions could result in mistrust in physicians and in the greater healthcare system (Blumenthal 2004; Marco et al. 2006; Katz et al. 2003; Brennan and Mello 2007). However, it is only recently that the engagement of public opinion and public participation in health policy making has been recognized as important to ensure public trust and credibility of the healthcare system (CADTH 2006b; Ministry of Health and Long-Term Care 2006). Because public programs such as our medical and drug plans require the public's trust that physicians hold their patients' best interests paramount, we believe it is important to determine public opinions on this issue. Consequently, we undertook a systematic review of the literature with the primary goal of examining the Canadian public's perceptions on physician-pharmaceutical industry interactions. As a secondary question, we sought to understand the international public's opinions on this topic.

# Methods

The literature search was oriented specifically to awareness, acceptability, desire for disclosure and perceived effects of physician—pharmaceutical industry interactions. The search was carried out in MEDLINE (1966 – April 2007), EMBASE (1980 – April 2007), Cochrane Database of Systematic Reviews (1966 – April 2007), Business Source Complete (1866 – April 2007) and ABI Inform Global (1971 – April 2007), using various combinations of the following terms: conflict of interest, drug industry, public opinion, physician, gift giving, medical ethics, drug manufacturer, pharmaceutical industry and marketing. Studies were limited to the English language, excluding letters and editorials.

In addition, the grey literature was searched using a general Internet search engine (Google.ca), as well as the online libraries of a number of relevant Internet sites (Healthyskepticism.org, Nofreelunch.org, Public Citizen Health Research group and Ipsos—Reid public polling). Finally, seven experts on the topic were contacted to make certain that no relevant studies were missed. Specific study characteristics were abstracted to determine those for inclusion, including (a) type of study — survey designs, focus groups or opinion polls, with either a random or convenience sampling method; (b) participants — adults, in the general public or patient groups. If public

opinions were gathered alongside other groups' views, these were included if analyzed independently. Studies involving Canadian subjects were to be analyzed separately; (c) outcomes – outcome measurements of at least one of the following: (i) awareness of physician–pharmaceutical industry interactions; (ii) acceptability of interactions; (iii) disclosure of interactions; and (iv) effects of interactions.

Studies were initially examined for appropriateness of inclusion by one reviewer (JA), who was not blinded to study authorship. A data extraction sheet was developed and pilot-tested by the two data abstractors (JA and WW). Subsequently, two reviewers (JA and WW) independently extracted data from the studies. Data were collected on study design, sample characteristics and outcome measures. Disagreement among abstractors was resolved by consensus. A qualitative summary and meta-analysis of each type of outcome related to physician—pharmaceutical industry interactions was planned.

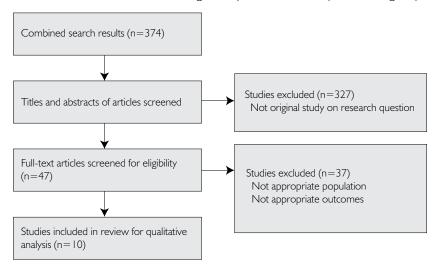


FIGURE 1. Flow of information through the systematic review (PRISMA diagram)

# Results

Three hundred and seventy-four studies were identified as potentially relevant. After review of the abstracts, 327 studies were discarded because they were not original studies on the proposed topic. Full text of the remaining 47 studies was retrieved for detailed evaluation, in which 37 studies were excluded because they did not meet inclusion criteria for participants or outcome measures. Ten studies met inclusion criteria for subsequent data extraction (Blake and Early 1995; Mainous et al. 1995; LaPuma et al. 1995; Gibbons et al. 1998; Eaton 2003; Wall Street Journal Online 2003; Kim et al. 2004; Hampson et al. 2006; Semin et al. 2006; Weinfurt et al. 2006). However, none of the 10 studies examined the primary study question regarding

the Canadian public's opinions on physician—pharmaceutical industry interactions; instead, all had an international focus. As a result, only the secondary research question could be examined in this review. Figure 1 outlines the aforementioned process.

Combined, the 10 studies surveyed a total of 13,637 participants (range of 139 to 5,478 participants per study). Seven studies used various survey designs (Blake and Early 1995; Mainous et al. 1995; LaPuma et al. 1995; Gibbons et al. 1998; Hampson et al. 2006; Semin et al. 2006; Kim et al. 2004), one study used focus groups (Weinfurt et al. 2006) and two used online Internet opinion polls (Eaton 2003; Wall Street Journal Online 2003) (Table 1). The studies examined various aspects of physician-pharmaceutical industry interactions, most notably awareness, acceptability, disclosure and perceived effects. The majority of studies focused on patient populations (Blake and Early 1995; LaPuma et al. 1995; Gibbons et al. 1998; Kim et al. 2004; Hampson et al. 2006; Semin et al. 2006; Weinfurt et al. 2006); however, one study used a random sample of adults (Mainous et al. 1995), while the studies with Internet opinion polls used a convenience sample of adults visiting their respective websites (Eaton 2003; Wall Street Journal Online 2003). None of the studies reported whether respondents were informed of the potential effects of physician-pharmaceutical industry interactions, or whether they were given any context regarding the interactions, prior to providing their opinions on the topic.

Meta-analysis of study results was not possible for a number of reasons, mainly because of the diversity in (a) reported outcomes, (b) types of physician—pharmaceutical industry interactions investigated and (c) populations sampled.

# Awareness of physician-pharmaceutical industry interactions

Six of the 10 studies (Blake and Early 1995; Mainous et al. 1995; Gibbons et al. 1998; Hampson et al. 2006; Semin et al. 2006; Weinfurt et al. 2006) examined the public's awareness of various physician—pharmaceutical industry interactions (Table 2). Each of these studies examined simply whether a respondent was aware of an interaction occurring, rather than whether the respondent had actually seen it occur and whether the respondent thought the interaction was appropriate or not. In one study, nearly 83% of respondents were aware of pharmaceutical promotion in general (Semin et al. 2006), while another study revealed that 54% of respondents were aware of gifts given to physicians by the pharmaceutical industry (Gibbons et al. 1998). However, one study suggested that less than one-quarter of patients in research trials were aware of financial interactions in clinical trials (Hampson et al. 2006). Furthermore, another study using a focus group design suggested that a minority of participants were aware of potential financial interactions in clinical research (Weinfurt et al. 2006).

Awareness of specific physician-pharmaceutical industry interactions ranged considerably. One study suggested that respondents have a greater awareness of office

# Public Perceptions of Physician-Pharmaceutical Industry Interactions

TABLE 1. Studies investigating patient or public opinions on physician—pharmaceutical industry interactions

Study, Year	Study design	Study site	Population (n)	Response rate	Interactions	Outcome measures
Blake & Early (1995)	Survey — Self- administered	Columbia, MO	Adult public and patients in two healthcare centres (486)	83.1%	Gifts overall Small gifts Large gifts CME Drug samples Meals Social events	Awareness of interactions Acceptability of interactions Effects of interactions
Mainous et al. (1995)	Survey – Telephone administered	Kentucky, USA	Random sample of adults (649)	55%	Office gifts Personal gifts	Awareness of interactions Acceptability of interactions Effects of interactions
LaPuma et al. (1995)	Survey – Self- administered	Chicago, IL	Patients in healthcare centre (200)	74%	Salary support Stock ownership Per-patient payment	Acceptability of interactions Disclosure of interactions Effect of interactions
Gibbons et al. (1998)	Survey – Face-to-face interview	Washington, DC	Patients in two healthcare centres (196)	96% at one centre; convenience sample at the other	Gifts overall Small gifts CME Drug samples Meals Travel	Awareness of interactions Acceptability of interactions Effects of interactions
Eaton, for the British Medical Journal (2003)	Online opinion poll	Online visitors to BMJ website, international	Online adults (1,479)	Convenience sample	Gifts overall Meeting with PR	Acceptability of interactions Disclosure of interactions
Wall Street Journal Online (2003)	Online opinion poll	Online members of Harris Interactive, USA	Online adult members (4,173)	Convenience sample	Meeting with PR CME	Acceptability of interactions Effects of interactions
Kim et al. (2004)	Survey – Internet administered	Online members of Harris Interactive Chronic Illness Database, international	Patient members (5,478):  - Coronary artery disease group (2,355)  - Breast cancer group (1,006)  - Depression group (2,117)	86%	Personal income Researcher patent Researcher stocks Per capita payments	Disclosure of interactions Effect of interactions
Hampson et al. (2006)	Survey – Face-to-face interview	Bethesda, MD Boston, MA Seattle, WA Denver, CO New Haven, CT	Cancer trial patients in five healthcare centres (253)	93%	Gifts overall Financial interactions Consulting Speaking fees Patent royalties Stock ownership	Awareness of interactions Acceptability of interactions Disclosure of interactions Effect of interactions

TABLE 1. Continued

Semin et al. (2006)	Survey – Face-to-face interview	Izmir Centrum, Turkey	Patients in 44 healthcare centres (584)	Not reported	Gifts overall Pharmaceutical promotion Small gifts Large gifts CME Drug samples Meals Travel	Awareness of interactions Acceptability of interactions Effects of interactions
Weinfurt et al. (2006)	Focus group	Durham, NC New York, NY Chicago, IL	16 focus groups of patients and adult public (139)	Not reported	Salary support Patent ownership Equity holdings Finder's fees Per capita payment	Awareness of interactions Disclosure of interactions Effects of interactions

CME = continuing medical education PR = pharmaceutical representative

gifts (82%) over personal gifts (32%) (Mainous et al. 1995). Another suggested that approximately half of the respondents were aware of small gifts such as pens (55.3%), although fewer respondents were aware of gifts such as coffee makers (13.8%) (Blake and Early 1995). In addition, 34.6% of respondents were aware of CME by way of a medical text (Blake and Early 1995), while 28.6% were aware of baby formula samples and nearly 90% were aware of drug samples (Blake and Early 1995). Furthermore, 22% of respondents were aware of dinners provided by a pharmaceutical company (Blake and Early 1995).

# Acceptability of physician-pharmaceutical industry interactions

Eight studies (Blake and Early 1995; Mainous et al. 1995; LaPuma et al. 1995; Gibbons et al. 1998; Eaton 2003; Wall Street Journal Online 2003; Hampson et al. 2006; Semin et al. 2006) examined the acceptability of interactions between physicians and the pharmaceutical industry (Table 3). Five of these studies investigated the acceptability of specific interactions, while an additional two focused on the acceptability of financial interactions in clinical trials, and one looked at the acceptable monetary value of gifts. Considerable variation was observed in the acceptability of physician—pharmaceutical industry interactions. However, there was generally greater acceptability for smaller, less costly gifts, or interactions that directly benefited patients.

### ACCEPTABILITY OF SPECIFIC INTERACTIONS

The majority of respondents in two independent studies agreed with the blanket statements "gifts are unethical" (71.2%) (Semin et al. 2006) and "physicians should

stop receiving gifts" (84%) (Eaton 2003). However, when specific interactions were cited, acceptability varied. A range of acceptability was found with regard to small gifts, such as pens, pocketknives and mugs. Few respondents found pens unacceptable (17.5%, Blake and Early 1995; 19%, Gibbons et al. 1998), and a minority of patients found various types of CME, such as medical texts, videos and conference expenses, unacceptable (16.9%–32.5%, Blake and Early 1995; 16%–20%, Gibbons et al. 1998). With regard to industry-sponsored meals, more respondents found dinners unacceptable (47%, Gibbons et al. 1998; 48.4%, Blake and Early 1995) than they did lunches (23%) (Gibbons et al. 1998). Finally, a range of acceptability was found for social interactions, such as cocktail parties, ice cream socials and participation in golf tournaments. Here, an ice cream social was found to be unacceptable by a minority of respondents (28.0%, Blake and Early 1995), while more respondents deemed a cocktail party (43.4%) and golf tournament (41.6%) unacceptable.

TABLE 2. Awareness of physician—pharmaceutical industry interactions

Percentage of respondents aware of physician-pharmaceutical industry interactions					
	Aware (%)				
Gifts overall	54 <sup>4</sup>				
Office gifts	822				
Personal gifts	32 <sup>2</sup>				
Pharmaceutical promotions	82.7°				
Small gifts – pen	55.31				
Large gifts – coffee maker	13.81				
CME – medical text	34.61				
Samples – baby formula	28.61				
Drug samples	871				
Meals – dinner	22.41				
Financial interactions in clinical trials	238				

<sup>&</sup>lt;sup>1</sup> Blake and Early, 1995 (self-administered survey, n=486); <sup>2</sup> Mainous et al. 1995 (telephone survey, n=649); <sup>3</sup> LaPuma et al. 1995 (self-administered survey, n=200); <sup>4</sup> Gibbons et al. 1998 (face-to-face survey, n=196); <sup>5</sup> Eaton 2003 (online poll, n=1,479); <sup>6</sup> Wall Street Journal Online 2003 (online poll, n=4,173); <sup>7</sup> Kim et al. 2004 (Internet-administered survey, n=5,478); <sup>8</sup> Hampson et al. 2006 (face-to-face survey, n=253); <sup>9</sup> Semin et al. 2006 (face-to-face survey, n=253); <sup>10</sup> Weinfurt et al. 2006 (focus group, n=139). CME = continuing medical education

### ACCEPTABILITY OF FINANCIAL INTERACTIONS IN CLINICAL TRIALS

Two studies investigated the acceptability of financial interactions between physi-

TABLE 3. Acceptability of physician—pharmaceutical industry interactions

Percentage of respondents in agreement with statements							
	Agre	ee (%)	Do no	t agree (%)	Unsure (%)		
"Gifts are unethical"	7	1.29		7.5 <sup>9</sup>	21.3°		
"Physicians should stop receiving gifts"	8	34 <sup>5</sup>		135	2 <sup>5</sup>		
Percentage of respon	ndents that find spe	cific interacti	ons accept	able			
	Accept	able (%)	Not acc	ceptable (%)	Unsure (%)		
Small gifts – pen	6	7.31	1	7.5 <sup>1</sup> ,19 <sup>4</sup>	131		
Small gifts – pocket knife	9	_		38 <sup>4</sup>	_		
Small gifts – mug		_		234	_		
Large gifts – coffee make	er 3	9.11		40.71	17.31		
CME – sponsorship	-	72 <sup>6</sup>		6	186		
CME – medical text	-	70¹	16 <sup>4</sup> ,	16.9 <sup>1</sup> , 20 <sup>4</sup>	9.91		
CME – video		_		184	_		
CME – conference expe	enses 5	52.71		32.51	11.51		
Samples – baby formula	. 4	41.41		44.21	10.91		
Drug samples	82.1	82.1 <sup>1</sup> , 82.5 <sup>9</sup>		<sup>9</sup> , 7.6 <sup>1</sup> , 22 <sup>4</sup>	7.2 <sup>9</sup> , 9.3 <sup>1</sup>		
Meals – lunch		_		234	_		
Meals – dinner	3	34.61		3.4 <sup>1</sup> , 47 <sup>4</sup>	14.61		
Social interactions – coc party	ktail 4	40.51		43.41	131		
Social interactions – golf tournament	f 4	).31		41.61	14.61		
Social interactions – ice social	cream 5	5.61	281		12.81		
Travel		_	594		_		
Percentage of respon	ndents that find var	iable value of	gifts acce	otable			
	Less than \$25 (%)	\$25-\$1,0	000 (%)	No limit (%)	Unsure (%)		
Office gifts	9 <sup>2</sup>	12	<u>2</u> 2	59 <sup>2</sup>	22 <sup>2</sup>		
Personal gifts	sonal gifts 32 <sup>2</sup> I		4 <sup>2</sup> 33 <sup>2</sup>		20 <sup>2</sup>		
Percentage of respondents that find interactions with a pharmaceutical representative acceptable							
	Should meet (%)	Should no		Doctor's decision (%)	Unsure (%)		
Meeting with PR	15 <sup>5</sup> , 21 <sup>6</sup>	8 <sup>6</sup> , 7 <sup>9</sup>	95	646	4 <sup>5</sup> , 7 <sup>6</sup>		

TABLE 3. Continued

Percentage of respondents that find financial interactions in clinical trials acceptable							
	Permitted (%)	Permitted with limits (%)	Prohibit (%)				
Consulting	82 <sup>8</sup>	5 <sup>8</sup>	138				
Speaking fees	818	5 <sup>8</sup>	138				
Patent royalties	70 <sup>8</sup>	5 <sup>8</sup>	238				
Stock ownership	64 <sup>8</sup>	88	278				
Per patient payment	_	_	56 <sup>3</sup>				

<sup>&</sup>lt;sup>1</sup> Blake and Early, 1995 (self-administered survey, n=486); <sup>2</sup> Mainous et al. 1995 (telephone survey, n=649); <sup>3</sup> LaPuma et al. 1995 (self-administered survey, n=200); <sup>4</sup> Gibbons et al. 1998 (face-to-face survey, n=196); <sup>5</sup> Eaton 2003 (online poll, n=1,479); <sup>6</sup> Wall Street Journal Online 2003 (online poll, n=4,173); <sup>7</sup> Kim et al. 2004 (Internet-administered survey, n=5,478); <sup>8</sup> Hampson et al. 2006 (face-to-face survey, n=253); <sup>10</sup> Weinfurt et al. 2006 (focus group, n=139).

cians and the pharmaceutical industry specifically in clinical trials. Of these, one study (Hampson et al. 2006) of cancer patients examined the acceptability of consulting, speaking fees and patent royalties and stock ownership, with 13% to 27% of patients prohibiting the above interactions. A second study (LaPuma et al. 1995) examined the acceptance of per-patient payments from the pharmaceutical industry and reported that 56% of respondents found this interaction unacceptable.

### ACCEPTABILITY OF INTERACTION WITH PHARMACEUTICAL REPRESENTATIVES

Two online opinion polls examined the acceptability of interactions between physicians and pharmaceutical representatives (PRs) (Eaton 2003; Wall Street Journal Online 2003). The findings of the two studies varied considerably, with one opinion poll suggesting that 79% of respondents believed physicians should not meet with PRs (Eaton 2003). Conversely, nearly two-thirds of respondents (64%) in the second study believed that meeting with a PR should be a doctor's decision (Wall Street Journal Online 2003).

### ACCEPTABLE MONETARY VALUE OF GIFTS

One study (Mainous et al. 1995) investigated the acceptable monetary value of both office and personal gifts. Fifty-nine per cent of respondents thought that no monetary limit should be placed on office gifts. In regard to personal gifts, 32% thought they should be valued at less than \$25, but a similar percentage of respondents (33%) thought that no limit was needed.

CME = continuing medical educationPR = pharmaceutical representative

# Disclosure of physician-pharmaceutical industry interactions

Five studies (LaPuma et al. 1995; Eaton 2003; Kim et al. 2004; Hampson et al. 2006; Weinfurt et al. 2006) investigated the disclosure of financial interactions between physicians and the pharmaceutical industry (Table 4). Combined, the studies investigated respondents' desire for disclosure of interactions, the importance of disclosing these interactions and whether disclosure was required for informed consent in clinical trials.

TABLE 4. Disclosure of financial interactions in clinical trials

Percentage of respondents that desire disclosure of financial interactions							
	<b>Y</b> es (%)	Yes, if above certain monetary value (%)	No (%)	Unsure (%)			
Gifts overall	318, 965	268	18	18			
Salary support	813	_	_	_			
Stock ownership	78³	_	_	_			
Per-patient payment	86³	_	_	_			

# Percentage of respondents that find disclosing financial interactions important

	Extremely important (%)†	Somewhat important (%)†	Little/not very important (%)†
Personal income	58, 69, 56 <sup>7</sup>	24, 19, 26 <sup>7</sup>	17, 12, 18 <sup>7</sup>
Researcher patent	59, 64, 59 <sup>7</sup>	21, 21, 21 <sup>7</sup>	20, 15, 20 <sup>7</sup>
Researcher stocks	66, 72, 65 <sup>7</sup>	17, 15, 19 <sup>7</sup>	17, 13, 17 <sup>7</sup>
Per capita payment	50, 61, 46 <sup>7</sup>	27, 23, 26 <sup>7</sup>	23, 16, 28 <sup>7</sup>

# Percentage of respondents that require disclosure of financial interactions for informed consent

	<b>Y</b> es (%) <sup>†</sup>	No (%) <sup>†</sup>
Personal income	68, 74, 64 <sup>7</sup>	_
Researcher patent	76, 82, 75 <sup>7</sup>	_
Researcher stocks	80, 85, 78 <sup>7</sup>	_
Per capita payment	70, 78, 64 <sup>7</sup>	_

Blake and Early, 1995 (self-administered survey, n=486); Mainous et al. 1995 (telephone survey, n=649); LaPuma et al. 1995 (selfadministered survey, n=200); 4 Gibbons et al. 1998 (face-to-face survey, n=196); 5 Eaton 2003 (online poll, n=1,479); 6 Wall Street Journal Online 2003 (online poll, n=4,173); 7 Kim et al. 2004 (Internet-administered survey, n=5,478); 8 Hampson et al. 2006 (face-to-face survey, n=253); <sup>9</sup> Semin et al. 2006 (face-to-face survey, n=253); <sup>10</sup> Weinfurt et al. 2006 (focus group, n=139)

<sup>†</sup> Results reported as coronary artery disease group (n=2,355), breast cancer group (n=1,006), depression group (n=2,117), respectively

### Public Perceptions of Physician-Pharmaceutical Industry Interactions

### DESIRE FOR DISCLOSURE OF FINANCIAL INTERACTIONS

All five of the studies examined respondents' desire for disclosure of financial interactions. An online opinion poll conducted by the *British Medical Journal* illustrated that 96% of visitors to its website wanted disclosure of interactions between physicians and the pharmaceutical industry (Eaton 2003). Three additional studies investigated patients' desire for disclosure in clinical trials. Seventy-eight per cent to 86% of patients at healthcare centres wanted doctors to disclose stock ownership, personal salary or per-patient fees from a sponsoring company prior to enrolment in a clinical trial (LaPuma et al. 1995). Furthermore, the majority of respondents in another study found the disclosure of interactions between physicians and the pharmaceutical industry "extremely important" (Kim et al. 2004). However, one study (Hampson et al. 2006) found that less than one-third of cancer patients (31%) wanted disclosure of researchers' financial interactions. Additionally, focus group data suggest that potential research participants varied considerably in their desire to know about such financial interactions as salary support, per capita payments, patent ownership and equity holdings (Weinfurt et al. 2006).

