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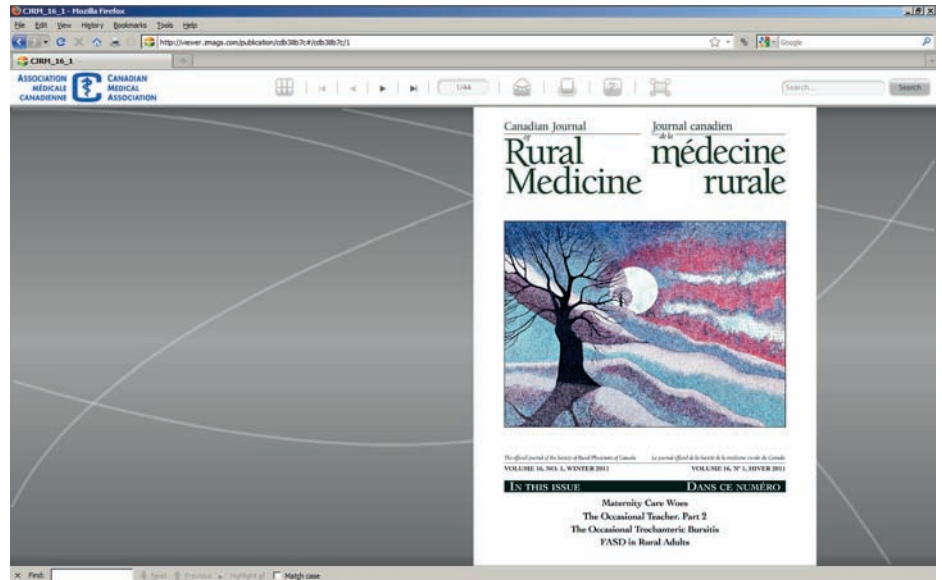
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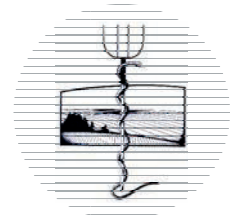


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## A legacy

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**W**ith this issue we complete the 15th year of *CJRM*. We have gone from a statement, a hope and words of encouragement, to an authoritative, perhaps even respected, voice of rural medicine. In effect, despite some skepticism among the old guard (as, alas, I would define myself), we have arrived.

If you are not sure, then look around a bit. I have heard new grads reference “the occasional series” and the journal as if it has always been there — an institution. There are now repeat authors publishing their fifth or sixth paper in our pages (and if you are a rural author, you know that after you have been published once, this editor does not hold your hand anymore). The journal is indexed by both Index Medicus and Google Scholar.

Still, it’s a little lonely out here, breaking trail as the first journal of rural medicine. There are a few other journals that are rural, and others that are not rural but have content that is relevant to rural medicine, or close to relevant, but they’re not considered mainstream. *CJRM* needs rural content to continue to make a difference.

For example, I need a manuscript about outcomes when you close a rural emergency department. We know what happens when you close an obstetrics department, but what happens when you close the ER? There are not enough data to help determine when such service reductions are reasonable to reduce human resources demands, and when they will worsen outcomes because sick people will not get or seek care, or will not get it in a timely fashion (regardless of the quality of the remaining distant facility).

We need that content to guide and sustain the art. Send me a procedural article. You know the format by now:

not so many words, a bunch of pictures and no more than 5 references, unless you want your obsessive tendencies questioned. There are a number of topics in The Practitioner “occasional” series that I would particularly like to see cross the desk:

- sedation for procedures
- foreign-body and rust-ring removal from the eye
- styte and eye cyst management
- temporomandibular joint dislocation
- Kirschner-wire fixation of a metacarpal fracture
- incision and drainage of a perineal abscess
- mechanical ventilation
- tracheotomy care and weaning
- nasal fracture
- nasal foreign body
- bone marrow aspiration
- thoracentesis and pleurodesis
- pericardiocentesis
- dental procedures
- dental fracture
- tooth extraction
- nonscalpel vasectomy
- male circumcision
- postpartum hemorrhage
- perineal tear repair
- cesarean delivery
- biopsy of the cervix
- culdocentesis
- urethral dilatation

We need to hear about who we are, with more “off call articles,” a grab-bag of material of general interest to rural doctors (e.g., travel, musings on rural living, essays) that describe what it is to be a rural doctor — we are unique.