### DISCLOSURE OF FINANCIAL INTERACTIONS REQUIRED FOR INFORMED CONSENT

One study (Kim et al. 2004) examined whether respondents believed disclosure of financial interactions was required for informed consent in clinical trials. The majority of respondents (64%–85%) believed that disclosure of personal salary, patent royalties, stock ownership and per capita payments was required for informed consent.

# Perceived effects of physician-pharmaceutical industry interactions

Six studies (Blake and Early 1995; Mainous et al. 1995; Gibbons et al. 1998; Wall Street Journal Online 2003: Semin et al. 2006; Weinfurt et al. 2006) examined the perceived effects of various physician—pharmaceutical industry interactions (Table 5). Four outcomes were measured: the effect on the cost of healthcare, the quality of healthcare, prescribing practices and participation in a clinical trial.

### EFFECTS ON THE COST OF HEALTHCARE

Two studies revealed that 33% (Gibbons et al. 1998) and 64% (Blake and Early 1995) of respondents believed that gifts to physicians increased the cost of healthcare. Additionally, one study suggested that 42% of respondents thought personal gifts increased healthcare costs, while only 22% thought the same of office gifts (LaPuma et al. 1995).

TABLE 5. Perceived effects of physician—pharmaceutical industry interactions

Percentage of respondents that perceive effects on the cost of healthcare								
	Incre	ase cost (%)	No effec	ct (%)	Decrease cost (	(%)	Unsure (%)	
Gifts overall	Gifts overall 33 <sup>4</sup>		<sup>4</sup> , 54.5 <sup>9</sup> , 64 <sup>2</sup> 23 <sup>1</sup> , 39 <sup>4</sup> ,		10.39 3.11		28 <sup>4</sup> , 35.2 <sup>9</sup>	
Office gifts		26 <sup>2</sup>	38	2	192		162	
Personal gifts		42 <sup>2</sup>	30	2	142		142	
Percentage of respo	ndents (	that perceive	effects on q	uality of	healthcare			
	Negat	ive effect (%)	No effec	ct (%)	Positive effect (	(%)	Unsure (%)	
Office gifts		13 <sup>2</sup>	61	2	142		122	
Personal gifts		23 <sup>2</sup>	54	2	8 <sup>2</sup>		152	
	Very	worried (%)	Some\ worried		A little worried	(%)	Not worried at all (%)	
Financial interactions		<   8	6 <sup>8</sup>		118		808	
Percentage of respo	ndents (	that perceive	effects on p	rescribir	ng practices			
		Influenc	:e (%)	Little/	Little/No influence (%)		Unsure (%)	
Gifts overall		236, 29.19,	23 <sup>6</sup> , 29.1 <sup>9</sup> , 36 <sup>1</sup> , 70 <sup>1</sup>		24.51			
Small gifts – pen		8.69, 314		76.6 <sup>9</sup>			14.89	
Small gifts – pocket knife	е	284		_			_	
Small gifts – mug		314		_			_	
Large gifts – medical de	vice	54.8, 6	54.8, 68.3°		10.9, 25.99		19.3, 20.89	
Large gifts – car seat co	ver	35.	35.3 <sup>9</sup>		46.19		18.69	
CME – medical text		21.69, 3	3 <sup>4</sup> , 37 <sup>4</sup>		57.7 <sup>9</sup>		20.79	
CME – video		38	4	_			_	
CME – conference exp	enses	37.8, 51.2 <sup>9</sup>		21.2, 32.49			27.6, 29.8 <sup>9</sup>	
Drug sample		42	4	_			_	
Meals – lunch		29	4	_			_	
Meals – dinner		48 <sup>4</sup> , 3	8.5 <sup>9</sup>	37.6°			22.9°	
Travel		56 <sup>4</sup> , 6	4.29		12.59		23.39	
Percentage of respondents that would be inclined to participate in a research study following disclosure of physician-pharmaceutical interactions								
	Less in	nclined (%) <sup>†</sup>	Depend amount				More inclined (%) <sup>†</sup>	
Personal income	22	, 31, 28 <sup>7</sup>	8, 13,	117	53, 46, 50 <sup>7</sup>		16, 10, 11 <sup>7</sup>	

### Public Perceptions of Physician-Pharmaceutical Industry Interactions

TABLE 5. Continued

TABLE 5, Continued								
Researcher patent	26, 23, 31 <sup>7</sup>	-	62, 67, 60 <sup>7</sup>	12, 11, 9 <sup>7</sup>				
Researcher stocks	37, 36, 40 <sup>7</sup>	-	55, 59, 54 <sup>7</sup>	8, 5, 6 <sup>7</sup>				
Per capita payment	16, 23, 17	-	68, 65, 70 <sup>7</sup>	17, 12, 13 <sup>7</sup>				
Percentage of respondents that would participate in a clinical trial following disclosure of physician– pharmaceutical interactions								
	Stop participation (%)	No effect on participation (%)	Encourage participation (%)	Other (%)				
Patent royalties	148	708	78	98				
Percentage of responding pharmaceutical inte		participate in a clinical	l trial following disclo	sure of physician-				
	Stop participation (%)	No effect on participation (%)	Encourage participation (%)	Other (%)				
Stock ownership	118	76 <sup>8</sup>	18	118				
Consulting	128	75 <sup>8</sup>	68	78				
Speaking fees	98	82 <sup>8</sup>	48	68				
	Would not participate (%)†	Depends on amount (%) <sup>†</sup>	Still consider participation (%)†	Unsure (%)†				
Personal income	12, 18, 18 <sup>7</sup>	9, 14, 12 <sup>7</sup>	79, 67, 70 <sup>7</sup>	_				
Researcher patent	13, 11, 17 <sup>7</sup>	_	75, 72, 68 <sup>7</sup>	12, 17, 14 <sup>7</sup>				
Researcher stocks	17, 14, 20 <sup>7</sup>	_	65, 61, 59 <sup>7</sup>	18, 26, 217				
Per capita payment	nent 7, II, 9 <sup>7</sup> — 83, 74, 80 <sup>7</sup>		10, 15, 11 <sup>7</sup>					
Percentage of respo	ondents that believe	financial interactions	influence a physician	to enrol patients				
Influence (%) No influence (%)								

Blake and Early, 1995 (self-administered survey, n=486); Mainous et al. 1995 (telephone survey, n=649); LaPuma et al. 1995 (selfadministered survey, n=200); 4 Gibbons et al. 1998 (face-to-face survey, n=196); 5 Eaton 2003 (online poll, n=1,479); 6 Wall Street Journal Online 2003 (online poll, n=4,173); 7 Kim et al. 2004 (Internet-administered survey, n=5,478); 8 Hampson et al. 2006 (face-to-face survey, n=253); 9 Semin et al. 2006 (face-to-face survey, n=253); 10 Weinfurt et al. 2006 (focus group, n=139).

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### EFFECTS ON THE QUALITY OF CARE

Per-patient payments

Three studies (LaPuma et al. 1995; Hampson et al. 2006; Weinfurt et al. 2006) investigated the perceived effects of gifts from the pharmaceutical industry on the quality of healthcare. In one study, 61% of respondents believed that the acceptance of office gifts had no effect on the quality of healthcare, while 54% thought the same

<sup>†</sup> Results reported as coronary artery disease group (n=2,355), breast cancer group (n=1,006), depression group (n=2,117), respectively CME = continuing medical education

of personal gifts (Mainous et al. 1995). A study of cancer patients in research trials revealed that the majority of respondents (80%) were "not worried at all" about financial interactions between physicians and the pharmaceutical industry (Hampson et al. 2006). Additionally, a study using focus groups noted that several patients thought financial interactions in clinical trials would make a physician do a better job (Weinfurt et al. 2006).

### EFFECTS ON PRESCRIBING PRACTICES

Four studies (Blake and Early 1995; Gibbons et al. 1998; Wall Street Journal Online 2003; Semin et al. 2006) examined the effect of physician-pharmaceutical industry interactions on prescribing practices. Twenty-three per cent (Wall Street Journal Online 2003) and 70% (Blake and Early 1995) of respondents believed that gifts in general influenced physicians' prescribing. With regard to specific interactions, a minority of respondents believed that small gifts such as a pen, pocket knife or mug influenced prescribing practices (8.6%, Semin et al. 2006; 31%, Gibbons et al. 1998). A gift such as a car seat cover was thought to influence prescribing by 35.3% (Semin et al. 2006) of respondents, while 54.8%-68.3% (Semin et al. 2006) of respondents thought that a larger gift such as a medical device affected prescribing. CME, such as payment for conference expenses, a medical text and an educational video, were thought to influence prescribing by 21.6%-51.2% (Semin et al. 2006) of respondents, depending on the specific interaction. Furthermore, 42% of patients thought that drug samples influenced prescribing choice (Gibbons et al. 1998), and meals were thought to affect prescribing by 29%-48% (Gibbons et al. 1998) of respondents. Finally, the majority of respondents (56%, Gibbons et al. 1998; 64.2%, Semin et al. 2006) thought that sponsorship of travel would influence a physician's prescription choices.

### EFFECTS ON CLINICAL TRIAL PARTICIPATION

Three studies (LaPuma et al. 1995; Kim et al. 2004; Hampson et al. 2006) investigated whether the disclosure of various financial interactions would affect clinical trial participation. Two studies revealed that the majority of patients would still participate in a trial, given disclosure of financial interactions. Specifically, one study found that 70% to 82% of potential participants would still participate, depending on the financial interaction, such as patent royalties, stock ownership, consulting and speaking fees; however, the specific amount of financial interactions was not examined (Hampson et al. 2006). An additional study found similar results, where 59% to 83% of patients would still participate in a trial depending on the physician—pharmaceutical industry interaction, where personal income, researcher patent, researcher stocks and per capita

payments were investigated (Kim et al. 2004). Finally, 69% of respondents believed that per-patient payments would influence physicians to enrol patients into a clinical trial (LaPuma et al. 1995).

# Interpretation

No studies were found that examined Canadian opinions on the issue of physician interactions with the pharmaceutical industry. However, 10 studies were identified that examined perceptions of international respondents. All but three of these 10 studies exclusively investigated American perceptions, while one survey examined patient opinions in Turkey and two others examined opinions of international participants. Although findings of American opinions are often generalized to Canadians, factors such as differing healthcare systems, differing policies regarding direct-to-consumer advertising (DTCA) and possible differing attitudes towards private enterprises may cause differences in opinions regarding physician—pharmaceutical industry interactions between these two populations. In the US, full product drug advertisements are allowed and are heavily used, as opposed to the disease-oriented reminder advertisements that are permitted in Canada (Mintzes 2006; Wilkes et al. 2000). While many Canadians also see American advertisements, studies suggest that Americans have greater exposure to DTCA than their Canadian counterparts (Mintzes et al. 2002, 2003).

We found evidence of considerable variation in public awareness, acceptability and perceived effects of potential physician—pharmaceutical industry interactions. There appears to be greater acceptability and fewer perceived effects for smaller, less costly gifts that directly benefit patients or the medical practice. Conversely, desire for disclosure of these interactions was consistent among the majority of participants. As suggested previously, we also found some evidence of differences in the opinions of the public and those of physicians on physician—pharmaceutical industry interactions. One of the studies included in this review (Gibbons et al. 1998) reported that patients generally perceived pharmaceutical gifts to be less appropriate and more influential on prescribing than did those physicians who were surveyed.

Although 10 studies of physician—pharmaceutical industry interactions were identified in the review, research in the area is limited and fragmented: studies investigated public opinions of different types of physician—pharmaceutical industry interactions, using different populations in distinct settings. Furthermore, the majority of studies were individually narrow in scope, focusing on a specific type of interaction (for example, financial interactions). The few studies that have explored a range of potential physician—pharmaceutical interactions are now dated and may not capture the opinions of the current population, particularly given the negative media attention that the pharmaceutical industry has received in recent years (Psaty and Kronmal 2008; Puttagunta et al. 2002; Kondro 2004; Olivieri 2003). Additionally, the majority of

studies examined the opinions of specific patient populations, rather than the general public. Patients with cancer, for example, may not be representative of the general public. It is likely that patients with cancer whose only access to a potentially effective chemotherapy is through entry in a clinical trial will be much less concerned about issues of conflict of interest than a healthy recent university graduate, for example.

### Limitations

Although our review followed established methodologies, it had several limitations. No databases or journals were hand-searched for studies. Also, only one reviewer was responsible for determining whether studies met pre-defined inclusion criteria, and no quantitative analysis could be conducted – therefore, meta-analysis was impossible. Additionally, only the interactions between physicians and the pharmaceutical industry were examined in this review, although many healthcare professionals interact with the pharmaceutical industry on a regular basis. Finally, we did not consider the degree of sophistication of study participants and whether they recognized the association between interactions and potential adverse effects, or whether they were familiar with principles of conflict of interest – factors that have been considered in previous observational studies (Spingarn et al. 1996; Taylor and Bond 1991; Lurie et al. 1990; Avorn et al. 1982; Orlowski and Wateska 1992; Bowman and Pearle 1988).

# Conclusion

Comprehensive research in this area should be undertaken to determine the opinions of the Canadian public on potential physician—pharmaceutical industry interactions in order to inform and direct policy regarding COI. This is important for four main reasons. First, private citizens are key stakeholders in the healthcare system, and therefore their opinions are important. Public trust in the largely publicly funded system is likely to be important to its ongoing efficiency. Second, the research may alert policy makers that the public needs further education on the consequences, both positive and negative, of physician—pharmaceutical industry interactions. Third, whatever is learned about these interactions is likely to be useful for further investigation of other health professions. Fourth, given the evidence found of varying opinions from other countries—divergence of opinion between the public and physicians—studying the Canadian context is essential to inform health professionals' current conflict-of-interest policies and guidelines.

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# Clinical Practice Settings Associated with GPs Who Take on Patients with Mental Disorders

Liens entre établissements de pratique clinique et omnipraticiens qui acceptent des patients présentant des troubles mentaux



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# Abstract

In light of current reforms to reinforce primary mental healthcare and service integration, this paper assesses general practitioners' (GPs') management of patients with mental disorders (PMD) and its associated practice settings and clinical characteristics. The study is based on a survey of 398 Quebec GPs. Results showed that GPs who receive patients with moderate and transient mental disorders (PMD-M) usually follow them on a continuous basis; conversely, only a quarter of GPs who see patients with severe and persistent mental disorders (PMD-S) provide follow-up. With the exception of walk-in clinics, all clinical settings are associated with GPs who take on PMD-M. No setting was found to be significantly associated with GPs taking on PMD-S. Competency, skills and confidence seem to be core factors in decisions to take on PMD. Group practice models (CLSCs, network clinics) and shared-care initiatives should be encouraged to manage more complex PMD cases.

# Résumé

Dans la foulée des réformes actuelles qui visent à renforcer les soins primaires et l'intégration des services en matière de santé mentale, cet article évalue comment les omnipraticiens gèrent les patients présentant des troubles mentaux (PTM) ainsi que le lien avec les établissements de pratique et les caractéristiques cliniques. L'étude se fonde sur un sondage effectué auprès de 398 omnipraticiens du Québec. Les résultats montrent que les omnipraticiens qui reçoivent des patients présentant des troubles mentaux modérés ou transitoires (PTM-M) assurent habituellement le suivi sur une base continue; à l'inverse, seulement un quart des omnipraticiens qui reçoivent des patients présentant des troubles mentaux sévères et persistants (PTM-S) assurent le suivi. À l'exception des cliniques sans rendez-vous, tous les types d'établissements cliniques sont associés à des omnipraticiens qui acceptent des cas de PTM-M. Il n'y a pas d'association directe entre un type donné d'établissement et la prise en charge des PTM-S par les omnipraticiens. La compétence et la confiance des omnipraticiens envers leurs habiletés à prendre en charge les patients semblent être les facteurs centraux dans la décision d'accepter des cas de PTM. Les modèles de pratique de groupe (CLSC, cliniques-réseaux) et les initiatives de soins partagés devraient favoriser la gestion de cas plus complexes de PTM.

HE PREVALENCE OF MENTAL DISORDERS WORLDWIDE RANGES FROM 4.3% to 26.4% per year, confirming its considerable significance (WHO World Mental Health Survey Consortium 2004). The burden of mental disorders has prompted efforts to reinforce primary mental healthcare in many countries, including Canada (Craven and Bland 2006; WHO/WONCA 2008). Increasingly,

shared-care models involving collaboration between general practitioners (GPs), psychiatrists, and psycho-social professionals are recommended to assist GPs in the management of patients with mental disorders (PMD) (Kates and Ackerman 2002). GPs are the main points of access to mental healthcare for PMD; annually, they receive more PMD than psychiatrists do (Gagné 2005; Lesage et al. 2006). GPs mainly treat patients with moderate and transient mental disorders (PMD-M) such as depressive and anxious disorders or adaptation problems (Kushner et al. 2001; Brown et al. 2002). Current reforms call on them to treat stable patients with severe and persistent mental disorders (PMD-S) as well (WHO/WONCA 2008; MSSS 2005), such as psychotic or bipolar disorders, particularly in remote regions where psychiatric services are scarce. For patients, the advantages of such a shift are service proximity, greater accessibility, less stigmatization and a more holistic approach because physical problems are managed along with their mental disorder (Rothman and Wagner 2003).

This is a pivotal shift in the role of GPs, yet few studies have examined variables that enable or hinder GP management of PMD or the estimated proportion of PMD-M or PMD-S followed on an ongoing (rather than a one-time) basis. What socio-demographic, clinical practice and interorganizational collaboration profiles encourage GPs to take on PMD? Increasingly, GPs practise in a variety of established (hospitals, walk-in clinics) and novel settings (family medicine groups, network clinics). Do different settings bring about different forms of PMD management? Given the shortage of GPs in Quebec (nearly 25% of the population are without a family physician) (ICIS/CIHI 2005a) and the importance of care continuity for PMD (Adair et al. 2005), these questions are central to improving care.

Accordingly, this study aims to (a) estimate GPs' management frequency of PMD-M as compared to PMD-S on a one-time or continuous follow-up basis, (b) assess variables associated with GPs who take on PMD-M versus PMD-S and (c) assess clinical settings associated with GPs who take on PMD-M or PMD-S when other important correlates are taken into account. In light of current healthcare reforms, this study's findings may help decision-makers identify clinical practice settings and other covariates that favour PMD management and address shortcomings in the primary care management of PMD.

# Method

The study (conducted using a cross-sectional design) targeted all GPs from nine Quebec local healthcare networks (LHNs) in five socio-sanitary regions, corresponding to 20% of the GP population in the province. With a population of about 7.5 million, Quebec has 7,199 equivalent full-time GPs (one GP per 1,041 inhabitants) (Savard and Rodrigue 2007). In Quebec, LHNs constitute the core of the healthcare system, where providers integrate services to provide a comprehensive care spectrum

(Fleury 2006). The LHNs selected for this study represent urban, suburban and rural areas and university, peripheral and intermediate settings. They encompass the whole range of practice settings: solo or group practice in private clinics; walk-in clinics; local health centres (CLSCs); family medicine groups (GMFs); network clinics (NCs); and hospital centres (acute, psychiatric or long-term). GMFs correspond to a primary care setting where patients are registered with GPs: here, nurses are responsible for patient screening, follow-up and referral. NCs are similar, but patients are not registered with GPs and nurses act mainly as liaison agents. A sample list of all GPs in these LHNs was provided by the Quebec Federation of General Practitioners (FMOQ), which represents all Quebec GPs. Every GP in these LHNs (n=1,415) was asked to participate in the study.

Study data were drawn from a self-administered questionnaire focusing on multiple variables potentially associated with PMD management (Figure 1, Table 1). The questionnaire, designed by a multidisciplinary research team (20 researchers, GPs, psychiatrists) based on a literature review of primary mental healthcare, was pre-tested on 10 GPs. It used continuous or categorical items or a five-point Likert scale and required 30 minutes for completion. It was mailed to GPs from September 2005 to February 2007, with letters of support from the Quebec College of Physicians and the FMOQ. There were three follow-ups: (1) mail, (2) phone calls from nurses and (3) contact by medical network administrators. The study was approved by the Douglas Institute research ethics board. The Régie de l'assurance maladie du Québec (RAMQ) data bank from 2006 was used to compare the study's sample with the GP population of Quebec as a whole wherever possible for the purpose of data validation (e.g., gender, age, PMD-M vs. PMD-S management).

# Variable definition and data analysis

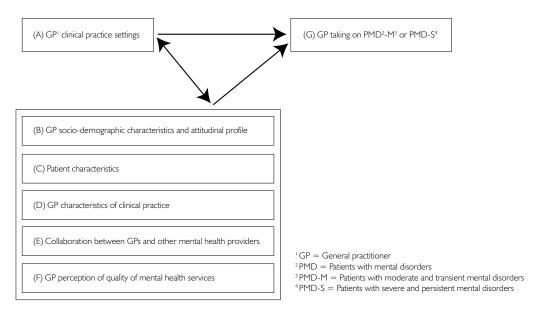
The study assessed two categories of patients: (1) those with moderate and transient mental disorders (PMD-M – also called common mental disorders), including anxiety, depression, adaptation disorders, personality disorders and substance abuse comorbid disorders and (2) those with severe and persistent mental disorders (PMD-S), excluding the above and for which three examples were provided: schizophrenia, bipolar disorder and delirious disorder. PMD-M differ considerably from PMD-S. PMD-M are generally employed; their problems are often less disabling though they may be recurrent, relapse or become chronic. PMD-S (2% to 3% of the population) are generally unemployed and need considerable help in many bio-psycho-social domains on a long-term basis (Nelson 2006).