There is so much that needs to be written and published and not enough scholarly content about issues that affect our lives and those of our rural patients. We will keep ‘em coming, you keep reading and *CJRM* will continue to be there for rural medicine.

Peter Hutten-Czapowski,  
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**A**vec ce numéro, nous bouclons la 15<sup>e</sup> année du *JCMR*. À partir d'une déclaration, d'un espoir et de mots d'encouragement, nous avons créé un journal qui est devenu la voix de la médecine rurale, fait autorité et est peut-être même respecté. En fait, en dépit d'un certain scepticisme chez la vieille garde (dont je dirais hélas que je fais partie), nous y sommes arrivés.

Si vous n'en n'êtes pas certains, jetez un coup d'œil autour de vous. J'ai entendu de nouveaux diplômés mentionner « la série occasionnelle » et le Journal comme s'ils avaient toujours existé — comme s'il s'agissait d'une institution. Des auteurs fidèles publient maintenant non seulement leurs premières communications, mais leur cinquième ou sixième dans nos pages (et si vous êtes un auteur rural, vous savez qu'après la publication de votre premier article, le rédacteur soussigné ne vous tient plus la main). Le journal est indexé à la fois dans Index Medicus et Google Scholar.

Il reste que c'est une démarche un peu solitaire que d'ouvrir la voie comme premier journal de la médecine rurale. Il existe quelques autres journaux de nature rurale et certains autres encore qui ne sont pas ruraux mais offrent du contenu pertinent pour la médecine rurale ou à peu près, mais ils ne sont pas considérés comme des publications typiques. Le *JCMR* a besoin de contenu rural pour continuer de faire une différence.

Par exemple, j'ai besoin d'un manuscrit sur les répercussions de la fermeture d'un service d'urgence en milieu rural. Nous savons ce qui se passe lorsqu'on ferme un service d'obstétrique, mais que se passe-t-il lorsqu'on ferme l'urgence ? Il n'y a pas suffisamment de données pour aider à déterminer quand ces réductions de services sont raisonnables pour diminuer les besoins en ressources humaines et quand elles aggraveront les résultats parce que les gens malades n'obtiendront pas de soins, n'en chercheront pas ou et n'obtiendront pas les soins en temps opportun (sans égard à la qualité de l'établissement éloigné qui reste).

Nous avons besoin de ce contenu pour guider et appuyer notre art.

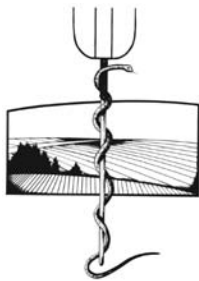
Envoyez-moi un article sur une intervention. Vous connaissez maintenant le format : texte pas trop long, quelques photos et au plus cinq références, à moins que vous vouliez que l'on remette en question vos tendances obsessionnelles. Il y a de nombreux sujets dans la série « occasionnelle » The Practitioner que j'aimerais particulièrement voir arriver :

- sédation en vue d'une intervention
- enlèvement de corps étrangers et de cerclés de rouille dans l'œil
- prise en charge des orgelets externes et des kystes aux yeux
- dislocation de l'articulation temporo-mandibulaire
- fixation par fil de Kirschner d'une fracture du métacarpe
- incision et drainage d'un abcès au périnée
- ventilation mécanique
- soins de la trachéotomie et sevrage
- fracture du nez
- corps étranger dans le nez
- ponction de moelle osseuse
- thoracentèse et pleurodèse
- péricardiocentèse
- interventions dentaires
- fracture dentaire
- extraction de dents
- vasectomie sans scalpel
- circoncision masculine
- hémorragie postpartum
- réparation d'une déchirure du périnée
- césarienne
- biopsie du col de l'utérus
- culdocentèse
- dilatation de l'urètre

Nous devons entendre parler de qui nous sommes par un plus grand nombre « d'articles non sollicités », c'est-à-dire qui traitent de sujets d'intérêt général pour les médecins ruraux (p. ex., voyages, réflexions sur la vie rurale, essais) et décrivent ce que veut dire être médecin rural — car nous sommes uniques.

Il y a tant de sujets sur lesquels il faut écrire et publier et pas suffisamment de contenu savant sur des enjeux qui ont une incidence sur notre vie et celle de nos patients ruraux. Nous allons donc continuer de publier, vous allez continuer de lire et le *JCMR* continuera d'être là pour la médecine rurale.





### President's message. Clinical courage

*John Wootton, MD  
Shawville, Que.*

*Correspondence to: Dr. John  
Wootton; jwootton@srpc.ca*

**A**s many of you will know if you are attending this year's Rural and Remote Medicine Course, the theme of the conference is clinical courage. I don't know whether he is the author of the term, but I first heard it from my colleague and former SRPC president, Dr. Keith MacLellan. It's a difficult concept to get one's head around. Clinical courage inhabits that grey zone at the fringe of competence, where the fog gets thicker as we approach the edge of the cliff. How far is it reasonable to go? How close to the edge must we be before we put down our heavy load?

I wonder how this dilemma might sound to a patient? Many would be forgiven if they wanted no part of it. "Pass on decisions to the next (presumably more competent) level at the first sign of trouble!", might be a very reasonable reaction from a patient faced with a medical problem being handled by his or her local rural physician. We all know, however, that in the real world such options are frequently not available, and even if they are, they may not be the best choice.

Take the single mother (with 3 other young 'uns in tow) who brings her febrile 5-year-old to see you in the middle of the night. Ninety-nine times out of 100 this child has a viral illness or some other easily identified non-life threatening illness that requires little in the way of investigation or treatment. The clinical picture this time, however, suggests that a full septic workup, including lumbar puncture, is the best option. Perhaps the child is more toxic than you are comfortable with. Perhaps the neck seems a little stiff ...

The last lumbar puncture you did was 2 years ago. The closest pediatrician

is in bed 100 km away. The child is squirmy and might need sedation to get through the procedure. You weigh your options.

It is still likely that this child does not have meningitis, but nevertheless the adage, "if you think it, do it" applies. It takes clinical courage to initiate a course of action at the edge of your comfort zone. It is far easier to transfer the problem to someone else.

Doing the lumbar puncture locally will likely result in the elimination of a serious diagnosis from consideration; reassurance of a worried mother; the avoidance of a disruptive, expensive and probably unnecessary middle-of-the-night transfer; and the rather straightforward initiation of treatment for fever of unknown origin, which, even if unknown, is now known to not be in the central nervous system.

The above example can be tweaked or replaced by something else to fit individual variations in scope of practice and the parameters that define one's willingness to act. Although to some this scenario is nowhere near their "cliff edge," something else is likely to be, and rest assured, someday it will walk through that ER door to challenge you.

Clinical courage is that inner debate that we must all have with ourselves, in that space where the needs of our patients and the extent of our training and experience intersect. Sessions at the Rural and Remote Medicine Course in Collingwood, May 5-7, will hopefully fill in the gaps and solidify confidence, and make the overlap just a little bit larger than it was before you came. Have fun, and if you are reading this after the fact, I hope you enjoyed yourself and that you will come back next year.

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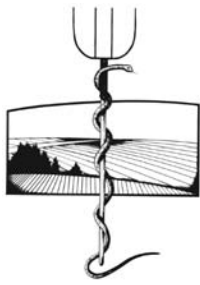
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## Message du président. Le courage clinique

**C**omme beaucoup d'entre vous le saurez si vous assistez au cours sur la médecine en milieu rural et éloigné de cette année, la conférence a pour thème le courage clinique. Je ne sais pas s'il est l'auteur de l'expression, mais je l'ai entendue pour la première fois dans la bouche de mon collègue et ancien président de la SMRC, le Dr Keith MacLellan. C'est un concept difficile à saisir. Le courage clinique réside dans la zone grise située en périphérie de la compétence où le brouillard s'épaissit à mesure que nous approchons du bord du précipice. Jusqu'où est-il raisonnable d'aller ? Jusqu'où faut-il nous approcher du bord avant de déposer notre lourde charge ?