The main independent variables were *GP clinical practice settings*. GPs were classified according to the practice setting where they spend 50% or more of their time. Other covariates considered in the analyses were organized in five categories: GP

socio-demographic and attitudinal profile, patient characteristics, GP clinical practice profile, collaboration between GPs and other mental health providers and GP perception of quality of mental health services (Figure 1, Table 1).

FIGURE 1. Conceptual framework

GP settings and co-variables independently associated with the taking on of PMD-M or PMD-S



The dependent variables were the proportion of *PMD-M* or *PMD-S* taken on by *GPs*, measured on a continuous scale. "Taking on" patients refers to more than simply receiving patients during a medical visit; it entails care continuity and follow-up for an initial or subsequent condition (both for mental health and for physical problems) and includes medical tests, drug prescription, side-effect monitoring, psychotherapy or any kind of bio-psycho-social support (i.e., acceptance as the GPs' own patients). "Patients received in consultation on a one-time basis only" refers to patients who visit a GP but are not followed over time by the physician. Both patient groups were identified by GPs as PMD (i.e., having a diagnosis of mental disorder or consultation for mental disorders).

Univariate, bivariate and multivariate data analyses were performed. Univariate analyses consisted in generating frequency distributions for categorical variables; bivariate analyses consisted in correlations and group comparisons using a t-test for continuous variables and a chi-square test for categorical variables. As illustrated by the conceptual model in Figure 1, bivariate associations were calculated between each

TABLE 1. Independent and dependent variables included in the conceptual model (Figure 1)

### **INDEPENDENT VARIABLES** - related to Figure 1

### A. General practitioner (GP) clinical practice settings

(i.e., GPs' principal practice setting where 50% or more of their time is spent)

solo private clinics\*\*(\*\*\*), group practice in private clinics\*\*(\*\*\*), walk-in clinics\*\*(\*\*\*), local health centres (CLSCs)\*\*(\*\*\*), family medicine groups (GMFs)\*\*(\*\*\*), network clinics (NCs)\*\*(\*\*\*) or hospital-based practice (acute, psychiatric or long-term)\*\*(\*\*\*)

### B. GP socio-demographic characteristics and attitudinal profile

Age\*, gender

Years since graduation\*\*

Proportion of income from fees for services\*(\*\*), from monthly rate\*, from hourly fees\*(\*\*)

Working hours per week

Number of practice settings\*\*

Number of medical education sessions in mental healthcare attended in the 12 previous months\*(\*\*\*)

Did these sessions enhance your knowledge in mental health?\*\*(\*\*\*)

Did these sessions enhance your ability to take on patients with mental disorders?\*\*(\*\*\*)

Did these sessions improve your collaboration with other mental healthcare professionals?\*\*

Importance attributed to assuming care of patients with moderate and transient mental disorders (PMD-M)\*\* versus severe and persistent mental disorders (PMD-S)\*\*\*

### C. Patient characteristics

Number of patients received in consultation per week (i.e., patient visits – typical week)\*(\*\*)

Proportion of patients with mental disorders received in consultation per week\*\*\*

Among patients with mental disorders, proportion of PMD-M (e.g., adaptation disorder, anxiety, depression)\*(\*\*)

Among PMD-M, proportion of anxiety disorder\*\*, depressive disorder, depressive and anxiety disorder, personality disorder\*\*, adaptation disorder, substance abuse

Among patients with mental disorders, proportion of PMD-S (e.g., schizophrenia, bipolar disorder, delirious disorder)\*(\*\*\*)

Among patients with mental disorders, proportion of co-morbid conditions\* (mental health and substance abuse\*(\*\*), somatic disease\*\* or mental deficiency)

### D. GP characteristics of clinical practice

Among PMD-M versus PMD-S, proportion of visits related to medication follow-up\*(\*\*\*)(\*\*\*\*), support therapy and psychotherapy\*(\*\*)(\*\*\*)

Yearly average number of times you receive in consultation your PMD-M and PMD-S\*\*(\*\*\*)

Delay in receiving patients with mental disorders calling for help in a crisis situation\*\*

When following a patient jointly with other professionals, how do you rate the following clinical or joint follow-up mechanisms: standardized referral forms, consultation report forms, follow-up and treatment protocols, medication protocols, intervention algorithm, giving access in your clinic to a professional on call, patient follow-up by phone

### E. Collaboration between GPs and other mental health providers

Number of PMD-M\*\* versus PMD-S\* referred weekly to other resources

Among patients referred to other resources, proportion of patients (PMD-M and PMD-S) referred to hospital emergency services, psychiatric outpatient clinics, mental health teams of CLSCs\*, psycho-social services of CLSCs, psychologist private offices\*, crisis centres or community-based organizations

Frequency of referrals of PMD-M versus PMD-S for diagnostic evaluation\*\*(\*\*\*), pharmacological treatment suggestion\*\*, joint follow-up with psychiatrists\*\*\* or other resources\*\*(\*\*\*), transfer to psychiatric services\*\*(\*\*\*)

Frequency of patient transfer due to case complexity\*\*\*, case seriousness\*\*\*, lack of expertise in mental health\*\*\*, lack of support from psychiatrists\*\*(\*\*\*), insufficient financial incentives\*\*\* or lack of interest in patients with mental disorders\*\*(\*\*\*)

### TABLE 1. Continued

When following a patient jointly with other professionals, what is the frequency of your contacts with psychiatrists, psychiatric teams\*(\*\*), CLSC professionals or psychologists in private offices?\*(\*\*)

When your patient is hospitalized for mental disorders, what is your frequency of involvement in the following processes: emergency service admission, development of treatment plan including medication, hospital discharge planning, post-hospital follow-up?\*\*(\*\*\*)

How do you rate your relationships with the following professionals for both PMD-M and PMD-S: hospital emergency service personnel, hospital psychiatric service personnel\*\*, CLSC mental health teams, CLSC psycho-social workers, psychologists in private offices\*(\*\*), crisis centre professionals\*, community organization personnel

When taking on PMD-M versus PMD-S, how important is it to work in collaboration with the following professionals: hospital emergency service personnel\*\*, hospital psychiatric service personnel\*\*, CLSC mental health teams\*\*, CLSC psychosocial workers\*\*, psychologists in private offices, crisis centre professionals, professionals at community-based organizations?\*\*

### F. GP perception of quality of mental health services

For patients with mental disorders, how do you rate geographic service accessibility, service accessibility with regard to opening hours\*\*, different professional categories accessibility\*\*, quantity of available services\*\*, diversity of available services\*\*, service continuity\*\* and global service quality?\*\*

Waiting period for feedback from psychiatrists when requesting expert opinion\*(\*\*)

### G. DEPENDENT VARIABLES - related to Figure 1

Proportion of PMD-M versus PMD-S taken on by GPs [Question: "In a typical week, what proportion of patients diagnosed with or consulting for mental disorders in your medical practice do you follow on a continuous basis (i.e., accept as your own patients)?" In the questionnaire, patients are divided into two categories: PMD-M and PMD-S.]

independent variable and the following variables: clinical practice settings; the proportion of PMD-M taken on; and the proportion of PMD-S taken on. Significant associations are marked by asterisks in Table 1 (alpha level=0.10). The final models were built using a multiple linear regression analysis, using the stepwise backward logistic regression technique, with successive block entry of variables that yielded significant associations in bivariate analyses with both clinical practice settings and the proportions of PMD-M and PMD-S taken on (alpha level=0.05).

# Results

# Sample

Of the 1,415 targeted GPs, 353 were excluded because they had retired or moved to another area, or could not be reached either by phone or e-mail. Subsequently, 37 questionnaires were excluded because they were not duly completed. The final sample comprised 398 subjects for a response rate of 41%. The sample was compared to non-responding GPs for gender distribution, which yielded a non-significant result ( $\chi^2$ =3.44; df=1; p=0.0637). Comparisons were also made between the study sample and Quebec's GP population as a whole, regarding gender, age, clinical practice set-

<sup>\*</sup>Significantly associated with clinical practice settings in bivariate analyses (alpha=0.10)

<sup>\*\*</sup>Significantly associated with taking on of PMD-M in bivariate analyses (alpha=0.10)

<sup>\*\*\*</sup>Significantly associated with taking on of PMD-S in bivariate analyses (alpha=0.10)

tings, territory of practice, income level from fee-for-services and volume of patients with mental disorders. When data were available, comparisons were made between the GP population in Quebec and in Canada. No significant difference was found in any of these comparisons (Fleury et al. 2008). Significant differences, however, were found between the study sample and Canadian GPs regarding gender (51.3% female in the sample vs. 36.7% for Canadian GPs;  $\chi^2$ =3.98, p=0.046) and income from fee-for-services (65% vs. 51%;  $\chi^2$ =4.02, p=0.045) (ICIS/CIHI 2005b; CMFC 2007).

### Profile of GPs who take on PMD

For a better understanding of GP management of PMD, physicians were divided into three groups, reflecting their level of involvement (Table 2), namely, absence of involvement (the "0% group"), intermediate involvement (the "1% to 74%" group) and significant involvement (the "75% to 100% group"). Eleven per cent of GPs do not take on PMD-M; however, the great majority of them (78%) take on 75% to 100% of such patients. Twenty-three per cent of GPs do not take on PMD-S, while 25% of them take on 75% to 100% of these patients.

**TABLE 2.** Distribution of GPs\* with regard to the proportion of PMD\*\* they receive in consultation (one-time basis) compared to treating these patients on a continuous basis

	PMD-	M***	PMD-S****		
% of PMD in GP clientele	GPs who receive in consultation PMD-M [n (%)]	GPs who take on PMD-M [n (%)]	GPs who receive in consultation PMD-S [n (%)]	GPs who take on PMD-S [n (%)]	
0%	8 (2.0)	44 (11.1)	29 (7.3)	93 (23.4)	
1%-74%	280 (70.4)	42 (10.5)	366 (92.0)	204 (51.3)	
75%–100%	110 (27.6) 312 (78.4)		3 (0.8)	101 (25.4)	
Total	398 (100)	398 (100)	398 (100)	398 (100)	

<sup>\*</sup> GPs = general practitioners; \*\*PMD = patients with mental disorders

For both PMD-M and PMD-S, differences were assessed between GPs who do not take on PMD and GPs who do so frequently.

• GPs who do not take on PMD-M (11%) practise in walk-in clinics; are younger; receive fewer patients; report shorter waiting periods in receiving feedback from psychiatrists; view collaboration with psychiatrists, emergency services and CLSCs as very important; and practise in fewer clinical settings.

<sup>\*\*\*</sup> patients with moderate and transient mental disorders

<sup>\*\*\*\*</sup> patients with severe and persistent mental disorders

- GPs who do not take on PMD-S (23%) have the same profile with the exception of the last characteristic. In addition, they spend fewer hours on duty, earn a lower proportion of income from fee-for-services and spend less time on continuing medical education (CME).
- GPs who take on 75%–100% of PMD-S (25%) present a reverse profile with regard to hours, income and CME; in addition, they receive more patients per week, report longer waiting time in receiving feedback from psychiatrists and work more frequently in suburban and rural areas.

# Settings associated with GPs who take on patients

Clinical settings and covariates independently associated with GPs who take on PMD-M or PMD-S are displayed respectively in Tables 3 and 4. The only setting that does not favour the taking on of PMD-M is the walk-in clinic. This model accounts for 43% of the variance (F=24,407, p<0.001). No setting is associated with the taking on of PMD-S; the model accounted for 17% of the variance (F=41,407, p<0.001).

# Discussion

The study found that the severity of mental disorder has an impact on GPs' decision to take on patients. The great majority of GPs who receive PMD-M also take them on. By contrast, only a quarter of GPs who receive PMD-S take these patients on, even if continuity of care is recognized as a vital component in PMD-S recovery (Adair et al. 2005). Numerous studies have reported the pivotal role GPs play in managing PMD-M and their discomfort in taking on PMD-S (Carr et al. 2004; Walters et al. 2008).

In this study, walk-in clinics – highly developed in Quebec and the rest of Canada (Jones 2000) – were associated with a smaller proportion of PMD-M taken on, or less care continuity (Trottier et al. 2003). Walk-in clinics, however, favour access to care (Barbeau et al. 2001). Suburban and rural areas are settings where GPs are more likely to take on PMD-S, possibly because of the scarcity of psychiatric services (Bambling et al. 2007). Also, the shorter the waiting period for responses from psychiatrists, the fewer patients taken on. GPs who considered interprofessional relationships with specialized care and local health centres (CLSCs) to be very important were also less willing to take on PMD. These surprising findings may be explained by PMD profiles, for example, treatment complexity, physical and social co-morbidity, time-consuming appointments, stigmatization of mental health (Kisely et al. 2006; Balanchandra et al. 2005) and competing patient demands, particularly given the current severe GP shortage in Quebec and in Canada. In addition, even if shared-care models are considered central to current reforms, few such initiatives have been implemented to encourage GPs to take on complex mental disorder cases (Pawlenko 2005).

### Clinical Practice Settings Associated with GPs Who Take on Patients with Mental Disorders

TABLE 3. GP\* clinical practice settings and covariables independently associated with the taking on of PMD-M\*\*

		В	t	Sig.	95% C	CI for B
	Model				Lower bound	Upper bound
	(Constant)	35.969	7.101	<0.001	26.009	45.928
Profiles	Solo practice in private clinics	13.651	3.001	0.003	4.706	22.595
	Group practice in private clinics	9.377	2.205	0.028	1.014	17.739
	Local health centres (CLSCs)	16.198	3.114	0.002	5.969	26.426
	Family medicine groups (GMFs)	9.914	2.324	0.021	1.525	18.303
	Network clinics	16.160	2.479	0.014	3.342	28.979
	Hospitals	12.371	2.653	0.008	3.203	21.539
Covariables	Number of patients received in consultation	0.059	1.700	0.090	-0.009	0.126
	Proportion of PMD and substance abuse disorders	-0.525	-4.046	<0.001	-0.780	-0.270
	Proportion of PMD-M visiting for support therapy	0.410	10.643	<0.001	0.334	0.485
	Perception of good relationships with psychologists	3.406	3.254	0.001	1.348	5.464
	Perception of good relationships with crisis centres	-1.974	-2.128	0.034	-3.798	-0.150
	Waiting time for feedback from psychiatrists	0.063	2.078	0.038	0.003	0.122

 $R^2$ =0.434; F=24.407; p<0.001

TABLE 4. GP\* clinical practice settings and covariables independently associated with the taking on of PMD-S\*\*

	Model	В	t	Sig.	95% CI for B	
					Lower bound	Upper bound
	(Constant)	26.646	7.580	<0.001	19.735	33.557
Covariables	Proportion of PMD-S visiting for support therapy	0.417	9.047	<0.001	0.326	0.508
	Perception of good relationships with psychologists	-2.724	-2.291	0.022	-5.06I	-0.386

 $R^2=0.174$ ; F=41.407; p<.001

<sup>\*</sup> GPs = general practitioners; \*\* PMD = patients with mental disorders; PMD-M = patients with moderate and transient mental disorders

<sup>\*</sup> GPs = general practitioners; \*\* PMD = patients with mental disorders; PMD-S = patients with severe and persistent mental disorders

Younger GPs were less likely to take on PMD-M. GPs with less CME in mental healthcare were less likely to take on PMD-S. GPs who saw higher volumes of patients (possibly linked to fee-for-services income and working hours) were more likely to take on PMD. Previous studies have shown that GPs' confidence and ability to treat patients are associated with fewer referrals (Younes et al. 2005; Kravitz et al. 2006), a finding that may be due to seniority, training and patient volume. In fact, GPs who receive more PMD in their practice are more likely to take them on. A GP's recognized willingness to manage these patients may also be a positive contributing factor.

All practice settings, with the exception of walk-in clinics, were found to be positively associated with GPs who take on PMD-M, but none with GPs who take on PMD-S. In this study, CLSCs and network clinics (NCs) were the practice settings most frequently involved in offering care continuity to PMD-M. With regard to CLSCs, this finding may be explained by the presence of mental healthcare teams on

The study's multivariate analyses show that good working relationships between GPs and psychologists enhance the likelihood that GPs will take on patients with moderate and transient mental disorders.

site. As for NCs in Quebec, they accept patients who do not have access to a regular GP, and benefit from liaison agents and a variety of specialized resources that favour PMD-M management. Solo private practice, followed closely by hospital-based practice, ranked three and four, respectively, with

regard to the taking on of PMD-M. In a recent study comparing GP practice settings, solo practice was associated with ongoing continuity of care and patient satisfaction (Pineault et al. 2008). Closer relationships between patients and GPs, and the fact that antidepressant medication, psychotherapy or both represent potentially effective treatment for most such disorders (CANMAT 2001), may account for the high level of PMD-M management reported for solo practice. As for GPs in hospital-based practice, the proximity and availability of psychiatric resources may explain their propensity to take on PMD-M.

Surprisingly, family medicine groups (GMFs) and group practice in private clinics do not yield the most conclusive association with PMD-M management. A possible explanation is that GMFs are not yet fully implemented, and that they focus largely on treating physical problems (MSSS 2009). As for group private practice, this model was developed mainly through management initiatives (e.g., shared office staff) (Pineault et al. 2008), which may be why such settings do not take on more PMD-M. The decision to treat PMD-S may be affected by GPs' perception that such disorders

require expertise beyond what is available in primary care (Stewart 2000). The willingness of GPs to take on PMD-S appears to be based on their individual interests and network of mental healthcare contacts.

The study's multivariate analyses show that good working relationships between GPs and psychologists enhance the likelihood that GPs will take on PMD-M. GPs who offer supportive therapy are also more likely to take them on. It may be that psychotherapy and supportive therapy (with or without the use of medication) are the most suitable treatment for PMD-M (Williams et al. 2007; Fournier et al. 2008). GPs who offer such treatment or have access to psychologists will then take on more PMD-M. There is a negative association between crisis centres (CCs) and GPs taking on PMD-M, which may suggest that CCs are effective in resolving crises and reducing the need for follow-up by a GP. The complexity of treating concurrent mental disorders and substance abuse disorder may suggest why GPs are reluctant to take on such cases (RachBeisel et al. 1999).

# Conclusion

While this study is among the first to investigate GP management of PMD in Quebec or in Canada based on an extensive sample, it does have some limitations. The study has a cross-sectional design. Data were collected from self-administered questionnaires and should be considered an approximation of actual mental health-care practice. No data were collected on the effectiveness of GPs' treatment of patients with mental disorders, a major issue. Only Quebec GPs were surveyed. Further study across Canada is desirable, especially as healthcare is a provincial jurisdiction.

The study, however, points to relevant political implications. It highlights GPs' significant involvement in mental disorder care management, mainly for PMD-M, in which all practice settings, save walk-in clinics, are active. This finding addresses the erroneous belief that GPs are relatively uninvolved in mental healthcare. Group practice models such as CLSCs and network clinics take on more PMD-M, perhaps because of greater available psycho-social resources. These clinical settings may be better equipped to treat complex PMD-M cases requiring more psycho-social care.

As for PMD-S, GPs' involvement is based on their interest in mental healthcare and mental health networking more than on practice settings. At least one-quarter of GPs take on PMD-S. Competency, skills and confidence seem to be core factors in decisions to treat or to decline treating PMD. Access to specialized resources seems to inhibit GPs from taking on PMD; this finding may be a result of the severe shortage of GPs and the stigmatization of mental disorders. Consequently, the need to develop shared-care models is more pressing. Shared-care models should include strong multimodal incentives (e.g., psycho-social resources working closely with GPs, clini-

cal guidelines, medical education sessions) to help GPs who deal with more complex mental disorder cases, for which prompt consultation with psychiatrists and bio-psycho-social interventions are needed. Stabilized patients with more complex mental disorders ought to have the same access to care and follow-up as the general population (both for physical and mental problems) and to services that are the least stigmatizing.

# Acknowledgements

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### ONLINE EXCLUSIVE

### Discussion and Debate



Equitable Access to Healthcare Services and Income Replacement for Cancer: Is Critical Illness Insurance a Help or a Hindrance?

Accès équitable aux services de santé et remplacement de revenu dans les cas de cancer : l'assurance contre les maladies graves est-elle une aide ou une entrave? CHRISTOPHER J. LONGO

# Abstract

Canada's publicly funded healthcare system ensures that medically necessary hospital and physician services are available without financial barriers, but not all community-based care is covered. Consequently, many patients experience financial shocks (FS) related to community-based healthcare services not funded by government, and perhaps also from lost income, a situation that may be difficult for patients to avoid. Critical illness insurance (CII) offers a patient-funded alternative to those who qualify and desire protection against FS, leaving those without CII exposed. The author discusses the benefits and limitations of CII to mitigate financially derived healthcare access inequities, using cancer as an example.

# Résumé

Le système de santé canadien financé par les fonds publics assure que les services médicaux et d'hospitalisation nécessaires sont accessibles sans obstacles financiers, mais les services communautaires ne sont pas tous couverts. Par conséquent, plusieurs patients vivent un contrecoup financier lié à l'utilisation des services de santé communautaires qui ne sont pas financés par le gouvernement, ou lié à une perte de revenu; une situation que les patients peuvent parfois difficilement éviter. L'assurance contre les maladies graves offre une possibilité, financée par le patient, pour ceux qui y sont admissibles et souhaitent une protection, ce qui laisse les patients sans cette assurance susceptibles de vivre un contrecoup financier. L'auteur discute les avantages et les limites de l'assurance contre les maladies graves dans l'atténuation des inégalités d'accès financières face aux services de santé, en utilisant comme exemple le cas du cancer.

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# Research Paper



# Living Environments for People with Moderate to Severe Acquired Brain Injury

Milieux de vie pour les personnes vivant avec une lésion cérébrale acquise modérée ou sévère

ANGELA COLANTONIO, DANA HOWSE, BONNIE KIRSH, TERESA CHIU, RACHEL ZULLA AND CHARISSA LEVY

# Abstract

Objective: This study examines the issue of living environments for persons with acquired brain injury (ABI), with the aim of identifying factors that enable or act as barriers to appropriate living environments.

*Method:* A qualitative study involving 31 semi-structured interviews conducted with 56 key informants representing various relevant sectors: institutional, community, residential and non-residential, consumer/advocacy and government/policy from six regions in the province of Ontario, Canada.

Results: The study identified such barriers as lack of ABI-specific facilities, beds and trained staff and a poorly coordinated system in many areas, with long wait lists for specialized residential settings. Clients with ABI need individualized treatment, making development of a standardized model of care difficult, particularly for those with co-morbid conditions. Solutions such as more flexible options for clients and better trained staff emerged.

Conclusions: The study presents solutions to challenges and limitations in addressing appropriate living environments for persons with ABI.

# Résumé

Objectif : Cette étude examine la question des milieux de vie pour les personnes vivant avec une lésion cérébrale acquise (LCA) dans l'objectif de déterminer les facteurs qui facilitent ou font obstacle à un milieu de vie adéquat.

Méthodologie : Il s'agit d'une étude qualitative comprenant 31 entrevues semi-dirigées auprès de 56 informateurs clés représentant divers secteurs : institutions, communautés, milieu résidentiel et non résidentiel, clientèle/groupes d'intérêts, gouvernement et politiques provenant de six régions de la province de l'Ontario, Canada.

Résultats : L'étude a permis de repérer six obstacles tels que le manque d'installations, de lits et de personnel formé pour les cas de LCA, de même qu'un système peu coordonné dans plusieurs zones et de longues listes d'attentes pour les résidences spécial-

isées. Les patients vivant avec une LCA ont besoin de traitements individualisés, ce qui rend plus difficile l'élaboration d'un modèle standard, particulièrement pour ceux qui présentent un état de comorbidité. Parmi les solutions, il pourrait y avoir une plus grande flexibilité de choix pour les clients et une meilleure formation pour le personnel. *Conclusions*: L'étude présente des solutions aux défis et aux limites touchant le milieu de vie approprié pour les personnes vivant avec une LCA.

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ONLINE EXCLUSIVE

#### RESEARCH PAPER



Exploring Wait List Prioritization and Management Strategies for Publicly Funded Ambulatory Rehabilitation Services in Ontario, Canada: Further Evidence of Barriers to Access for People with Chronic Disease

Examen des stratégies de priorisation et de gestion des listes d'attente pour les services ambulatoires de réadaptation subventionnés par les fonds publics en Ontario, Canada: données additionnelles sur les obstacles d'accessibilité pour les personnes souffrant d'une maladie chronique

LAURA A. PASSALENT, MICHEL D. LANDRY AND CHERYL A. COTT

#### Abstract

*Background:* Timely access to publicly funded health services is a priority issue across the healthcare continuum in Canada. The purpose of this study was to examine wait list management strategies for publicly funded ambulatory rehabilitation services in Ontario, Canada.

Methods: Ambulatory rehabilitation services were defined as community occupational therapy (OT) and physiotherapy (PT) services. A mailed self-administered questionnaire was sent to all 374 Ontario publicly funded sites. Descriptive statistics were used to explore management strategies.

Results: The response rate was 57.2%. Client acuity was the most common method used to prioritize access across all settings. The most frequently reported methods to manage wait lists included teaching self-management strategies (85.0%), implementing attendance policies (69.5%) and conducting wait list audits (67.3%).

Conclusions: Ambulatory rehabilitation settings have implemented a number of strat-

egies for wait list management. The results of this study suggest that an increasing number of Ontarians encounter barriers when accessing publicly funded ambulatory rehabilitation services.

#### Résumé

Contexte : L'accès en temps opportun aux services de santé financés par les fonds publics est un enjeu prioritaire du continuum des services au Canada. L'objectif de cette étude était d'examiner les stratégies de gestion des listes d'attente pour les services ambulatoires de réadaptation financés par les fonds publics en Ontario, Canada. Méthodologie : Nous avons défini les services ambulatoires de réadaptation en tant que services communautaires d'ergothérapie et services de physiothérapie. Nous avons envoyé un questionnaire autoadministré aux 374 établissements ontariens financés par les fonds publics. Les stratégies de gestion ont été examinées à l'aide de la statistique descriptive. Résultats : Le taux de réponse a été de 57,2 %. Dans tous les établissements, le degré d'affection des patients est la méthode la plus fréquemment utilisée pour prioriser l'accès. La méthode la plus souvent indiquée pour la gestion des listes d'attente comprend, notamment, l'enseignement des stratégies d'autogestion (85,0 %), la mise en place de politiques d'assiduité (69,5 %) et le contrôle des listes d'attente (67,3 %). Conclusions: Les établissements ambulatoires de réadaptation ont mis en place un certain nombre de stratégies pour la gestion des listes d'attente. Les résultats de cette étude laissent croire qu'un nombre grandissant d'Ontariens se heurtent à des obstacles en matière d'accessibilité aux services ambulatoires de réadaptation financés par les fonds publics.

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#### Research Paper



# Anthropological Approach to Adherence Factors for Antihypertensive Drug Therapy

Approche anthropologique des déterminatnts de l'observance dans le traitement de l'hypertension artérielle

ALINE SARRADON-ECK, MARC EGROT, MARIE ANNE BLANC AND MURIELLE FAURE

#### **Abstract**

Objective: Uncontrolled high blood pressure leads clinicians to wonder about adherence degree among hypertensive patients. In this context, our study aims to describe and analyze patients' experience of antihypertensive drugs in order to shed light on the multiple social and symbolic logics, forming part of the cultural factors shaping personal medication practices.

Methods: The medical inductive and comprehensive anthropological approach implemented is based on an ethnographic survey (observations of consultations and interviews). Semi-structured interviews were conducted with 68 hypertensive patients (39 women and 29 men, between the ages of 40 and 95, of whom 52 were over 60) who had been receiving treatment for over a year.

Results: Antihypertensive drugs are reinterpreted when filtered through the cultural model of physiopathology (the body as an engine). This symbolic dimension facilitates acceptance of therapy but leads to a hierarchization of other prescribed drugs and of certain therapeutic classes (diuretics). Prescription compliance does not solely depend on the patient's perception of cardiovascular risk, but also on how the patient fully accepts the treatment and integrates it into his or her daily life; this requires identification with the product, building commitment and self-regulation of the treatment (experience, managing treatment and control of side effects, intake and treatment continuity). Following the prescription requires a relationship based on trust between the doctor and patient, which we have identified in three forms: reasoned trust, emotional trust and conceded trust.

Conclusion: Consideration and understanding of these pragmatic and symbolic issues by the treating physician should aid practitioners in carrying out their role as medical educators in the management of hypertension.

This paper was originally published in French, in the journal *Pratiques et organisation des soins* 39(1): 3–12.

#### Résumé

Objectif : Les hypertensions artérielles non contrôlées conduisent les cliniciens à s'interroger sur les niveaux d'observance des hypertendus traités. Dans ce contexte, notre étude visait à décrire et à analyser l'expérience des hypotenseurs par les hypertendus, afin de mettre à jour les logiques plurielles, sociales et symboliques, permettant de comprendre ce qui construit culturellement les pratiques médicamenteuses des individus. Méthodes: La démarche anthropologique, inductive et compréhensive, mise en oeuvre reposait sur une enquête ethnographique (observations de consultations et entretiens). Nous avons interviewé 68 hypertendus (39 femmes et 29 hommes, âgés de 40 à 95 ans, 52 d'entre eux ayant plus de 60 ans) traités depuis plus d'un an. Résultats : Le médicament hypotenseur était réinterprété au travers du filtre des représentations populaires de la physiopathologie (corps machine). Cette dimension symbolique facilitait l'adhésion thérapeutique, mais conduisait à une hiérarchisation des autres médicaments prescrits, et de certaines classes thérapeutiques (diurétiques). Le suivi de l'ordonnance était conditionné par la perception du risque cardiovasculaire, mais également par l'appropriation du traitement et son intégration dans la vie quotidienne nécessitant une identification au produit, une fidélisation, et une autorégulation du traitement (expérimentation; maîtrise du traitement; contrôle des effets indésirables, de l'ingestion, de la continuité du traitement). Le suivi de l'ordonnance requiert une relation de confiance entre le médecin et le patient dont nous avons relevé trois formes : la confiance raisonnée, la confiance affective, la confiance concédée. Conclusion: La prise en compte et la compréhension de ces différentes logiques pragmatiques et symboliques par le médecin traitant devraient pouvoir aider les praticiens dans leur fonction d'éducation thérapeutique des personnes hypertendues.

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# Equitable Access to Healthcare Services and Income Replacement for Cancer: Is Critical Illness Insurance a Help or a Hindrance?

Accès équitable aux services de santé et remplacement de revenu dans les cas de cancer : l'assurance contre les maladies graves est-elle une aide ou une entrave?



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#### **Abstract**

Canada's publicly funded healthcare system ensures that medically necessary hospital and physician services are available without financial barriers, but not all community-based care is covered. Consequently, many patients experience financial shocks (FS) related to community-based healthcare services not funded by government, and

perhaps also from lost income, a situation that may be difficult for patients to avoid. Critical illness insurance (CII) offers a patient-funded alternative to those who qualify and desire protection against FS, leaving those without CII exposed. The author discusses the benefits and limitations of CII to mitigate financially derived healthcare access inequities, using cancer as an example.

#### Résumé

Le système de santé canadien financé par les fonds publics assure que les services médicaux et d'hospitalisation nécessaires sont accessibles sans obstacles financiers, mais les services communautaires ne sont pas tous couverts. Par conséquent, plusieurs patients vivent un contrecoup financier lié à l'utilisation des services de santé communautaires qui ne sont pas financés par le gouvernement, ou lié à une perte de revenu; une situation que les patients peuvent parfois difficilement éviter. L'assurance contre les maladies graves offre une possibilité, financée par le patient, pour ceux qui y sont admissibles et souhaitent une protection, ce qui laisse les patients sans cette assurance susceptibles de vivre un contrecoup financier. L'auteur discute les avantages et les limites de l'assurance contre les maladies graves dans l'atténuation des inégalités d'accès financières face aux services de santé, en utilisant comme exemple le cas du cancer.

f Y anada's publicly funded healthcare system provides hospital and physician services to all residents without financial costs in accordance with  $\checkmark$  the Canada Health Act (CHA). However, government funding decisions for non-CHA healthcare services often result in exclusions, limits on service quantity, co-payments or deductibles. Additionally, services that are considered essential from a patient's perspective may be deemed non-essential by government, with these costs borne fully by patients and their families. Finally, many illnesses have impacts on patients' ability to work. Although Canadian health programs attempt to address issues related to equity of access without financial barriers, some aspects of care still raise financially based access issues. In other words, the current healthcare system does not fully address inequities based on the ability to pay. Although the resulting inequities may be much less significant than those seen among our American neighbours, they nonetheless still occur with some regularity. These issues surrounding equity of access are often presented as horizontal equity issues. Horizontal equity ensures that those with similar needs are treated similarly (Culyer 1995). The Canada Health Act addresses the issue of horizontal equity effectively for medically necessary hospital and physician care. However, there remain inequities in the access to many communitybased health services.

This inequity is illustrated by the fact that some individuals experience financial shocks associated with illness while others do not. Financial shocks (FS) are defined as large financial expenditures that are both unexpected and beyond the financial means of those experiencing them. There are insurance products capable of addressing those FS precipitated by illness, namely critical illness insurance (CII). CII is a fixedreimbursement policy that pays a lump sum to the insured once he or she is diagnosed with a specific illness. The payout is conditional upon a physician's diagnosis and provided the insured survives 30 days beyond the diagnosis. The popularity of CII may be influenced by the fact that although the risk for most purchasers is relatively low, individuals are likely to exaggerate this risk for rare events, making CII appear more attractive (Viscusi 1990). Hence, CII demand is growing despite the fact that other forms of private health insurance are provided to the majority of working Canadians through their employers or individual purchases (Colombo and Tapay 2004). These insurance policies provide coverage for many of the services that fall outside the Canada Health Act or public funding, and include drug plans, hospital room upgrades, eye care, dental care and coverage for a variety of healthcare professional services delivered outside the hospital setting. However, even for those who have private healthcare benefits, issues with service limits, co-payments or deductibles can create inequities and result in a reduced consumption of healthcare services (Keeler 1992; Anis et al. 2005). Additionally, some working Canadians have no employer-sponsored health insurance; when they need these unfunded healthcare services, they must pay for them out of pocket, thereby generating FS (Applied Management 2000).

Illness carries with it not just medically related patient expenditures, but also has impacts on the ability of patients and their caregivers to attend work. Although many working Canadians have employer-funded supplemental disability insurance that will provide income replacement while recovering from an illness, these are typically optional employee benefits that are provided for a fee. Moreover, not all employers offer such benefits. Recent Canadian statistics suggest that short-term disability is provided to approximately 50% of the labour force and long-term disability to about 30%, based on data from 1980 to 1996 (Campolieti and Lavis 2000). Hence, private insurance programs are capable of addressing both non-CHA health services and income loss, but there still remain patients for whom insurance coverage is incomplete or non-existent. Some of these uninsured patients may be eligible for publicly funded income replacement, but in most cases this coverage constitutes only partial income replacement, and would not apply if work loss is sporadic. Thus, CII has the potential to cover patient costs beyond what is offered using both public and private mechanisms.

#### The Case of Cancer

Previous studies in the Canadian setting have shown that healthcare coverage in cancer

is both inconsistent and incomplete (Menon et al. 2005; Longo et al. 2007; Aronson 2002). Additionally, in many cases cancer treatment results in a significant amount of lost income for both the patient and the patient's caregivers (Longo et al. 2006; Lauzier et al. 2008). Even for those with private healthcare insurance, co-payments for non-CHA healthcare services can become significant for cancer care, where the pharmaceutical therapies and healthcare professional usage often generate FS for patients and their families. Previous Canadian research has suggested that the aggregate of these cancer-related FS (non-coverage, co-payments, lost income) have been described by 20% of patients as a "significant or unmanageable burden" (Longo et al. 2006). Whether governments should take full responsibility for all health-related financial expenditures is certainly debatable (Wilson and Rosenberg 2004; Musgrove 1999). However, if we accept that one of the principal premises of publicly funded cancer care is to eliminate inequities based on ability to pay (Hutchison 2007), there is evidence that government policies have not been fully successful for cancer treatment. Cancer is also an interesting case to examine, as in most instances decisions to forgo treatment for financial reasons are likely to have implications on patients' health. Perhaps the risk of FS and its implications for access to treatment explains why Canadians are increasingly purchasing CII. Data show that in Canada, 70% of CII claims are for cancer, although coverage includes other illnesses (Munich Reinsurance 2006). The growth in these policies was in excess of 20% per annum between 2000 and 2005 (Munich Reinsurance 2006), and was approaching 400,000 individually purchased policies by year-end 2005.

#### Critical Illness Insurance: Benefits

Insurance products such as CII are a potentially useful mechanism to address FS. This is because there are no restrictions on how the funds may be used once a diagnosis is confirmed. A patient may therefore use the funds, for example, to purchase more inhome health services as a supplement beyond government coverage limits. In addition, patients may use the funds to obtain the most recent advances in technology that have not yet been funded through government programs, or to supplement income and allow themselves or a family member to take time freely from work without concern over the financial implications of this decision. It is even possible for patients to use the funds to take a needed vacation in a pleasant environment to aid in their recovery. In this regard, CII has a direct impact on quality of life by reducing financial stresses for patients and their family members during what may well be their most trying times.

Although the reasons for the popularity of CII products in Canada have not been fully researched, some of the rationales mentioned above may be possible explanations. Further research in this area is needed to clarify the demand for these types of insurance products. It is safe to say, however, that the market for CII exists only if there is a public perception that a diagnosis of cancer (or other devastating illnesses covered

under these policies, such as heart attack and stroke) carries with it a risk of FS. A recent examination of CII purchasing behaviour concludes that the motivation is likely a combination of coverage for cancer expenditures, lost income and a state-utility transfer to compensate for being sick (Longo and Grignon 2009). Thus, for some segment of the population, there is a suggestion that private health insurance products such as CII are a prudent way to manage these potential FS.

#### Critical Illness Insurance: Limitations

An important consideration in identifying program solutions for illness-related FS is ensuring that all citizens have equitable access to these programs. To be effective, at least in terms of equity goals, CII needs to provide coverage to all populations, including those most in need. Interestingly, individuals who are most likely to have high expenditures or have a higher risk of expenditures are those with limited private health coverage (Roetzheim et al. 1999), lower incomes (MacKillop et al. 2000) and existing co-morbidities (Gonzales et al. 2001). These same populations are also more likely to have high out-of-pocket costs compared to those at low risk. Typical premiums for these CII policies are unaffordable by individuals in the lowest income categories. This affordability assumption is based on the premise that more than 4.5% of gross income would be deemed unaffordable, a marker typically used for a drug expenditure means test (Ontario uses 4.5% and Manitoba uses 3.5% of gross family income). A working paper by Longo and Grignon (2009) suggests that more than 20% of the Canadian population would be unable to afford the CII premiums needed for illness-related expenditure coverage (cancer care services and compensation for lost income) related to cancer. Additionally, insurers exclude many patients who are deemed high risk, either because of pre-existing conditions, family history of covered diseases, or previous health events. Consequently, up to 30% of applicants are denied coverage, or are offered coverage with specific exclusions such as a cancer diagnosis (Munich Reinsurance 2006).

The result is that although CII has the potential to address the FS that many Canadians with cancer may experience, there is evidence that many of those individuals most likely to benefit would in fact be unable to obtain, or unable to afford, the necessary coverage. Hence, those individuals who do actually receive CII coverage may prove to be those who least need it.

#### Government Policies Related to Cancer Care

Current health policies ensure that much of the essential care for cancer is covered through the public purse, including physician services, hospitalization and drug therapies delivered in hospital. However, the current funding strategies employed in most provinces almost guarantee that some of the financial burden will be borne by patients

and their families, and is especially pronounced in those with inadequate insurance. It is likely that most Canadians would not expect all cancer-related costs to be covered, but they might expect that health policies would ensure they are not expected to manage FS while managing their illness. Governments should be aware of these FS in cancer care and the burden they place on patients and their families. Governments should consider adopting policies that minimize or mitigate these FS for those most in need. The evidence in cancer suggests that problems can occur when policy strategies rely too much on private sector solutions for non-CHA services. These problems stem from private sector interests in maximizing profits rather than ensuring equitable access. Private sector profitability is achieved partly by excluding those at highest risk ("cream skimming"), leaving the excluded individuals with no protection from FS, especially those who are uninsured or underinsured.

#### Conclusion

CII can offer coverage not provided by public and private health insurance and does ensure that those who are willing and able to purchase it are in a better position to weather FS; but many of those most in need are either unable to obtain or afford the coverage and so are no better off. In fact, it can be argued that these insurance offerings provide more latitude for governments to encourage private sector solutions for non-CHA healthcare services. Recent evidence of this is illustrated by the opening of private infusion clinics beginning in 2005, and the growing number of unfunded cancer drugs in recent years (Cancer Advocacy Coalition of Canada 2007). A potential concern is that the resulting inequity may in fact become worse when these private sector solutions are utilized. It is also not hard to imagine that as more targeted drugs enter the market with premium pricing, the demand for products like CII will only increase, as will the risk of FS. Governments interested in ensuring equitable access for all citizens would do well to pay attention to the implications of private financing of non-CHA healthcare services for cancer treatment.

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# Living Environments for People with Moderate to Severe Acquired Brain Injury

Milieux de vie pour les personnes vivant avec une lésion cérébrale acquise modérée ou sévère



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#### Living Environments for People with Moderate to Severe Acquired Brain Injury

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#### **Abstract**

Objective: This study examines the issue of living environments for persons with acquired brain injury (ABI), with the aim of identifying factors that enable or act as barriers to appropriate living environments.

*Method:* A qualitative study involving 31 semi-structured interviews conducted with 56 key informants representing various relevant sectors: institutional, community, residential and non-residential, consumer/advocacy and government/policy from six regions in the province of Ontario, Canada.

Results: The study identified such barriers as lack of ABI-specific facilities, beds and trained staff and a poorly coordinated system in many areas, with long wait lists for specialized residential settings. Clients with ABI need individualized treatment, making development of a standardized model of care difficult, particularly for those with co-morbid conditions. Solutions such as more flexible options for clients and better trained staff emerged.

Conclusions: The study presents solutions to challenges and limitations in addressing appropriate living environments for persons with ABI.

#### Résumé

Objectif: Cette étude examine la question des milieux de vie pour les personnes vivant avec une lésion cérébrale acquise (LCA) dans l'objectif de déterminer les facteurs qui facilitent ou font obstacle à un milieu de vie adéquat.

Méthodologie : Il s'agit d'une étude qualitative comprenant 31 entrevues semi-dirigées auprès de 56 informateurs clés représentant divers secteurs : institutions, communautés, milieu résidentiel et non résidentiel, clientèle/groupes d'intérêts, gouvernement et politiques provenant de six régions de la province de l'Ontario, Canada.

Résultats: L'étude a permis de repérer six obstacles tels que le manque d'installations, de lits et de personnel formé pour les cas de LCA, de même qu'un système peu coordonné dans plusieurs zones et de longues listes d'attentes pour les résidences spécialisées. Les patients vivant avec une LCA ont besoin de traitements individualisés, ce

qui rend plus difficile l'élaboration d'un modèle standard, particulièrement pour ceux qui présentent un état de comorbidité. Parmi les solutions, il pourrait y avoir une plus grande flexibilité de choix pour les clients et une meilleure formation pour le personnel. Conclusions: L'étude présente des solutions aux défis et aux limites touchant le milieu de vie approprié pour les personnes vivant avec une LCA.