Je me demande ce qu'un patient penserait de ce dilemme. On pardonnerait à beaucoup de ne pas vouloir y penser. « Il faut laisser la décision au niveau suivant (que l'on présume plus compétent) dès le premier signe de difficulté ! » — voilà une réaction qui pourrait être très raisonnable chez un patient confronté à un problème médical traité par son médecin rural local. Toutefois, dans la réalité, nous savons tous qu'il arrive souvent que de telles options ne soient pas disponibles et que même si elles le sont, elles ne constituent peut-être pas le meilleur choix.

Prenons l'exemple de la mère célibataire (suivie de ses trois autres petits enfants) qui vous amène son enfant de cinq ans fiévreux, au beau milieu de la nuit. Quatre-vingt-dix-neuf fois sur 100, cet enfant a une maladie virale ou une autre maladie facile à identifier qui ne met pas sa vie en danger et qui exige peu comme examen ou traitement. Le tableau clinique dans ce cas indique toutefois qu'une analyse infectieuse complète, y compris la ponction lombaire, constitue le meilleur choix. L'enfant est peut-être plus toxique que vous êtes à l'aise de le voir. Il a peut-être le cou qui semble un peu raide ...

Il y a deux ans que vous avez pratiqué

vos dernière ponction lombaire. Le pédiatre le plus proche est au lit chez lui à 300 km. L'enfant se tortille et pourrait avoir besoin de sédation pour subir l'intervention. Vous analysez vos choix.

Il est quand même probable que cet enfant n'a pas la méningite, mais le dictionnaire selon lequel « si vous y pensez, faites le » s'applique néanmoins. Il faut du courage clinique pour prendre une décision à la limite de sa zone de confort. Il est plus facile de passer le problème à quelqu'un d'autre.

Si vous pratiquez la ponction lombaire sur place, vous pourrez probablement éliminer un diagnostic grave, rassurer une mère inquiète, éviter un transfert au beau milieu de la nuit qui perturbera tout le monde, coûtera cher et sera probablement inutile; vous pourrez initier un traitement plutôt simple contre une fièvre d'origine inconnue dont vous saurez au moins qu'elle ne réside pas dans le système nerveux central.

Il est possible de modifier à l'infini l'exemple ci dessus pour le remplacer par un autre qui correspond aux variations individuelles du champ d'exercice et aux paramètres qui définissent la volonté d'agir. Si, pour certains, ce scénario est loin du « bord du précipice », dans leur cas, c'est probablement autre chose qui s'y trouve et vous pouvez être sûrs de voir un jour ce cas se présenter à l'urgence pour vous mettre au défi.

Le courage clinique, c'est le débat intérieur que nous devons tous avoir avec nous-même, au point de convergence entre les besoins de nos patients et l'étendue de notre formation et de notre expérience. Les séances du cours sur la médecine en milieu rural et éloigné, tenu à Collingwood du 5 au 7 mai, combleront les lacunes, nous l'espérons, solidifieront la confiance et rendront le chevauchement des compétences un peu plus étendu qu'avant votre arrivée. Amusez-vous et si vous lisez ceci après coup, j'espère que vous avez eu du plaisir et que vous reviendrez l'an prochain.

## The supply of physicians and care for breast cancer in Ontario and California, 1998 to 2006

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**Introduction:** We examined the differential effects of the supply of physicians on care for breast cancer in Ontario and California. We then used criteria for optimum care for breast cancer to estimate the regional needs for the supply of physicians.

**Methods:** Ontario and California registries provided 951 and 984 instances of breast cancer diagnosed between 1998 and 2000 and followed until 2006. These cohorts were joined with the supply of county-level primary care physicians (PCPs) and specialists in cancer care and compared on care for breast cancer.

**Results:** Significant protective PCP thresholds (7.75 to  $\geq 8.25$  PCPs per 10 000 inhabitants) were observed for breast cancer diagnosis (odds ratio [OR] 1.62), receipt of adjuvant radiotherapy (OR 1.64) and 5-year survival (OR 1.87) in Ontario, but not in California. The number of physicians seemed adequate to optimize care for breast cancer across diverse places in California and in most Ontario locations. However, there was an estimated need for 550 more PCPs and 200 more obstetrician-gynecologists in Ontario's rural and small urban areas. We estimated gross physician surpluses for Ontario's 2 largest cities.

**Conclusion:** Policies are needed to functionally redistribute primary care and specialist physicians. Merely increasing the supply of physicians is unlikely to positively affect the health of Ontarians.

**Introduction :** Nous avons étudié les effets différentiels de l'offre de médecins sur le soin du cancer du sein en Ontario et en Californie. Nous avons ensuite utilisé les critères de soin optimal du cancer du sein pour estimer les besoins régionaux en médecins.

**Méthodes :** Les registres de l'Ontario et de la Californie ont fourni 951 et 984 cas de cancer du sein diagnostiqués entre 1998 et 2000 et suivis jusqu'en 2006. Ces cohortes ont été reliées à l'offre de médecins de première ligne (MPL) et de spécialistes en soin du cancer au niveau des comtés et comparées en termes de soin du cancer du sein.

**Résultats :** On a observé des seuils protecteurs importants de MPL (7,75 à  $\geq 8,25$  MPL pour 10 000 habitants) dans le cas du diagnostic du cancer du sein (rapport de cotes [RC] 1,62), de la réception d'une radiothérapie d'appoint (RC 1,64) et de la survie à 5 ans (RC 1,87) en Ontario, mais non en Californie. Le nombre de médecins semblait suffisant pour optimiser le soin du cancer du sein à divers endroits en Californie et à la plupart des endroits en Ontario. On a toutefois estimé qu'il fallait 550 MPL de plus et 200 obstétriciens-gynécologues de plus dans les régions rurales et les petites villes de l'Ontario. Nous avons estimé l'excédent brut en médecins dans les deux plus grandes villes de l'Ontario.

**Conclusion :** Des politiques s'imposent pour redistribuer de façon fonctionnelle les médecins de première ligne et les médecins spécialistes. Il y a peu de chances que le simple fait d'augmenter l'offre de médecins ait un effet positif sur la santé de la population de l'Ontario.

### INTRODUCTION

Social policy analysts in Canada and

the United States have identified apparent problems related to the supply of physicians.<sup>1-4</sup> Canadian advocates

have called for more physicians overall, and their counterparts in the US have called for more primary care physicians (PCPs). What are the population health effects of such physician shortages, if indeed they do exist? How strong are the relations between physician supply and sentinel health indicators in Canada and the US? Valid answers to such questions are needed to help inform policies on physician supply in both countries. This observational study makes opportunistic use of surveillance systems on physician supply and cancer in Canada and the US. It explores the effects of one critical health care resource, physician supply,<sup>5,6</sup> on one important aspect of health care, cancer care, in Ontario and California.

A number of within-country analyses of physician supply and cancer care have focused on the sentinel health indicator of breast cancer care.<sup>7-9</sup> The supply of PCPs was directly associated with timely diagnosis and survival in Canada and the US, but stronger associations were observed in Canada.<sup>10-14</sup> Neither overall supply of physicians nor the supply of specialists were associated with breast cancer care in either country after the supply of PCPs was accounted for. These findings were systematically replicated in the US for another important health indicator, care for colon cancer.<sup>15,16</sup> We are aware of only one between-country analysis of physician supply and cancer care.<sup>17</sup> The authors observed a direct association between PCP supply and adjuvant chemotherapy, as well as a direct association between gastroenterologist supply and early diagnosis and survival in Ontario, but not in California. The authors suggested that, first, more health care resources, including more PCPs, would probably not fix the central health care problem in the US (that so many people do not have access). Second, in Canada, where health care resources seem to matter more to the health of the population, research to identify specific areas of undersupply of physicians is needed.<sup>17</sup> The present study responds with an examination of the differential effects of supply of physicians (PCPs and key specialists) on care for breast cancer in Ontario and California.