CQUIRED BRAIN INJURY (ABI), WHICH CAN RESULT FROM TRAUMATIC OR non-traumatic events, is a leading cause of death and disability worldwide (O'Reilly and Pryor 2002; Cameron et al. 2001; Thurman et al. 1999). A recent report identified over 30,000 emergency visits and/or hospitalizations for ABI in Ontario in one year alone (Colantonio et al. 2009). Advances in medicine, medical technology and rehabilitation have increased survival rates and life expectancies such that survivors may live for decades with disability. Persons who sustain traumatic injuries are often young, and even mild injuries can lead to long-term disability (Colantonio et al. 1998; O'Connor et al. 2005). The consequences for families and caregivers, in terms of caregiving responsibilities and quality of life, are enormous (Kolakowsky-Hayner et al. 2001; DeMatteo et al. 2008). Families require long-term support, but most professional interventions are provided during the acute period (Lefebvre et al. 2005; Leith et al. 2004). In addition, a large percentage (11%) of all acute care admissions have at least one alternate level of care day, indicating difficulties in care options beyond the acute care setting (Colantonio et al. 2009).

The goal of this study was to gain a better understanding of placement issues related to living environments for adults with moderate to severe ABI in the post-acute phase. Specifically, we explored inappropriate living environments, defined as those that fail to meet all of an individual's ABI-specific housing, support and treatment needs, as well as potential solutions to improve quality of life, by capturing the perspectives of a broad range of providers, consumer advocates and government policy administrators.

#### Methods

An "inappropriate living environment" was defined a priori by the study researchers as one that fails to meet all of an individual's ABI-specific housing, support and treatment needs. A qualitative approach generated the perspectives of ABI service providers, consumer advocates and government representatives, using data obtained from semi-structured interviews (Miles and Huberman 1994).

#### Participants

Purposeful sampling was used to recruit information-rich participants (Patton 2002).

Potential participants were identified from the investigators' resources, the Toronto ABI Network, provincial ABI service providers and related agencies (i.e., rehabilitation facilities, advocacy groups, community care access centres [CCACs], residential care providers, acute care facilities) and the provincial Ministry of Health and Long-Term Care (MOHLTC). Key staff members known to have extensive experience with the ABI population were selected from each organization and invited to participate in semi-structured interviews. Invitation letters were mailed to all potential key informants. Additional letters were later mailed to people who were suggested by recruited participants or by people on the original mailing list who declined the invitation to participate. Interviews were scheduled with willing participants during follow-up phone calls within one to two weeks after the mailing. In some cases, several telephone exchanges were required before interview dates could be scheduled. The interviewer would attempt to contact the informant up to three times before conceding loss-to-follow-up. Representation was obtained from each type of service provider and organization (Table 1) across MOHLTC-defined geographical regions.

**TABLE 1.** Number of interviews, by stakeholder category

Provider category	Number of interviews (%) n=31
Residential	9 (29)
Non-residential	6 (19)
Institutional	7 (23)
Government/CCAC	6 (19)
Advocacy/Consumer groups	3 (10)

Fifty-six respondents participated in 31 interviews. Sixteen interviews involved one participant; the remainder involved two to five participants. Respondents represented several different ABI-related job positions (Table 2) and had worked with the ABI population for a mean of 12.4 years, with 60% for 10 or more years. Twenty-nine per cent of respondents reported that their experience with the ABI population was in the public sector, and 8% had experience working with privately funded clients. Of the 63% who reported experience in both public and private sectors, more than half (59%) reported that "about 90% of their experience was with the public sector."

Respondents were asked to read and sign a consent form at the beginning of each interview. They were informed of the study's purpose, the interview's content and the confidential and voluntary nature of their participation.

TABLE 2. Number of respondents in job position

Current position	Number of respondents (%) n=56
Director/Executive Director	17 (30)
Program Manager (oversees programs but has little direct contact with client)	13 (23)
Caregiver/Practitioner	13 (23)
Care Coordinator (ensures program of care is appropriate to client needs)	6 (11)
Program Consultant	3 (5)
Intake Facilitator (manages referrals and intake of clients)	2 (4)
Case Manager/Community Liaison (assists client with referrals, accessing services in community)	2 (4)

#### Data collection

The interview consisted of preliminary closed-style screening questions for demographic purposes, and open-ended questions about resources available, protocols followed and challenges faced by both service providers and clients in trying to find appropriate living environments for people with ABI. The interview format was pilottested with a service provider and adjusted accordingly. See the Appendix for the open-ended interview questions.

Thirty interviews were conducted face-to-face; one was conducted over the phone. Interviews lasted 45–90 minutes and were audiotaped and later transcribed.

#### Data analysis

Interview transcripts were imported into a qualitative software program, N6 (purchased online from QSR International – 2007 Cambridge, MA), for analysis.

A process of inductive analysis was employed. One researcher (DH) carefully reviewed the transcripts, coded the data line by line (open coding) and grouped them into categories and themes. The "lack of resources" theme, for example, emerged from several sub-themes (lack of appropriate structural facilities; lack of ABI-trained staff; accessibility), which were created as a result of collapsing several codes: space/resource issues, lack of properly trained staff, lack of awareness among doctors, no resources for young people, distance between clients and service, and several codes related to suggested changes/solutions to the existing ABI system. Initial codes were created from the interview schedule, and more codes were added after the researcher reviewed the

transcripts and identified common ideas/responses. Then, interview data (participant responses) pertaining to the codes were organized accordingly. Consistent with a "triangulation of researchers" method, whereby researchers work in partnerships or teams to bring different perspectives to the research to explore themes and interpretations across those perspectives (Denzin 1970; Brannen 1992), a second researcher (RZ) examined the transcripts to become familiar with the data. Together, the researchers refined the coding scheme and re-coded the data using an axial coding process (Lincoln and Guba 1985) to bring previously coded data together under broader categories (Creswell 1998; Glaser and Strauss 1967). Selective coding involved developing theoretical propositions (Creswell 1998; Glaser and Strauss 1967).

#### Results

Analyses revealed five challenges associated with finding appropriate living environments for individuals living with the effects of ABI: (1) lack of resources, (2) minimal coordination of services, (3) inappropriate waiting environments, (4) a two-tiered ABI system and (5) the need for individualized treatment.

#### 1. Lack of resources

The greatest challenge in providing appropriate services and living arrangements for people with ABI that was reported by all types of providers was the lack of resources and infrastructure, specifically the lack of structural facilities, ABI-trained staff and accessibility.

#### LACK OF APPROPRIATE STRUCTURAL FACILITIES

One of the main barriers to finding appropriate living environments for the growing number of clients with ABI is a lack of ABI-specific community placements. Many patients, once ready to be released from acute care and rehabilitation facilities, have nowhere to go.

... the single [biggest] impediment in finding a placement is that there's no space. So even if we do assist them in finding a pathway ... the end goal is probably not going to be realized because it's just a lack of resources. (Non-residential provider)

Keeping patients with ABI in hospital beds longer than necessary reduces the number of beds available for new patients who require acute care (associated with high healthcare costs), a situation that unnecessarily inflates system costs and is an inefficient allocation of resources. A common solution is to discharge patients with ABI to long-term care homes that often have beds available to accommodate non-geriatric patients but which often do not offer ABI-specific or age-appropriate services to address the unique cognitive and behavioural needs of these patients. Many providers noted the lack of spaces in residential facilities designed for individuals at an advanced stage of recovery who are ready to integrate back into society. This type of facility is usually the final destination for clients and has little turnover. Clients at this stage of recovery may be ready to live in income-based housing. However, these spaces are also limited owing to rising rental costs and injury-related symptoms and disability, factors that prevent most clients with ABI from finding employment with sufficient income to afford this type of living arrangement.

Respondents noted that residential providers and CCACs offer support to clients with ABI living at home or in long-term care facilities through day programs, which provide special rehabilitative care and offer family members a break from full-time caregiving responsibilities. Limited resources and funding, however, make offering this type of programming difficult, and availability varies across regions, residential providers and CCACs. Only some residential providers and CCACs have the staff or space to run such programs in-house, and the selection of off-site locations is limited by small budgets. Day programs are commonly offered in older buildings that lack elevators and wheelchair ramps, making attendance difficult for those with physical limitations.

Providers also indicated that few living environments are structurally equipped to deal with clients with ABI who exhibit behavioural problems or aggression. Many lack a secured unit where individuals exhibiting dangerous behaviours can be contained, a measure that is necessary to ensure the safety of clients with ABI, staff and other patients. The alternative – treating behavioural clients in psychiatric wards – is often inappropriate, as many clients with ABI exhibit violent behaviour in episodes (Eames and Wood 2003) and may not require full-time psychiatric care.

#### LACK OF ABI-TRAINED STAFF

Over the course of their recovery, individuals with ABI require the services of various healthcare professionals and providers, but respondents reported that the availability of these services does not meet the need. In many environments (i.e., nursing homes, residential facilities) the ratio of patients to caregivers is high, making provision of adequate care difficult. Many living environments, such as supported living apartments and residential facilities, have no on-site healthcare professionals to deal with medical emergencies.

Providers also reported a shortage of healthcare professionals with formal training specific to ABI.

They are not comfortable with and don't have the training for the behavioural and the cognitive ... coming out of university they have ... great backgrounds, they don't have the practical training so ... in terms of challenges, it's finding enough staff who have the qualifications to work with ABI. (Residential provider)

Finally, many providers perceived that misdiagnosis or delayed diagnosis of ABI is common. They noted that medical professionals may not be trained or experienced in differentiating between symptoms of mental illness and symptoms of brain injury. Diagnosis is further complicated by an overlap of symptoms across conditions and the latent manifestation of symptoms months or even years after the injury (Karon et al. 2007; Brenner et al. 2009). Providers reported that patients who are misdiagnosed or diagnosed late are deprived of rehabilitation, regular monitoring and long-term follow-up critical for them to reach their full rehabilitation potential.

#### ACCESSIBILITY

Providers said that geographic distance and boundaries often pose challenges in providing ABI services. Rural regions of the province, in particular, have fewer ABI facilities and programs. Clients must often travel long distances to access needed services and must choose between obtaining less appropriate care in or near their home community and moving away from their family and community to receive the best care available.

So I think sometimes, there has ... [to be some] sort of a compromise – like do you want services close to home or do you want the absolute right services which are eight hours away. (Institutional provider)

Respondents reported that in large urban centres, clients without transportation may be unable to access valuable ABI care-related programs or services. The use of public transit requires certain cognitive and motor-related abilities that may have been compromised since the injury, and yet many survivors of ABI do not have the required visible physical disability to access special transportation services.

#### 2. Lack of coordination of services

Another commonly reported challenge to finding appropriate living environments for people with ABI is the minimal coordination of services. Many respondents reported that the delivery of healthcare for survivors of ABI is a "patchwork of services" in which "pockets of services are available and usually with wait lists."

Provincially, there is no formal systematic approach to link clients to services. Many respondents who serve clients outside the GTA reported a lack of organization in the current system and indicated that the absence of a central process has led to gaps, primarily at the rehabilitation and community re-integration stages.

... there's confusion of roles – no one knows how does the CCAC handle it, compared to how does the acute care system handle it, compared to how do other services handle it ... [things] occur by happenstance, ... it's kind of good fortune when placement happens, as opposed to logical result of. (Residential provider)

Providers noted that because there is no coordination of services, individuals in similar situations and exhibiting the same symptoms might take different pathways for the same type of care.

Many providers reported that the absence of a provincial registry to catalogue all facilities in the province that offer services to the ABI population impedes communication among service providers and with ABI clients. Many respondents indicated that they did not know the full range of services available within their community and region and found it difficult to connect clients with appropriate care facilities, forcing patients to wait in their current living arrangement. Communication is especially limited between acute care centres and residential or community support providers.

Many clients are lost in the system because their movements between different stages of care are not monitored. The current system lacks a clear protocol on patient follow-up and on transference of patient information during transition periods. All providers felt strongly that individuals with ABI need to be tracked to ensure that they receive the best care as soon as possible and in the most appropriate living environment available.

#### LACK OF A POLICY FRAMEWORK

Respondents suggested that the MOHLTC lacks an ABI policy and uses a haphazard approach to ABI service provision.

... with the MOH there's really no policy framework for acquired brain injury. There are services that are funded, but there is nothing in mind ... [unlike] mental health, which sort of lays it out and says that ... for people with this type of problem, these are the kinds of services that you ... would want to see ... . We have the definition of services, but how people get to them ... it often seems ad hoc. (Residential provider)

#### 3. Inappropriate waiting environments

The mandate at every stage of care is to rehabilitate the patient to a point where he or she can progress to the next stage of care. However, discharge from the current living environment is often not possible because appropriate facilities for survivors of ABI are often full and have long wait lists. Residential facilities have the longest waiting periods, where waits of two to five years or more were reported. Furthermore, the available facilities may be inappropriate for the client's gender, age or both.

... putting a 22-year-old woman who has a brain injury that requires lifelong support and 24-hour supervision ... into an Alzheimer's ward ... it's an inappropriate placement. (Consumer advocate)

Clients with ABI who cannot access the next stage of care are forced to wait or settle for alternative living arrangements. Remaining in an environment that no longer addresses the patient's needs may delay further rehabilitation, and while alternative environments (e.g., nursing homes, long-term care homes) provide the basic required care, they are inappropriate because they are primarily devoted to geriatric care and do not offer ABI-specific services such as rehabilitative care and vocational opportunities.

... and what that means, of course, is you've just spent a whopping big whack of my taxpayer's money to put people through a program ... approaching their maximum potential for independence, and then you're going to discharge them ... you will see those gains disappear very quickly and you've wasted my taxpayer's money. (Consumer advocate)

As with children and youth with ABI (DeMatteo et al. 2008), the most commonly reported default placement for adults with ABI is at home with family. The family home is often an inappropriate living environment for survivors of ABI because the family may have difficulty coping with the demands placed on them. Alternatively, family members capable of providing care in the short term are subject to caregiver burnout over the long term, particularly if the caregiver is aging and is eventually unable to provide care.

... oftentimes the families just reach a point where their own mental health is beginning to suffer because of it ... and maybe there are a host of services coming in ... but it's not a full quality of life ... and ... the family just gets to the point where they're burnt out and so they're looking for permanent placement. (Government provider)

#### 4. Two-tiered system: Private versus public funding

Interviews suggested that the ABI system is two-tiered, having a private and public sector. The nature and cause of a client's brain injury seem to determine whether he or she will access private or public care. Individuals who suffer a traumatic brain injury (TBI) in a motor vehicle or workplace accident generally receive compensation from an insurance settlement. Some respondents reported that clients with ABI in the private sector typically have quicker access to services and receive more appropriate care than those in the public sector.

... Is there types of insurance? ... so they're going to pick up some of the cost. Because then those people can tap into attendant care services, like a level of service that might not be available through [publicly funded services]. So for the person who has that extra insurance or maybe they had some kind of a lawsuit and there was a settlement ... there's monies available to pay for those extra kind of things. (Government representative)

Conversely, some providers indicated that private services are not automatically provided to clients using private funds. Private funding sources first assess the individual to ensure that he or she meets eligibility criteria for compensation and healthcare. For this reason, access to care may be delayed or denied, and the patient's health outcome may be compromised. In addition, many clients with ABI require lifelong support, and private funding, which lasts for a finite period of time, is often insufficient.

#### 5. Need for individual treatment

Inappropriate placements were defined by the majority of providers as placements that do not meet or adapt to an individual client's ABI-specific needs. People with ABI differ with respect to their behaviours, mental health, physical health, co-morbid conditions and substance abuse problems, yet the current system's generic, one-size-fits-all program of care does not reflect these differences and is challenged in finding appropriate placements for individuals at each stage of care. Respondents suggested that the need for treatment on an individual basis makes developing a standard approach to placing and treating clients with ABI difficult.

... they're different from each other ... so it's very hard to get a common set of cognitive disabilities, and psycho-social [problems] ... they're like snowflakes ... it's very difficult to ... develop the right basket of services ... . (Residential provider)

The presence and complexity/stability of co-morbid conditions makes placing clients with ABI more difficult. Many facilities, for instance, are not equipped to monitor and treat patients with tracheotomies or schizophrenia, conditions that require high levels of medical care in addition to the care required for the ABI.

Clients also have varying cognitive, behavioural and psychiatric needs that may present significant barriers to receiving appropriate care. Aggressive behaviours – specifically, violent outbursts often associated with brain injury – are especially problematic.

... clients who present with forensic and mental health dual-diagnosis issues are often not accepted into placement facilities because their staff cannot cope with the behaviours ... . Aggressive behaviour seems to be a very common barrier for placement. (CCAC provider)

Residential facilities do not have medical personnel on staff available 24 hours a day, and clients may not be able to access acute care centres should immediate psychiatric care be required. Finally, ABI has been linked with increased substance abuse (Graham and Cardon 2008), a problem that many facilities are not equipped to handle.

Providing support to clients with ABI who have cognitive deficits, especially short-term memory loss, can be challenging. The level of consistent supervision and time commitment required for this type of care is often difficult for caregivers to provide. As a result, such clients are inappropriately placed in highly supervised environments (e.g., long-term care homes) that provide personal care (e.g., assistance with showering, medication), but rarely offer rehabilitative care or opportunities for clients to complete tasks independently.

#### Solutions

It is evident from the results above that much modification to the current system is needed. Solutions include additional resources, coordination of services, and respite and individualized care (Table 3).

Some respondents suggested that the MOHLTC should mandate ABI care providers to join the Toronto ABI Network, an association of 20 publicly funded ABI service agencies and organizations that offers information for providers about available resources and wait-listed services, as well as educational materials (Toronto ABI Network 2009). It was cited as invaluable in linking patients and case workers with resources. Other regions are attempting to create similar networks.

A variety of services are required to meet the needs of all clients in the ABI system and allow patients and their families to customize their program of care.

TABLE 3. Proposed solutions

Recommendation	Potential goals and benefits	
Additional investments		
Living environments and discharge locations including apartments serviced by other agencies, outpatient programs and conversion of space in long-term care settings into specialized units and/or for short-stay housing	Provision of long-term appropriate living environments	
More secured units incorporated into facilities	Meet demands of clients with aggressive and other challenging behaviours	
Programs to enhance the knowledge and skills of ABI healthcare professionals and support workers across the province	Address the need for more ABI trained staff and professionals	
Funding of accessible transportation that is available to all consumers, including those without physical disability	Reduce transportation barriers	
Community partnerships and networks to promote greater exchange of information and reduce delays in service provision	Enhanced coordination across services	
A province-wide tracking system of patients	Identify resource needs and system weaknesses and promote consistent case coordination	
Intra-governmental coordination and collaboration	Address range of health/social/environmental needs of ABI patients	
More respite care, home visits, counselling, etc. for families as well as financial and/or technical assistance to physically modify homes	Reduce the rate of caregiver burnout and address resultant placement challenges	
Individualized care via continuous coordination from the beginning of care	Allow for better decision-making regarding care and greater flexibility to address client/family needs within the community in order to keep people out of more costly institutionally based services for a longer period.	

I'd like to see a larger range of options available to us for placement. Right now ... if folks cannot go to long-term care, and their families cannot care for them, there are few other viable options. (Residential provider)

Two providers noted the economic benefit of offering more flexible services. Because many families require services for only part of the day, many functional patients with ABI could live at home instead of at an expensive long-term care facility. To provide ABI care on an individual basis, services should be coordinated from the beginning of care. However, within the public sector, this intensive case management would require more case managers, discharge planners, social workers and, ultimately, more funding.

#### Discussion

This study explored the perspectives and experiences of ABI service providers, consumer advocates and government representatives regarding the availability and accessibility of appropriate living environments for persons with ABI in a Canadian setting. Interviews revealed that challenges associated with finding appropriate living environments result from structural and systemic weaknesses, including insufficient resources and coordination of services, inappropriate waiting environments, a two-tiered funding system and an absence of services that meet the individualized needs of the ABI population. Solutions to these issues were also proposed.

The challenges reported by the ABI service providers are similar to those reported by survivors of ABI and their families. In a US study (Leith et al. 2004), persons with traumatic brain injury and their families reported a need for an early, continuous and comprehensive service delivery system. They felt that a state-wide agency devoted to the coordination and execution of a comprehensive service delivery system would address the challenges in accessing appropriate ABI care. They identified a need for survivors of ABI to connect with the system early, to enable families to make informed decisions, to encourage survivors of ABI to live as independently as possible, to assist family caregivers by offering more respite and in-home health services, and to maintain follow-up contacts. They also reported a need for information and education for service providers, clients and their families, including more specialized training for ABI support staff and health professionals.

Providers in this study indicated that survivors of ABI generally have quicker access to more appropriate services if the cause of their injury makes them eligible for private funding such as insurance payments or legal settlements. However, they also noted that private funding can create other barriers to appropriate care. Previous research found that Canadian and US survivors of ABI and their families experience frustration in trying to access private funding, reporting that compensation and services were often difficult to obtain and that they had to justify their needs repeatedly to the compensation agent (Lefebvre et al. 2005; Leith et al. 2004).

Providers offered a number of solutions that may begin to address problems within the existing ABI system. They felt that a wider range of options would provide more choice and availability, allowing service providers to develop programs of care to meet the individual needs of ABI survivors.

Many of the reported challenges result from a lack of sufficient funding allocated for the ABI population. Providers in this study stated that government funding is allocated on the assumption that patients with ABI get better, move through the system and recover; however, this is not the reality for all ABI survivors. US survivors of ABI felt that law- and policy makers do not know enough about their short- and long-term needs (Leith et al. 2004). Policy makers must be better informed about the needs of survivors of ABI so that more funding, and more long-term funding, can be devoted

to this population, and ABI-specific living environments and services can be made available. Increased funding could also help provide more professional services and specialized settings with trained staff. In the long run, this approach may be less costly to society, because a stable living environment with early interventions may reduce hospitalization or the use of health services.

Despite the weaknesses in the ABI system, some progress has been made in the last few years. Some publicly funded ABI-specific housing already exists. The MOHLTC recently provided \$5.6 million to provide better care for patients with severe behavioural problems and has expressed interest in building more specialized ABI units. The presence of the Toronto ABI Network has enabled providers to offer more adequate and efficient services, and many providers felt the Toronto ABI Network should be a model for developing a province-wide network to improve ABI service provision in Ontario. A centralized system, whereby information about all ABI service providers in Ontario (e.g., services offered, availability and information about ABI clients) is updated and shared, would address the problems associated with the current lack of coordination within the ABI system.

A potential limitation of this study is that interview participants were not specifically asked who should be responsible for implementing the recommendations that they were proposing. It is evident, however, that most of these solutions, particularly the provision of post-acute care, fall within the mandate of the MOHLTC both centrally and more locally, as more funding is being transferred to local health integration networks (LHINs). While efforts to improve the system should start with the MOHLTC, many of the solutions listed in Table 3 require collaboration between the MOHLTC and a wide range of ministries, agencies, associations and brain injury networks at the municipal, provincial and federal levels.

The Ministry of Training, Colleges and Universities, for example, could have an additional role to play in addressing the lack of interest in or sufficient availability of health-related training programs that have a focus on brain injury. Specialized community agencies and advocacy groups also have a role in promoting and providing ABI-related training to those already working with ABI survivors. The Ministry of Transportation and relevant municipal governments are key players in addressing the lack of appropriate transportation (both within and between urban centres/regions) for clients to access care and support. The Ministry of Municipal Affairs and Housing, as well as other arms of government that offer financial assistance to people renovating their homes to accommodate disability (i.e., Canadian Mortgage and Housing), should be involved to address the need for affordable supportive housing. Should there be an increase in lockdown/secure units, the Ministry of Community Safety and Correctional Services would have a role in promoting awareness/training for staff regarding clients who may benefit from referral to such resources. Finally, efforts to monitor, track and document patient needs and care programs, as well as initiatives to exchange informa-

tion, would require the participation of provincial ministries as well as established brain injury networks. Overall, it is evident that intra-governmental coordination and collaboration are necessary to address post-acute care needs of ABI consumers.

Because respondents represented existing organizations and institutions, many of the solutions offered were within the range of existing options. Innovative approaches – such as the use of technology for individual support (especially in more underserved areas), home modifications to complement or reduce staffing requirements, and more accessible education programs for staff in residential or institutionalized settings – did not emerge. Consideration should be given to innovative technology and its ability to enhance the quality of life of long-term consumers.

The results of this qualitative study represent the perspectives of stakeholders from different parts of Ontario who deal directly with ABI survivors daily and are intimately aware of the challenges faced by people who are seeking ABI-appropriate living environments. Because the participants represented a wide variety of organizations, job positions and provincial regions, we believe that the results offer a fairly accurate and broad portrayal of what is happening in the existing ABI system province-wide. The study's findings should, however, not be generalized or assumed to be representative of the perspectives and experiences of all ABI service providers in Ontario. This study provides an overview of challenges to appropriate living environments for persons with ABI as well as a range of possible solutions, and we hope it will form the basis for improving post-acute care after acquired brain injury.

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#### Appendix: Open-Ended Interview Questions

#### Overview questions

- 1. How does the health/rehabilitation system enable placement of persons with TBI/ABI?
- 2. What are some of the challenges within the system in placing people with TBI/ABI?
- 3. Are there typical "pathways" followed by people seeking placement? If so, what are they?
- 4. What are your organization's admission criteria? What are your exclusion criteria?
- 5. What catchment area do you serve?
- 6. How large is your staff?
- 7. What programs/services are provided by your organization?
- 8. (For residential programs) What is the average length of stay? How many clients does your organization serve per year?
- 9. Can you estimate how many clients have been referred to your organization but are still waiting for services? How long have the clients at the head of your wait lists been waiting?
- 10. How many clients have been referred to your organization but were denied service? What reasons were given for denying service?
- 11. (For residential programs) Where are clients with TBI/ABI living while they wait? Do you consider it to be appropriate or inappropriate for them and why?
- 12. What changes would you like to see in the system that would enable more effective and efficient placement?

#### Specific questions

- 1. Is there a difference between ABI and TBI in how it affects placement (what is considered appropriate/inappropriate)? If yes, how so?
- 2. What are some of the needs of persons with TBI/ABI that are important to consider in placement?
- 3. How are these needs being addressed?
- 4. How are they not addressed?
- 5. How would you define/describe an *appropriate* placement for persons with TBI/ABI?

- 6. How would you define/describe an *inappropriate* placement for persons with TBI/ABI?
- 7. Are there any specific characteristics of TBI/ABI patients that put them at greater risk for needing placement and for being more likely not to get it?
- 8. What are some additional factors affecting placement (e.g., co-morbid conditions, age, etc.)?
- 9. What changes would you like to see that would enable more effective and efficient placement?
- 10. What are the characteristics of individuals who were denied access? Why were they denied access?

Exploring Wait List Prioritization and Management Strategies for Publicly Funded Ambulatory Rehabilitation Services in Ontario, Canada: Further Evidence of Barriers to Access for People with Chronic Disease

Examen des stratégies de priorisation et de gestion des listes d'attente pour les services ambulatoires de réadaptation subventionnés par les fonds publics en Ontario, Canada : données additionnelles sur les obstacles d'accessibilité pour les personnes souffrant d'une maladie chronique



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#### **Abstract**

*Background:* Timely access to publicly funded health services is a priority issue across the healthcare continuum in Canada. The purpose of this study was to examine wait list management strategies for publicly funded ambulatory rehabilitation services in Ontario, Canada.

Methods: Ambulatory rehabilitation services were defined as community occupational therapy (OT) and physiotherapy (PT) services. A mailed self-administered questionnaire was sent to all 374 Ontario publicly funded sites. Descriptive statistics were used to explore management strategies.

Results: The response rate was 57.2%. Client acuity was the most common method used to prioritize access across all settings. The most frequently reported methods to manage wait lists included teaching self-management strategies (85.0%), implementing attendance policies (69.5%) and conducting wait list audits (67.3%).

Conclusions: Ambulatory rehabilitation settings have implemented a number of strategies for wait list management. The results of this study suggest that an increasing number of Ontarians encounter barriers when accessing publicly funded ambulatory rehabilitation services.

#### Résumé

Contexte: L'accès en temps opportun aux services de santé financés par les fonds publics est un enjeu prioritaire du continuum des services au Canada. L'objectif de cette étude était d'examiner les stratégies de gestion des listes d'attente pour les services ambulatoires de réadaptation financés par les fonds publics en Ontario, Canada. Méthodologie: Nous avons défini les services ambulatoires de réadaptation en tant que services communautaires d'ergothérapie et services de physiothérapie. Nous avons envoyé un questionnaire autoadministré aux 374 établissements ontariens financés par les fonds

publics. Les stratégies de gestion ont été examinées à l'aide de la statistique descriptive. Résultats: Le taux de réponse a été de 57,2 %. Dans tous les établissements, le degré d'affection des patients est la méthode la plus fréquemment utilisée pour prioriser l'accès. La méthode la plus souvent indiquée pour la gestion des listes d'attente comprend, notamment, l'enseignement des stratégies d'autogestion (85,0 %), la mise en place de politiques d'assiduité (69,5 %) et le contrôle des listes d'attente (67,3 %). Conclusions: Les établissements ambulatoires de réadaptation ont mis en place un certain nombre de stratégies pour la gestion des listes d'attente. Les résultats de cette étude laissent croire qu'un nombre grandissant d'Ontariens se heurtent à des obstacles en matière d'accessibilité aux services ambulatoires de réadaptation financés par les fonds publics.

S SHIFTS IN THE DEMOGRAPHIC CHARACTERISTICS OF THE POPULATION continue to occur at an unprecedented pace, and as other factors affecting L supply and demand for healthcare change over time, timely access to comprehensive health services has become elusive (Murray et al. 2002). Multiple demands on healthcare systems are occurring across the continuum, and much of the policy focus has recently been placed on wait times for surgical and diagnostic services (CIHI 2005; OMHLTC 2006; Esmail and Walker 2002; Frankel et al. 1999; Juni et al. 2003; Trypuc et al. 2006). Despite the ongoing research and policy interest in the hospital-based aspects of care delivery, others have noted that wait lists for community-based services have become overshadowed by surgical and medical wait times (Young and Turnock 2001). A recent study examining wait times for community rehabilitation indicated that individuals with chronic conditions have excessive wait times for outpatient and community occupational therapy (OT) and physiotherapy (PT) services in Ontario, particularly if these individuals are waiting for services in hospital outpatient departments (Passalent et al. 2009). The consequences of lack of access to rehabilitation services have been explored previously, and the outcomes seem to suggest that individuals who require and receive services are statistically more likely to self-report improved health status compared to those who are unable to access services (Landry et al. 2007). Landry and colleagues (2007) suggest that given the association between poor self-reported health status, morbidity and mortality, future research needs to examine the long-term impact to determine the extent to which barriers to access, including long wait times, may be associated with increased utilization of hospitals and family physicians.

As chronic disease continues to place increasing demands on the healthcare system, some chronic conditions such as arthritis, musculoskeletal disorders and stroke are more likely than other conditions to be associated with disability, and are presumably more likely to require rehabilitation intervention to optimize function, mobility and independence in the community (Barr et al. 2003; Wagner 1998; Rothman and

Wagner 2003; Beaglehole et al. 2007; Tsasis and Bains 2009). Moreover, the recent shift in emphasis for service delivery from hospital-based to community-based settings has resulted in additional demand on community rehabilitation providers (Landry et al. 2007; Baranek et al. 2004; Randall and Williams 2006). These factors, in combination, appear to be placing increased demand on rehabilitation service provision and therefore affecting timely access to appropriate healthcare providers.

Few studies have examined wait lists and wait times for outpatient PT and OT services. For instance, the provincial regulatory body for physiotherapists in Ontario reported that patients waited, on average, 10 days longer for urgent PT outpatient care through hospitals than through community PT clinics (College of Physiotherapists of Ontario 2000). In a 2007 study of rehabilitation in primary care, wait times were found to be shorter in privately funded practice settings compared to publicly funded settings, and for acute patient populations compared to those with chronic conditions (Cott et al. 2007). The literature that has examined community OT wait times indicates that over half of community occupational therapists wait an average of one week or less from receipt of referral to a client's first visit (Cott et al. 2007). Furthermore, data from the 2004 Ontario Auditor General's report of community healthcare services suggest that 45.6% of all people waiting for such services were waiting for home-based OT (Auditor General of Ontario 2004).

Most recently, an Ontario study (Passalent et al. 2009) indicates that (a) wait times for community PT were longer than OT wait times, with the median wait time for OT and PT being 12.5 and 35 days, respectively; (b) maximum wait times for PT are more than twice as long compared to maximum wait times for OT (114 days waiting for PT compared to a maximum of 63 days waiting for OT); and (c) over 10,000 people reported waiting for OT or PT services across Ontario. Despite this limited examination of wait time and wait lists for outpatient and community rehabilitation services, little in the literature examines the *management* of these extensive wait lists. The purpose of this study was to explore the various wait list management strategies currently used for OT and PT services across publicly funded outpatient and community settings in Ontario.

## Methods

In order to explore wait list prioritization and management strategies used within publicly funded ambulatory rehabilitation services, we employed a mail-out survey across Ontario. The development of the survey tool has been reported elsewhere (Passalent et al. 2009) and will be only briefly reviewed in this paper. The study protocol was approved by the University Health Network Research Ethics Board, Toronto, Ontario, Canada.

## Survey development process

Individuals working in a management position in outpatient OT and PT settings across Ontario were invited in July 2006 to participate as key informants to obtain information on the extent, management and perceptions of wait lists in communitybased rehabilitation in Ontario, and to inform the development of the questionnaire used in the survey. A purposive, snowball sample of healthcare providers involved in community-based rehabilitation were invited to participate as key informants in this study. The purpose of the sampling was to ensure that key informants represented a range of community-based rehabilitation settings, geographic settings and health professions. Key informants were identified by the researchers as known experts or those who were in a position to discuss current issues surrounding wait times and wait lists in community-based rehabilitation. These individuals were identified through existing and emerging contacts with professional associations, rehabilitation academics and service delivery organizations. A semi-structured interview guide was developed for the key informant interviews based on review of recent national and international peer-reviewed and grey literature on the topic of waiting times and rehabilitation. Questions regarding wait time and wait list measurement, management of wait lists and perceptions of the impact of community-based rehabilitation wait times and wait lists on the healthcare system were posed to key informants. Data were collected during the key informant interviews using written field notes and audiotape. Audiotapes were not transcribed but were used as a supplement to field notes when the interviews were summarized.

A questionnaire was developed based on the results of the key informant interviews. The key informants reviewed the survey and made important suggestions regarding the clarity, scope and feasibility of completing the questionnaire. This process served to strengthen the questionnaire's face and content validity, clarity, relevance and format. Among the more important findings gained from the key informants was that wait times and wait lists are generally not an important issue among settings that deliver privately funded rehabilitation services. For instance, a private for-profit clinic that delivers rehabilitation services funded through private sources (e.g., out-of-pocket, third-party insurance) and quasi-public sources (e.g., workers' compensation insurance, motor vehicle accident insurance) generally do not have wait lists or long wait times to access services. As a result, we did not sample private for-profit clinics or other privately owned settings that access private funding for service delivery in this survey; rather, we sampled not-for-profit settings that deliver publicly funded services.

We acknowledge that restricting our sample limits the generalizability of our analysis; on the other hand, it did allow us to explore these issues with a relatively homogenous cohort. Nevertheless, we chose to include designated physiotherapy centres (DPCs), formerly known as schedule 5 clinics, in the study sample because, although they are privately owned and operate on a for-profit basis, they invoice the Ontario Hospital Insurance Plan (OHIP) for services on a fee-for-service basis, which

qualifies them as delivering publicly funded services. DPCs provide publicly funded community-based PT services, and there are no equivalent structures for OT in the province of Ontario.

## Sampling

In this study, community rehabilitation managers, professional practice leaders or senior therapists of all (N=374) publicly funded outpatient and community sites that provide OT and/or PT services to adults (age 19 years and older) in Ontario were surveyed using a self-administered mailed questionnaire. This included hospital outpatient departments (OPDs); community health centres (CHCs); community care access centres (CCACs); the Arthritis Society Rehabilitation and Education Program (AREP); and designated physiotherapy clinics (DPCs).¹ Community rehabilitation services provided through mental health institutes or institutes that provide rehabilitation to children and adolescents, as well as specialty ambulatory programs (such as amputee programs or hand clinics), were excluded.

Identification of all the sites and key contact persons who provide publicly funded outpatient and community OT and PT services in Ontario was obtained from the following sources: the Ontario Ministry of Health and Long-Term Care website (for DPCs, n=93); the Ontario Hospital Association website (for Hospital OPDs, n=208); the Ontario Association of Community Care Access Centres (for CCACs, n=42); the College of Occupational Therapists of Ontario; the College of Physiotherapists of Ontario (for OTs and PTs working in CHCs, n=10); and the Senior Director of Client Programs, AREP (for regional directors of client services and individual therapists, n=21). Where necessary, organizations were contacted directly by telephone to identify the most appropriate person in the organization to receive the questionnaire. A key contact was identified for each setting for PT services and for OT services. If there was one contact for both PT and OT services, this individual served as the single key contact for the setting.

Potential participants were mailed an information letter, a questionnaire and a prepaid return envelope on November 14, 2005. Three weeks after the initial mailing, all non-respondents were mailed a second information letter, a questionnaire and a prepaid return envelope. The final cut-off date for returned questionnaires was January 12, 2006. Return of a completed questionnaire implied informed consent. The data from the questionnaires were entered into a database management system (Access for Windows 2000). Double data entry was undertaken to ensure data quality.

## Key study variables/measures

SETTINGS

Settings included hospital outpatient departments; community health centres (CHCs); community care access centres (CCACs); the Arthritis Society Rehabilitation and Education Program (AREP); and designated physiotherapy clinics (DPCs) that provided either community outpatient occupational therapy, physiotherapy or both.

#### GEOGRAPHIC REGION

Outpatient and community OT and PT settings were defined as urban or rural using Canada Post's most basic definition as indicated by the second digit of the respondent's postal code. The number "0" indicates a rural location, and the numbers "1" through "9" indicate an urban location.

#### WAIT LIST MANAGEMENT STRATEGIES

A list of 14 management strategies was provided (based on the results of a literature review and the key informant interviews). These included: use a centralized wait list (a single wait list for all patients within a setting or with other OT/PT facilities or institutions); hire more staff; allow clients with episodic needs to re-enter rehabilitation without having to re-enter the system at the point of screening/referral; accept only in-house referrals (i.e., a specific clinical setting does not accept community referrals); provide education to clients regarding self-management; ensure strict enforcement of attendance policies; use group intervention rehabilitation for patients with similar conditions; use an "ad hoc" appointment to start the patient on a simple home program while the patient awaits assessment; use rehabilitation assistants to offset intervention time; use evidence-based benchmarks for wait list management; use guaranteed maximum waiting times; audit routine wait lists to determine whether clients awaiting assessment continue to require rehabilitation services; refer wait-listed clients to other clinics or facilities; use a computerized wait list to track referrals and wait times. Respondents were asked which wait list management strategies they have used in the past, currently used or never used. They were also asked to rate the perceived effectiveness of strategies they used to manage wait lists.

#### METHODS TO PRIORITIZE WAIT LISTS

A list of 10 ways of prioritizing wait lists was provided. Respondents were asked which methods they had ever used and which they used most frequently.

#### EFFECTIVENESS OF MANAGEMENT STRATEGIES

The choices were very effective, somewhat effective and not at all effective.

#### Data analysis

Descriptive statistics were used to describe the study sample, to summarize results from the study questionnaires and to address the study objectives. SAS Version 9.1 was used for all analyses. Open-ended response items from the questionnaire were entered into N6/NVivo, coded and analyzed in order to explore the key informants' beliefs and interpretations of the status of their wait list management. The qualitative analysis allowed for a rich description of the issues being explored, and permitted some degree of interpretation of the quantitative data.

### Results

The overall response rate to the survey was 57.2%, or 214 out of a possible 374 responses. As indicated in Table 1, the response rates according to each setting were as follows: CCAC (45.2%), CHC (70.0%), OPD (58.7%), DPC (50.5%) and AREP (90.5%).

The majority of the respondent settings were located in urban locations. The proportion of settings reporting that they have a wait list varied. Thirty-six per cent of DPCs reported having a wait list, whereas more than 85% of OPDs and AREP reported having a wait list for OT outpatient services, PT outpatient services or both.

## Approaches used to prioritize wait lists

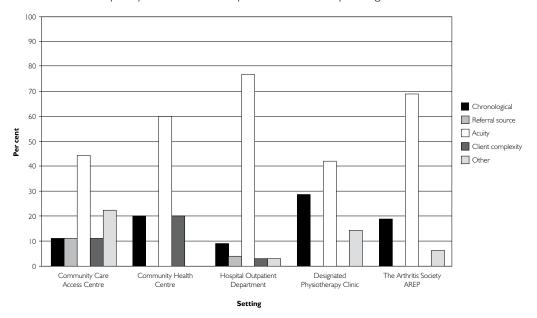
Respondents across all settings described the challenges they face when dealing with long wait lists. For instance, as one respondent from a hospital outpatient department (OPD) reported, "You do the best you can with the ever-decreasing resources, giving some attention to those that have greater potential for rehabilitation. The rest either wait or get nothing." The primary way in which to prioritize clients was by acuity, and was reported across all settings (see Figure 1). In other words, clients who presented with greater acuity were ranked as a higher priority for ambulatory rehabilitation services across Ontario. Respondents indicated that chronic conditions have the lowest priority; according to one professional in a community setting, "We will put re-referrals for the same person and the same condition, especially if it is a chronic condition and physio didn't help the first time, at the bottom of the wait list." The other common strategies to prioritize wait lists included chronology, referral source, client complexity and other. There was wide variation in the proportion of different methods used by each setting. For example, CCACs used a number of different prioritization methods, whereas DPCs used primarily acuity and chronological prioritization methods.

TABLE 1. Description of sample by setting

Characteristic	Setting				
	Community Care Access Centres n (%)	Community Health Centres n (%)	Hospital Outpatient Departments n (%)	Designated Physiotherapy Clinics n (%)	The Arthritis Society Rehabilitation and Education Program n (%)
OT services only	0	2 (28.6)	18 (14.8)	n/a	4 (21.1)
PT services only	0	5 (71.4)	75 (61.5)	47 (100)	10 (52.6)
OT and PT services	19 (100)	0	29 (23.8)	n/a	5 (29.3)
Urban setting	19 (100*)	7 (100)	85 (69.7)	47 (100)	19 (100*)
Report having a waiting list for OT or PT outpatient services	9 (47.4)	5 (71.4)	108 (87.8)	17 (36.2)	18 (94.7)

OT = occupational therapy; PT = physiotherapy; n/a = not applicable

FIGURE 1. Most frequently used methods to prioritize wait lists by setting



## Wait list management strategies

The most common methods used to manage wait lists are presented in Figure 2. Self-management methods (e.g., education pamphlets, generalized exercise) (85%) were the

<sup>\*</sup> Although community care access centres and the Arthritis Society Rehabilitation and Education Program centres are all located in urban settings, services offered by these settings can extend to rural communities.

most commonly used, followed by attendance policies (69.5%), regular wait list audits (67.3%) and referral to other clinics (67.0%). The least common methods to manage wait lists included the use of a computerized wait list management system (14.8%), guaranteed maximum wait times (14.5%) and centralized wait lists (10.1%).

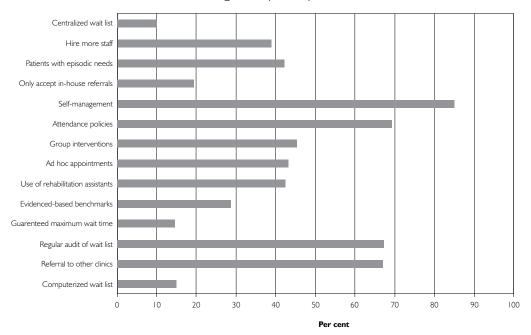


FIGURE 2. Methods used for wait list management (n=214)

The most common wait list management strategies used by hospital OPDs included prioritizing wait lists by acuity or referral source, encouraging clients to utilize other community-based services and educating referral sources. Many hospital OPDs described putting clients with chronic musculoskeletal conditions at the bottom of the list. As one respondent reported, "We have closed our wait list and no longer accept chronic referrals (only acute referrals and specialty programs accepted)."

Encouraging patients to utilize other rehabilitation services by providing information about other PT clinics is one strategy that is often used, but it is limited in effectiveness owing either to the lack of other publicly funded options or to clients' inability to pay because of lack of private insurance. This situation arose particularly in rural and remote areas. As one rural hospital OPD stated, "Geographically, we are quite isolated. For much of our clientele, a private clinic would be over 50 kilometres away ... so we're it." One respondent concluded, "Many patients are denied treatment as a result [because] they cannot afford private." The partial delisting of designated physiotherapy clinics has also limited the options available. "We used to refer patients to [DPCs] ...

but this is very limited now due to changes in Ministry of Health guidelines."

Hospital OPDs are in a relatively unique position in that they do not receive their funding directly from OMHLTC; rather, their funding comes through their hospital's global budget. As a result, they are more limited than other settings in their ability to utilize various wait list management strategies. Whereas a DPC has the option to hire more staff to meet wait list demands, a hospital OPD must compete with other services within the hospital for funding. As one respondent stated, "We continue to put in increased staffing requests but have been restricted by the hospital budget." Another said, "We have discontinued seeing or accepting referrals for chronic musculoskeletal disorders since we can't see them in a timely manner anyway. We don't have the ability to hire more staff. Our priority is to support post-total joint replacements and acute orthopaedic injuries (within 6 weeks)."

Further, some respondents reported that in response to the need to balance budgets, many hospitals are considering reducing outpatient rehabilitation services in order to save money. In some of these situations, the hospital OPD represents the only publicly funded outpatient rehabilitation service in the region (often rural or remote), leaving huge issues of access to community-based rehabilitation for Ontario residents living in these areas.

The survey also asked respondents to rank the perceived effectiveness of their wait list management strategies (Figure 3). Based on self-reports, self-management, attendance policies, regular wait list audits and referrals to other clinics were identified as the most commonly used management methods; however, these were not the methods identified as most effective. Over half of respondents (54.2%) reported that self-management is an effective wait list management strategy, whereas only about a third (36.3%) found attendance policies to be effective. Not surprisingly, hiring more staff was seen as the most effective method (71.2%), followed by the use of evidence-based benchmarks (65.4%), accepting only in-house referrals (64.5%) and using rehabilitation assistants (64.0%).

## Discussion

Acuity of condition is the primary way in which publicly funded rehabilitation settings prioritize clients on wait lists in the province of Ontario. However, it is unknown whether this method, or other methods, is effective in prioritizing wait lists in rehabilitation settings. A study examining the accuracy of referral priorities for OT within the United Kingdom indicated that 56% of low-priority cases were inappropriately prioritized, with a tendency to underestimate an accurate level of priority (Wright and Ritson 2001). While many agree that patients should be prioritized on a wait list based on need, and that this prioritization should be based on the best possible evidence (OMHLTC 2004; Wait Time Alliance 2005; Shortt and Shaw 2003; Sanmartin et

al. 2000; Elwyn et al. 1996; DeCoster 2002; Meiland et al. 2002; Western Canadian Waiting List Project 2001), few organizations implement evidence-based practice for prioritization within rehabilitation settings (GTA Rehab Network 2003).

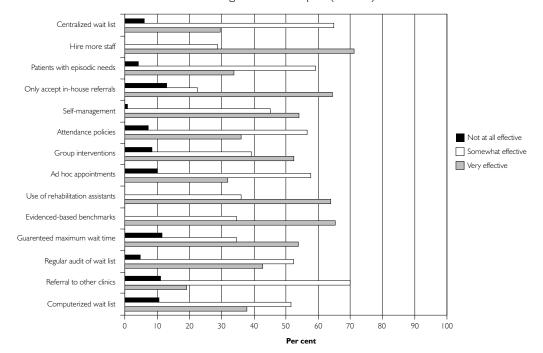


FIGURE 3. Perceived effectiveness of management techniques (n=214)

In terms of managing wait lists, the use of centralized wait list management systems was not a common approach. The literature suggests, however, that the use of a central referral system allows patients to be triaged to the appropriate service, ensuring that there is no duplication of referrals and that appropriate referrals are received and managed through a systematic process (Maddison et al. 2004). Centralized systems facilitate wait list management by redirecting referrals to clinicians with shorter waiting times (OMHLTC 2004; Sanmartin et al. 2000). In the United Kingdom, the use of centralized systems reduced wait times for PT from 16 to four weeks and decreased non-attendance rates from 18% to 2% (Pattinson 2003). The Auditor General of Ontario (2004) has recommended the establishment of consistent policies for maintaining centralized wait lists for community rehabilitation services in lieu of the common practice of maintaining separate lists by individual service providers.

An essential component of the centralized wait list management strategy is the need to perform regular audits to ensure that patients are listed appropriately (Romanow 2002; Sanmartin et al. 2000; Elwyn et al. 1996; Sullivan and Baranek 2002). Wait lists may be inflated by 20% to 30% owing to a change in condition, the patient's death or move from the jurisdiction, change of mind regarding the procedure, or resolution of symptoms (McDonald et al. 1998). Despite these evidence-based findings, very few respondents reported using this management strategy. Further inquiry into why this approach is seldom used for community and outpatient OT and PT wait list management would be beneficial.

Despite findings in the literature suggesting specific strategies for wait list management, few settings employed evidence-based strategies, as indicated above. A recent review examining the determinants of wait time management suggests that culture, human resources and information management tools are important factors for successful wait time management (Pomey et al. 2008). In their work, Pomey and colleagues used a mixed-methods approach to report that wait list management appears not to have been a linear process across Canada; rather, there are a multitude of interacting complex factors. In order to improve wait list management approaches, these authors suggested a series of factors, raging from increased physician involvement to targeted funds. Given the few empirical studies in this particular area, future health services research may be warranted to examine the impact (or lack thereof) of such factors on wait list management strategies used in community rehabilitation settings.

The results presented in our study add to the growing body of evidence indicating that the various management methods used by outpatient physiotherapy clinics do not necessarily help to ameliorate the barriers to access to community physiotherapy services for persons with chronic disease. As found in the study by Passalent and colleagues (2009), people with chronic disease make up the largest proportion of those waiting for physiotherapy services, and this situation is compounded by management strategies that further disadvantage this patient population, such as prioritization based on acuity, that were found in all the settings we surveyed. This finding highlights the issue of potential complications, such as prolonged dependency on social benefits and indirect societal costs that may arise from the inability of patients with chronic conditions to seek service. For instance, persons with chronic diseases such as arthritis and stroke contribute the most to the burden of disease in Canada (Health Canada 2003; Perruccio et al. 2004; BC Ministry of Health 2004), and the projected rates of chronic diseases by the year 2028 (for those aged 65 and older) will constitute 20.3% of Ontario's population (Ontario Ministry of Finance 2002). The evidence that the presence of chronic conditions in older persons can lead to progressive disability signals the need to assess policies affecting access to community rehabilitation services. Another potential complication could be the costly hospitalizations that might ensue if chronic conditions are not well managed at the earlier pathogenesis. For instance, other research has suggested that poor access results in poor self-reported health status (Landry et al. 2007), and other literature has reported that a higher utilization of costly hospital and physician services occurs when individuals self-report

poor health status (Alarcon et al. 2004; Borglin et al. 2005; Frankenberg and Jones 2004; Kind et al. 2005; Lindquist and Lindquist 1999; Nelson et al. 2001; Nord et al. 2005; Reijneveld 2000; Reijneveld and Stronks 2001). Although empirical research is required to substantiate such hypotheses, it stands to reason that long wait times could drive overall healthcare costs, especially in light of the growing proportion of people reporting chronic disease.

#### Limitations

There are limitations to this study that affect the degree to which our data and analysis can be generalized to other settings. First, the exclusion of specialty ambulatory rehabilitation services (e.g., amputee programs and hand clinics), where PTs and OTs are employed, may underrepresent the methods used to manage wait lists in community OT and PT settings. Furthermore, this study examined wait lists and wait times only for adult rehabilitation, excluding paediatric settings, a factor that may also contribute to an underestimation of wait list management utilization. Second, although there was an acceptable response rate (57.2%) to the survey, there remains a potential for response bias. For instance, it is unclear whether the non-responders did not participate in the survey because they did not have a wait list and were therefore not interested, or alternatively, whether they did have wait lists but were reluctant to represent these data. Lastly, it would appear that there was underrepresentation from settings where OT services are provided at CHCs, OPDs and through the AREP program of the Arthritis Society, with less than a 30% response rate from these settings. This situation may be a result of fewer OT services being offered in community settings throughout Ontario; however, the potential for non-response bias should be considered in terms of underestimating the wait list management strategies utilized by this subgroup.

## Conclusions

The data from our survey indicate that acuity is a primary indicator for access to publicly funded ambulatory rehabilitation service in Ontario. Moreover, the results have also highlighted that the ways in which wait lists are managed are not consistent across the continuum. Collectively, these results add further evidence that a growing number of individuals with chronic disease may increasingly encounter barriers to accessing service.

These results signal a need for stewardship within the publicly funded healthcare system to ensure that all residents have equal access to community rehabilitation services, especially in light of the forecasted increase in prevalence of chronic conditions.

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#### Notes

1. Regarding DPCs, the Ontario Ministry of Health and Long-Term Care introduced strict eligibility criteria to access community-based, publicly funded physiotherapy provided in the network of DPCs across the province in 2005. Prior to this, there were no criteria and all residents were eligible for 150 visits per year. After April 2005, Ontarians were required to meet any of the following eligibility criteria: (a) under 20 years or over 64 years of age; (b) resident of a long-term care facility; (c) clients who require home PT services after hospitalization; and (d) individuals who qualify for Family Benefits, Ontario Works or the Ontario Disability Support Program (Government of Ontario 2002, last updated 2009).

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#### Further Evidence of Barriers to Access for People with Chronic Disease

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# Anthropological Approach of Adherence Factors for Antihypertensive Drugs

## Approche anthropologique des déterminatnts de l'observance dans le traitement de l'hypertension artérielle



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## Abstract

Objective: Uncontrolled high blood pressure leads clinicians to wonder about adherence degree among hypertensive patients. In this context, our study aims to describe and analyze patients' experience of antihypertensive drugs in order to shed light on the multiple social and symbolic logics, forming part of the cultural factors shaping personal medication practices.

Methods: The medical inductive and comprehensive anthropological approach implemented is based on an ethnographic survey (observations of consultations and interviews). Semi-structured interviews were conducted with 68 hypertensive patients (39 women and 29 men, between the ages of 40 and 95, of whom 52 were over 60) who had been receiving treatment for over a year.

Results: Antihypertensive drugs are reinterpreted when filtered through the cultural model of physiopathology (the body as an engine). This symbolic dimension facilitates acceptance of therapy but leads to a hierarchization of other prescribed drugs and of certain therapeutic classes (diuretics). Prescription compliance does not solely depend on the patient's perception of cardiovascular risk, but also on how the patient fully accepts the treatment and integrates it into his or her daily life; this requires identification with the product, building commitment and self-regulation of the treatment (experience, managing treatment and control of side effects, intake and treatment continuity). Following the prescription requires a relationship based on trust between the doctor and patient, which we have identified in three forms: reasoned trust, emotional trust and conceded trust.

Conclusion: Consideration and understanding of these pragmatic and symbolic issues by the treating physician should aid practitioners in carrying out their role as medical educators in the management of hypertension.

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## Résumé

Objectif: Les hypertensions artérielles non contrôlées conduisent les cliniciens à s'interroger sur les niveaux d'observance des hypertendus traités. Dans ce contexte, notre étude visait à décrire et à analyser l'expérience des hypotenseurs par les hypertendus, afin de mettre à jour les logiques plurielles, sociales et symboliques, permettant de comprendre ce qui construit culturellement les pratiques médicamenteuses des individus. Méthodes: La démarche anthropologique, inductive et compréhensive, mise en œuvre reposait sur une enquête ethnographique (observations de consultations et entretiens). Nous avons interviewé 68 hypertendus (39 femmes et 29 hommes, âgés de 40 à 95 ans, 52 d'entre eux ayant plus de 60 ans) traités depuis plus d'un an.

Résultats: Le médicament hypotenseur était réinterprété au travers du filtre des représentations populaires de la physiopathologie (corps machine). Cette dimension symbolique facilitait l'adhésion thérapeutique, mais conduisait à une hiérarchisation des autres médicaments prescrits, et de certaines classes thérapeutiques (diurétiques). Le suivi de l'ordonnance était conditionné par la perception du risque cardiovasculaire, mais également par l'appropriation du traitement et son intégration dans la vie quotidienne nécessitant une identification au produit, une fidélisation, et une autorégulation du traitement (expérimentation; maîtrise du traitement; contrôle des effets indésirables, de l'ingestion, de la continuité du traitement). Le suivi de l'ordonnance requiert une relation de confiance entre le médecin et le patient dont nous avons relevé trois formes: la confiance raisonnée, la confiance affective, la confiance concédée. Conclusion: La prise en compte et la compréhension de ces différentes logiques pragmatiques et symboliques par le médecin traitant devraient pouvoir aider les praticiens dans leur fonction d'éducation thérapeutique des personnes hypertendues.

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patients who are exempt from co-payments for severe hypertension have controlled blood pressure in 44.9% (±2.6) of cases (Tilly et al. 2004). Nevertheless, hypertension classified as "resistant to treatment" or "refractory" presents a threefold problem: clinical, owing to treatment failures; public health, because of its risks for cardiovascular complication; and economic, because of the increase in antihypertensive drug prescriptions. Confronted with refractory high blood pressure, practitioners have been encouraged to follow a clinical approach that aims to determine the cause of treatment failures, including inadequate patient adherence to therapy, the use of drugs that can neutralize the effect of antihypertensive drugs and drug-induced hypertension (ANAES 2000). Clinical studies suggest that inadequate compliance with antihypertensive treatments would be responsible for two-thirds of non-controlled hypertension (Bertholet et al. 2000; Mar and Rodriguez-Aratalejo 2001; Wuerzner et al. 2003); others show that improved drug adherence through the use of electronic pill-boxes is correlated to a decrease in blood pressure (McKenney et al. 1992).

Uncontrolled high blood pressure indirectly raises the issue of therapeutic adherence among hypertensive persons. In its broadest definition, adherence means the degree to which patients apply medical prescriptions in terms of dosage, number of daily doses, drug intake schedule, treatment duration and correlated recommendations. Adherence is quantified by a percentage demonstrating the degree or level of the patient's compliance. This quantification defines the threshold below which the treat-

ment is no longer effective or complications appear (for example, pharmacoresistance). This threshold has not been the subject of any study specifically addressing antihypertensive treatments. It has been classically accepted in medical literature since the studies by Haynes and colleagues (1976) suggested that the minimum threshold for therapeutic adherence to control blood pressure is an actual intake of 80% of the prescribed drug dosage. However, this biomedical definition of an adherence threshold for antihypertensive drugs has been recognized as arbitrary, lacking sufficient basis to estimate correlations with measurements of blood pressure (Ebrahim 1998). Moreover, it does not take into account new galenic formulations (preparations providing 24-hour efficacy on a once-daily basis) or newly available molecules, nor does it specify the maximum interval between two intakes. Nevertheless, several clinical and epidemiological studies have striven to measure the level of adherence to antihypertensive drugs. However, although simple methods such as self-monitoring questionnaires seem to be as effective as the more sophisticated use of electronic pillboxes (Girerd et al. 2001), objective and rigorous assessment of therapeutic adherence remains difficult (Farmer 1999).

Despite its imprecise and arbitrary definition, the quality of adherence to antihypertensive drugs is classically, and from a biomedical perspective, considered "poor" (Girerd et al. 1998). The level of antihypertensive drug adherence varies significantly in the biomedical literature according to the characteristics of hypertensive patients. It is lower among people with follow-up in ambulatory care settings (55% in a Canadian study¹) than for patients in clinical trials who are highly motivated to adhere to their treatment (71% to 80%) or for those who are monitored in hospitals and are also highly motivated (90%) (Dunbar-Jacob et al. 1995). We do not have quantitative data on the degree of adherence to antihypertensive drugs among those French patients who are monitored by private doctors.

The level of adherence on a specific day of the treatment cannot confirm that an individual has not been adherent (Chesney et al. 2000). This construction of indicators of adherence can objectivize only one single dimension at a time in patients' behaviours towards adherence. Numerous studies have been conducted to determine explanatory factors for "good" or "poor" adherence in order to explain, predict and monitor patients' behaviours. Factors determining the level of antihypertensive drug adherence have been identified as follows<sup>2</sup>:

- Factors linked to treatment: The complexity of the treatment (the number of daily doses) and the drugs' side effects (sexual dysfunction, polyuria) in specific social situations are considered barriers to adherence (Reugel et al. 2000).
- Factors linked to the doctor-patient interaction: It has been shown that physicians' acceptance of the treatments they prescribe in other words, the balance between established medical guidelines and their own convictions is an important condition for the patient's therapeutic adherence (Myers and Midence 1998; Kjellgren

- et al. 2000). Communication between patient and doctor has also mobilized researchers' attention. Therefore, information given to patients (quantity, content, re-interpretation of this information), patients' understanding of the treatment based on the relationship of trust established with the practitioner, and the patient's satisfaction with the healthcare system are considered factors that promote adherence (Kjellgren et al. 2000).
- Factors linked to the patient: Socio-economic factors have been highlighted in studies conducted in African countries (Konin et al. 2007), where the cost of treatment for hypertensive patients, especially owing to lack of medical insurance, is the cause of inadequate adherence. Other social conditions for drug treatment seem to be determining factors in the United States, such as belonging to a medical network (frequent doctor or nurse consultations, telephone reminders) (Ebrahim 1998). In addition, a study showed that in France, patients who forget to take their treatment on the weekend or who shift their intake schedules on Saturday and Sunday are younger (and more involved in professional activities) than the average hypertensive patient and are more often Parisians (Mallion et al. 1995). Finally, some authors have described "personality profiles" in arterial hypertension as being significantly linked to the degree of adherence (Consoli and Safar 1985).

Nevertheless, social science research on adherence (and notably since the AIDS epidemic) has shown the limitations of these predictive approaches, "mechanical and simplistic hypotheses that hope to continuously and definitively predict and control the role of isolated factors on adherence behaviour" (Morin 2001). They have emphasized the complexity and variability of the relationship between social or cultural factors and the level of adherence (Chesney et al. 2000) and the need for a "dynamic approach to adherence" while "continuously monitoring the impact" that treatment has on patients' daily lives (Spire et al. 2002).

Based on the work of Conrad (1985) and from a patient-centred approach, some social scientists consider the varying levels of adherence as individual strategies that regulate the patients' day-to-day relationship with the drug and their drug consumption (Lerner 1997; Collin 1999, 2002, 2003; Haxaire 2002; Pierret 2007). They study the "medication practice" in order to understand "the meanings of medication in people's everyday lives" (Conrad 1985). In a critical approach towards the concept of compliance itself, particularly its inherently coercive nature regarding the extent of the patient's respect for the implicit order in the doctor's prescription (Lerner 1997; Fainzang 2001; Trostle 1988), some studies have preferred to position their analysis within a rationale constructed around the patient's experience of the medication (Ankri et al. 1995; Desclaux 2003; Wallach 2004). In this approach, the point is not knowing who are the "good" and "poor" adherents, but to "understand which social and cultural conditions lead to following a prescription or not" (Fainzang 2001).

Our anthropological study is part of this comprehensive perspective. It aims to describe and analyze high blood pressure patients' experience of antihypertensive drugs in order to reveal the plural social and symbolic logics that clarify how individuals' medication practices are culturally constructed.

## Methods

Our anthropological approach is based on an ethnographic survey conducted from October 2002 to April 2004 in a rural area of southeastern France. The study sample comprised hypertensive patients receiving treatment and general practitioners. This paper focuses exclusively on results related to patients; the ethnographic materials obtained through the survey of doctors have been analyzed in other publications (Sarradon-Eck 2007a,b). The survey combined semi-structured interviews of 68 persons treated for arterial hypertension and a study of the verbal exchanges between some of them (45/68) and their physicians. The distribution of the 68 interviewees according to gender (39 women and 29 men) and age (ranging from ages 40 to 95 years, with 52 of them over age 60) reproduces the prevalence of high blood pressure among gender and age groups in the French population (Duhot et al. 2002). The majority of respondents were exempt from co-payments for long-term illness (hypertension alone or associated with other diseases). All had been treated for over one year on the day of the survey. In using a comprehensive approach, we did not investigate correlations between the respondents' socio-demographic and economic characteristics<sup>3</sup> and the survey results. In the interviews, we were committed to understanding the day-to-day management of the drug-thing, its links to representations of the disease and body and the social experience of the treatment (patient status, treatment continuity and social and material constraints inherent to treatments).

Our study did not seek to assess the interviewees' adherence, even though we did question them about following their prescriptions. Aimed at understanding why and how these persons follow their medical prescriptions, our analysis is in line with an ethnology of experience, as theorized by Kleinman and Kleinman (1991) and Good (1994).

## Results and Discussion

The ethnology of the experience of hypertension and antihypertensive treatments enabled us to construct a semantic network for high blood pressure, to analyze the underlying logics that influence treatment acceptance and following prescriptions and to analyze the perceptions that individuals may have about cardiovascular risk and how to reduce this risk.

### 1. Confidence<sup>4</sup> in treatment

Confidence in treatment corresponds to the consistency between the patient's and doctor's perceptions of its value (Sow and Desclaux 2004). The concept of confidence is subjective and refers to individual and social perceptions of hypertension and hypertensive treatments. Confidence in treatment predetermines the patient's willingness to approve of the treatment.

#### SOCIAL REPRESENTATIONS OF THE BODY AND PHYSIOLOGY

Analogous and metaphorical logics contribute to ascribing the event (the illness) to instrumental causes within cultural etiological models. In the interviewees' discourses, these causal logics refer to the "blood" and "nerves" that are central to the patients' cultural representations of the body and to their models for interpreting high blood pressure. Such models are typically based on a lay conception of the body as a hydraulic engine in which the heart corresponds to the pump, the vessels to pipes and the flow to its motive force. This social representation, described by Durif-Bruckert (1994), still seems valid for the cardiovascular system in the survey population that - as previously noted – was over 40 years old (52/68 individuals over 60 years old). It provided a framework to interpret the symptoms and the mechanism causing high blood pressure in the realm of excess pressure, compression or loss of motive force. Nerves had the capacity to raise blood pressure through their action on the blood ("heating up the blood,"5 interruption of blood circulation). The physiological and metaphorical relationship between blood and nerves was close, as evidenced by the popular labelling of "nervous tension,"6 a basic folk illness model linking the nervous system to high blood pressure. In our study, as with studies from the United States (Heurtin-Roberts 1993; Wilson et al. 2002) or Sweden (Kjellgren et al. 1997), popular etiological categories for arterial hypertension placed "stress" as this disorder's number-one cause. "Stress" - in its emic meaning signifying social pressure, emotional shock or both - and hypertension were connected by a metaphorical logic in popular thought. The semantic register used to describe the body's experience was that of overflow and repressed excess. Social life or events overwhelmed the individual, who could no longer tolerate the accumulated emotions and feelings. Therefore, arterial hypertension became the metaphor for social pressure and even worrying and emotions.

As Van der Geest and Whyte (2003) have written, metaphors make it possible to think in concrete terms about the body and illness and to assign meaning to drugs. Interviewees understood antihypertensive drugs as a remedy that re-establishes an internal equilibrium and perpetuates proper functioning of the body engine. It works by ensuring the circulation of fluids and energy (the "force") while regulating pressure by fluidizing blood and cleaning the vessels, eliminating excess liquid, dilating the vessels and protecting the heart as the force that pumps blood.

The social representation of the body as a hydraulic engine that performs work is deep-seated in rural culture (Julliard 1994) as in the culture of manual labour (Pierret 1984), from which most of the survey participants come and for whom the cardiac muscle, as a "pump," was an "essential" organ. In this system of thought, arterial hypertension did not expose the heart to the risk of explosion (contrary to the blood vessels or the nervous system) but to a power failure. Nevertheless, placing importance on the heart was also intimately linked to a cultural representation of the body in Western society that assigns a symbolic dimension to the cardiac muscle (Sarradon-Eck 2007b; Durif-Bruckert 1994; Loux 1979). Whether sacred or sentimental, the heart is a propulsive force, an organ that protects humans and which should be protected specifically to the point that one interviewee described these drugs as "drugs for survival."

The mechanical and symbolic perceptions of how these drugs function can explain the way in which some hypertensive patients classify their drugs according to a hierarchy, with drugs perceived as "for the heart" taken more regularly than those perceived as being secondary (lipid-lowering agents, hypoglycaemic agents). This hierarchization also applies to diuretics, which some did not regard as a specific treatment for arterial hypertension but rather as a "supplement." In effect, the diuretic was often re-interpreted by interviewees as a "thinner," making it possible to "thin out" or "air out" the blood, and thus facilitating its circulation in the blood vessels, or even as a drug "to relieve the kidneys." In the latter case, the drug's action was considered to be supplementary, enabling the evacuation of excess liquid in the blood during episodes of increased blood pressure, as in the example of blood-letting, long associated in the popular imagination with medical thinking. Hence, diuretics were perceived as a treatment for increased pressure and not as the basic treatment for arterial hypertension; for some, this misperception has caused misuse of medication through irregular intake.

#### SOCIAL REPRESENTATIONS OF HIGH BLOOD PRESSURE: BETWEEN RISK AND DISEASE

Some of the interviewees did not see hypertension as a "disease" because of the absence of noticeable symptoms, discomfort or physical limitations. Nevertheless, two-thirds maintained it was a "disease" that should present symptoms, even if all patients did not feel them. This social representation of a symptomatic disease, also prevalent in the United States (Schoenberg and Drew 2002), has been constructed on the medical and societal discourse of the first 70 years of the 20th century. Until screening and treatment were generalized in the 1970s, only acute high blood pressure accompanied by a series of symptoms was treated. Medical advertisements for one of the first antihypertensive drugs in the middle of the 20th century portrayed middle-aged men whose faces were tortured with pain and were wracked by headaches, vertigo and profuse

sweating (Postel-Vinay and Corvol 2000). Today, medical treatises consider hypertension as an asymptomatic disorder, and active, smiling people who appear to be in good health represent hypertensive patients in medical advertisements. However, traces of hypertension's "loud" period remain fixed in memories and popular knowledge, all the more so since our informers were older and had witnessed severe cases of symptomatic, though untreated, hypertension during their youth. Moreover, high blood pressure also had an image as a "silent disease" and "sneaky," similar to its reputation as the "silent killer" perpetuated in the 1950s (Postel-Vinay and Corvol 2000) and dreaded because of its cardiovascular complications familiar to most of the interviewees.

The collected data show that the perception of cardiovascular risk for hypertensive patients has been constructed mainly on personal experience regarding complications due to hypertension and affective trauma caused by repercussions or deaths suffered in their close circle. Such objectification of the risk contributes to confidence in treatment and promotes adherence to antihypertensive medications. Hypertensive patients mainly fear strokes with their consequences for mobility, cognition and social interaction. They are less afraid of the myocardial infarction still associated in the collective unconscious with the "beautiful death," previously shown in the study by Aïach (1980). Individuals were primarily afraid of a failure of the body, a disqualification that prevents them from fully playing their present roles in society and assigning them a new role as someone who is sick or disabled.

When facing risk, our interviewees' attitudes ranged from denial of the risk to controlling it; these attitudes are based on individual, cultural or social factors. Therefore, the absence of noticeable physical symptoms can be an obstacle to treatment, with some "forgetting" to take their drugs or refusing to take them because they do not feel "sick." For others, despite the lack of symptoms, the fear of death and complications from arterial hypertension increased with age and awareness of the human body's fragility. This perception of the aging body's vulnerability eliminated the ordeal-like dimension of risk taking (Le Breton 1996), allowing the individual to exercise free will when choosing to take his or her drugs regularly. For still others, high blood pressure was a common and frequent illness starting at a certain age, a disorder that is practically normal since it affects a large percentage of the population and signifies the body's natural decline. "Having high pressure" equated with "being like everyone else." Consequently, individuals did not feel they belonged to a "risk group," which was reassuring to those who felt excluded (Paicheler 1998).

## 2. Self-regulation of treatment

EXPERIMENTING WITH TREATMENT AND CONTROLLING SIDE EFFECTS

As described in other chronic diseases (Conrad 1985; Collin 2002, 2003; Haxaire 2002; Pierret 2007), the occasional or prolonged failure to take drugs, whether acci-

dental or voluntary, allowed high blood pressure patients to experiment with the effects on the body of treatment interruption and thus to gain knowledge about the disease. Several interviewees stated that they did not take the drug on certain days in order to limit the adverse effects with consequences on family and social life (effects on sexuality, incapacitating effects of diuretics linked to increased urination, fatigue affecting the quality of life). Most of the interviewed hypertensive patients were avid readers of drug leaflets, which they primarily perused looking for adverse effects, to prepare for or possibly prevent them. As the primary (and sometimes only) source of information on the interviewees' drugs, the drug leaflet gave the patient an active role in managing his or her treatment and contributed to building commitment to the drugs. It allowed individuals to connect their own experience with the drugs to biomedical knowledge. Obtaining a device to self-monitor blood pressure also fulfills this need for knowledge about one's own body and disease. The patients used it to verify the reality of high blood pressure, to test their assumptions on the causal links between the symptoms they felt and their blood pressure values and to find factors that cause a rise in blood pressure. Knowledge obtained through information, experience and experimentation also led to lay control of hypertension as a cardiovascular risk factor.

#### ENSURING TREATMENT CONTINUITY

Analysis of the ethnographic data also revealed personal strategies for adjusting treatment to avoid accidents in adherence or running out of drugs packaged in boxes of 28 tablets. In effect, patients – and doctors8 – perceived the prescription's temporality through a cultural schema that defines a month as 30 or 31 days and not four weeks. Packaging drugs in 28-tablet boxes was thus seen as a constraint imposed on the individual who must manage his or her behaviour according to a definition of "time" that had ceased to correspond to society; instead, "time" was based on a social institution with rules that are not understood and that the individuals judged as "ridiculous" or "stupid." We collected many accounts of incomprehension and, particularly, declarations of treatment interruptions of two to three days per month. Some patients had no tablets at the end of the treatment. Others, anticipating the end of the "month" of treatment suspended their treatment one or two days per month ("Me, I have my trick; I don't take any the 15th ... and the 30th," woman, age 70 years, employed). How drugs are packaged leads to other practices that involve some "tinkering" and the complicity of patients' family circle and health professionals; these include pharmacists delivering a treatment without a prescription, doctors doubling dosages and patients stocking up on reserve boxes of drugs.

In addition, the fact that hypertension requires a long-term prescription (often for an entire lifetime) and that it causes neither discomfort nor disability has led to tem-

porary treatment interruptions among some patients. For others, the lack of symptoms made the consultation for prescription renewal more constraining. The constraint was perceived as all the greater for professionally active patients who faced a significant social cost. Consequently, those who felt negatively about how the healthcare system worked (follow-up consultations and required monthly trips to the pharmacy to pick up drugs) sometimes interrupted their treatment voluntarily (temporarily or over time). This institutional determinant could be alleviated by recent measures authorizing pharmacists to deliver the quantity of drugs needed for three months of treatment.

## 3. Accepting "individualized" treatment

DRUG LOYALTY

Several respondents expressed the confidence they have in "their" hypertensive drugs; they describe having evaluated their efficacy, often after many "trials," and state that they "tolerated" them relatively well and are accustomed to taking them. Those interviewed were quite insistent about the complexity of their treatment and "trial and error" by doctors to find "the correct treatment" that was compatible with them. Respondents often mentioned the idea of compatibility between the drug and the individual to explain therapeutic success. Both the observed doctors and patients regarded the effectiveness of antihypertensive drugs as the compatibility between an individual and a product and not the appropriate therapeutic action for a particular dysfunction. Consequently, a kind of treatment personalization ("my drugs") has occurred, explaining patients' reluctance to change brand-name drugs for generics (Sarradon-Eck et al. 2007). Such change disrupts the process of brand loyalty, built up over time, to the drug. Moreover, this substitution rarely involves just one generic drug that remains constant, but different generic brands based on the pharmacy's supply, creating a lack of reference points (name, colour and shape of tablets) for patients. It compromises the product identification process for building a strong connection between the drug and the individual who takes it.

#### INTEGRATING TREATMENT INTO DAILY LIFE

Loyalty to a drug has also been found in ordinary practices among people who have integrated drug intake into their daily activities, favouring the perpetuation of drug use already described for long-term treatments (Fainzang 2001; Sow and Desclaux 2004; Pierret 2007). This translates into an intake routinization, often organized around meals. Antihypertensive drugs were usually stored, or at least taken, in the kitchen<sup>10</sup> to ensure their visibility; they were kept in salvaged everyday objects converted from their original function.<sup>11</sup> Storage space in the kitchen fulfills a practical logic (not forgetting

to take the drug and being able to take it with liquid), but also a logic to integrate the drug as an ordinary thing. According to Fainzang (2003), places where medicines are kept correspond to various modes of perception of these drug-things and the importance attached to them. Keeping drugs in the kitchen, "the main social space," reflects the drugs' position in the patients' lives. Along with ingesting them at mealtime, it underlines the close relationship between food and drugs, also attesting to the patients' acceptance of treatment and confidence in a therapy that is necessary for their survival, similar to the need to eat food several times a day.

How drugs are stored and ingested and the multiple tricks used to avoid forgetting them convey the individuals' pragmatism. Moreover, it also reveals their creativity in the use and ultimate appropriation phase of a good (such as drugs) that has been imposed on them. In effect, the survey demonstrated the "tactics" used by hypertensive patients and "the ways to deal with medication" (paraphrasing De Certeau 1998) to re-use it in their own way and not by following the dictated medical rationale. One of these tactics was skipping hypertension treatment during the weekends. Often described in biomedical literature as a "drug holiday" (Urquhart 1997), clinicians considered this practice "neglect" that can cause overdoses and even rebound effects with serious clinical consequences (Burnier et al. 1997). And yet, our study showed that what we have termed a "therapeutic break" was not due to "neglect," but to a deliberate choice by the hypertensive patient that corresponds to the need to temporarily efface the disease: "Every other Sunday, I don't take them voluntarily [...] Just like that. I don't know why but often voluntarily on Sunday, I don't take them. It's not forgetting. It's a day of complete rest! Is it to rest my stomach? I have no idea. Even so, I take my treatment very regularly, every morning after breakfast" (man, operator, age 54).

Therefore, we can hypothesize that the therapeutic break perpetuates the use of the drug – and possibly strengthens long-term adherence – because it is a transitory break in the daily repetition of activities, making it possible to tolerate the monotony of the routine.

## 4. The doctor-patient relationship

THE MODEL "GOOD PATIENT"

Patients mentioned instances of voluntarily skipping or involuntarily forgetting to take a tablet in a roundabout way ("maybe one or two times a month," the morning one or the evening one") and did not consider them as infringing on medical prescriptions. They did not define adherence in terms of a threshold or doses of ingested drugs. The term adherence never appeared anywhere in their comments. They used the expression "being serious" or "being careful" to describe their drug-intake practices and how they followed a prescription. These locutions alternately designated watching their diet, avoiding alcohol and tobacco, regularly taking their drugs, maintaining regular follow-up consulta-

tions and following medical advice. Individuals also used the expression "taking care of myself" to signify simultaneously what they consider to be satisfactory compliance with the medical prescription, their acceptance of the biomedical system and the idea of promoting health through behaviours that, in their view, conformed to medical standards. These locutions are evidence of a behavioural model of the "good patient" that patients believed they should adopt if they wanted to maintain the image of the ideal patient expected by doctors; conversely, when they wanted to tell us that they did not follow medical directives exactly, they felt this reflected the image of the "bad patient."

Consequently, doctors' suspicion about inadequate drug compliance for uncontrolled hypertension was poorly accepted by patients because it attests to the doctor's lack of confidence in them. Indeed, the hypertensive patient's narratives revealed that following a prescription referred to an asymmetric doctor—patient relationship marked by submission to medical decision-making and obedience to the doctor, the holder of knowledge. Moreover, the coercive connotation of the French word *ordonnance*<sup>12</sup> (prescription) was fully perceived by the patients, as demonstrated by this extract from an interview with a person who stated having had repeated temporary treatment interruptions: "Now, I've gotten everything back in order. I go for my appointment when ordered and all that" (man, age 66, farmer).

Nevertheless, obedience does not exclude negotiation, and several hypertensive patients described situations in which they negotiated decisions (about seeking a specialist or the prescribed drug) by sometimes imposing their viewpoint on the doctor. The patients also expressed dissatisfaction concerning the lack of information provided by doctors on the drugs' mode of action or their adverse effects. They ascribed this insufficient information to the doctor's unavailability. However, by excusing the doctors, they disregarded other factors such as the social distance, directivity or paternalism associated with practitioners in the doctor–patient interaction that are often objectified by the social sciences (Fainzang 2006).

#### THE VARIOUS FORMS OF TRUST

According to the hypertensive patients<sup>13</sup> and doctors who were interviewed, submission to medical authority could not exist outside a "relationship of trust" that, for them, defines the doctor–patient relationship. The sociology of trust (Giddens 1990; Watier 2002) has shown the fundamental role that trust plays in structuring social relationships. Although there exist negative feelings among patients and practitioners, as well as areas of mistrust, the trust relationship is a cultural schema that codifies each partner's behaviour in the doctor–patient relationship and allows them to interpret conduct. Collected narratives from the patients explicitly or implicitly described an idealized relationship that most recognize or aspire to recognize, in which trust simultaneously results from an interpersonal relationship and the sine qua non condition of

confidence in and adherence to treatment.

Based on narratives from hypertensive patients, the idea of trust was a complex and polysemous notion. Our analyses found several forms of trust. Reasoned trust concerns the practitioner's professional competence, mentioned by patients who were attentive to their doctor's knowledge, professional experience and scientific rigour. However, it goes beyond this, and the analysis showed another dimension that we have termed emotional trust. In effect, the interviews have described the ideal general practitioner<sup>14</sup> as an attentive and conscientious expert, who is also available, knows how to listen, is financially disinterested and has humane qualities such as "kindness" or "sympathy." This conception of the role and characteristics of the treating physician corresponds to a social representation of the "family doctor" found in our ethnographic results. The general practitioner was first and foremost the doctor for "the whole family," treating people at all stages of life. This doctor was so close to patients that he or she was sometimes perceived as a family member or friend. Therefore, the relationship with the doctor was a personalized and long-lasting relationship that resulted in gaining greater, enduring mutual trust.

In the doctor-patient interaction – whether it corresponds to the paternalistic model or the shared decision-making model – drugs participate in symbolic exchanges. Indeed, as Van der Geest and Whyte (2003) write, "they facilitate, shape and strengthen social relationships because they express and confirm friendship, devotion and concern, particularly in interactions between the doctor and his/her patient." Through the prescription, the practitioner transfers the power to heal to the patient, while symbolizing the patient–doctor relationship through the drug (Collin 2002; Van der Geest and Whyte 2003).

Nevertheless, adherence can be considered a form of symbolic gratification objectifying the trust granted to the doctor as well as submission to medical authority based on medical expertise. We have termed this third dimension of trust conceded trust. Here, a high level of adherence was also conceded by the patient based on medical expertise and the doctor's professional responsibility, as highlighted by Collin (2003). In effect, some hypertensive patients have underscored that they had no other choice than to trust the practitioner.

## Conclusion

Following long-term treatment is a complex process that combines the patient's acceptance of a drug with its integration into daily life, identification and personalization of the drug as well as loyalty to it; additionally, it integrates loyalty to the doctor. It objectifies the patient's level of trust towards the doctor and recognition of his or her role as expert and as family physician. However, it also involves factors that are external to the patient, the drug and the therapeutic relationship as well as involving the drug's

symbolic dimensions. The hypertensive patient self-regulates his or her medication from day to day. This regulation corresponds to logics of experimentation, controlling health risks, controlling the body and treatment, controlling side effects, controlling ingestion, limiting constraints imposed by the prescription (renewing the prescription), ensuring treatment continuity (drug packaging), managing social integration, developing drug-taking habits and routinization.

Consideration and understanding of these pragmatic and symbolic issues by the treating physician should aid practitioners in carrying out their role as medical educators in the management of hypertension.

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#### NOTES

- <sup>1</sup> Overall, 22% took less than 50% of the treatment, 23% between 50% and 80% of the treatment and 55% took more than 80% of the treatment (Unger 1995).
- <sup>2</sup> To avoid overloading this paper and its bibliography, we have limited the list to compliance with antihypertensive drug prescriptions. However, similar studies in other chronic pathologies show the same categories of factors, with the addition of institutional factors (constraints on patient linked to follow-up, such as consultation schedules, the patient's travel distance to the institution, travel costs, etc.) particularly determinant in low-income countries (see, in particular, Moatti et al. 2004).
- <sup>3</sup> The majority of respondents were inactive (retired or on disability). Socio-professional categories included farmers (9%); artisans, retailers, business owners (16%); management and highly educated professionals (9%); intermediate professionals (7%); employees (50%); and labourers (9%). The population's education level was predominantly low: 79% had a degree lower than the baccalaureate (the French equivalent to a high school diploma), including 12% without any degree. Some 12% had achieved a level equivalent to the baccalaureate, and 9% had a degree higher than the baccalaureate.
- <sup>4</sup> Adhésion in French.
- <sup>5</sup> Excerpts from the interviewees' narratives are transcribed in italics.
- <sup>6</sup> Tension nerveuse in French.
- <sup>7</sup> This refers to diuretics prescribed specifically as antihypertensive drugs.
- <sup>8</sup> Only one doctor in our study summons his patients every 28 days (or a multiple of 28 days); the

others set appointments every "month" (or a multiple of "months").

- <sup>9</sup> The timeframe of 28 days for the drugs suggests the lunar calendar, and implicitly the menstrual cycle, as suggested by one hypertensive patient's ironic remark: "There are boxes of 10 and boxes of 15. As for me, I don't have any boxes of 28; that's for women!" (man, age 73 years, employed)
- <sup>10</sup> Unlike the rest of the family's pharmaceuticals that are stored in another part of the home (bathroom, bedroom).
- We were able to observe that antihypertensive drugs, similar to drugs that are taken daily for other chronic illnesses, are stored in empty detergent boxes, small wicker baskets, plastic food containers, plastic bags and old drug containers large enough to be used as a "daily pharmacy."
- <sup>12</sup> The primary meaning of the French word *ordonnance* is "order" in the legal sense. *Ordonnance* means the promulgation of decisions that are related to a law. Another meaning is "to put in order."
- <sup>13</sup> Some 41/68 expressed thoughts on this subject (24/39 women and 17/39 men). Their narratives are quite homogeneous. At the start of the study, we thought that this homogeneity could result from a selection bias for those interviewees met through their treating physician (n=43), who more or less consciously select which hypertensive patients to interview. Hence, we conducted other interviews with hypertensive patients (n=25) recruited through a "chain referral" method without the intermediary of the doctor. In this second group, we actually collected more negative narratives towards doctors, but these implicitly show an ideal relationship based on trust.
- <sup>14</sup> Conversely, patients' narratives about trust designate the characteristics of the "bad doctor": negligence, lack of availability, intrusion in private life, lack of altruism and engaging in a business relationship.
- <sup>15</sup> This representation of the treating doctor as the "family doctor" is deep-seated in our survey, which was conducted in a rural or semi-rural area (where the general practitioner is also called the "country doctor") among an older population that is accustomed to regular doctor visits, but the representation cannot be generalized to the entire French population. Unlike Anglophone cultures, the term "family doctor" does not pervade established categories for physicians in the French healthcare system and reflects popular labelling.

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