It seems plausible that adequate supplies of PCPs and key specialists could positively affect the availability, accessibility and continuity of breast cancer screening, treatment and survival.<sup>18-23</sup> This study aims to observe independent relations between physician supply and breast cancer care in Ontario and California. Accounting for income is probably critical, because income has consistently explained little of the variability in Canadian cancer

care, and it has been highly predictive of cancer care in the US.<sup>14,24-28</sup> The effects of the supply of PCPs have also been moderated by region and by characteristics of places within regions, such as urbanity.<sup>15,29-32</sup> Gorey and colleagues have theorized that the effects of the supply of physicians adjusted for place are stronger in Canada than in the US.<sup>15,14,17</sup> The theory essentially posits that with guaranteed access, personal income and its correlates matter less, and the availability of community resources, including physicians, matter more. For the present study, we hypothesized that the supply of PCPs and specialist physicians is more strongly associated with breast cancer care (early diagnosis, treatment access and survival) in Canada than in the US. The magnitude of regional physician shortages or surpluses were then estimated for diverse urban and rural places in Ontario and California.

## METHODS

We randomly selected from Ontario and California cancer registries instances of breast cancer that had been diagnosed between 1998 and 2000 and followed until 2006 (Ontario,  $n = 951$ ; California,  $n = 984$ ). Samples were stratified by places that included large metropolitan areas (e.g., Toronto and San Francisco), small metropolitan areas (e.g., Windsor and Modesto) and rural areas. We defined rural areas in Ontario and California according to Statistics Canada criteria:<sup>33,34</sup> fewer than 10 000 inhabitants and population densities of fewer than 400 people per km<sup>2</sup>. We calculated the distance between each patient's residence and the nearest urban centre with an ArcGIS Euclidean algorithm, with categories of remoteness defined as follows: remote (100–199 km), very remote (200–299 km) and extremely remote ( $\geq 300$  km).<sup>35,36</sup> The Ontario and California cancer registries comprehensively survey the most populous Canadian province and US state with demonstrated validity. Both ascertain nearly all instances of breast cancer with nearly perfect rates of microscopic confirmation.<sup>37-40</sup> Variables related to stage of disease at diagnosis and treatment routinely coded by the California registry were abstracted from patient charts for the Ontario sample.<sup>41-43</sup> Reliability assessments of 150 randomly selected health records among 3 abstractors found  $\kappa$  coefficients that ranged from 0.88 to 0.96. The following treatment variables were also included: receipt of initial cancer-directed surgery, receipt of adjuvant chemotherapy and radiotherapy, and wait time from diagnosis to treatment.

Patients with breast cancer were matched to Canadian or US censuses (from 2001 and 2000, respectively) based on their residential census tracts.<sup>44,45</sup> Rural patients in Ontario were matched to census subdivisions. We constructed low to high annual household income quintiles using Statistics Canada's low-income criterion and the US Census Bureau's poverty threshold. Median incomes, adjusted for purchasing power, were very nearly identical in Ontario's and California's lowest-income neighbourhood quintiles: US\$30 725 and US\$31 050, respectively.<sup>46,47</sup> Counts of active physicians in Ontario and California were based on physician databases of the Canadian Institute for Health Information and the American Medical Association physician databases (from 2001 and 2000, respectively).<sup>48,49</sup> We defined PCPs as physicians who reported their primary specialty area as general or family practice. Because they often provide primary care for women, we also categorized obstetrician-gynecologists (Ob-Gyns) as PCPs.<sup>11,13,50-52</sup> Physicians who reported that most of their clinical time was spent in the practice of general surgery, medical oncology or radiation oncology, or who were so board certified in 2000/01 were defined accordingly. We calculated physician supply densities per 10 000 inhabitants for PCPs and per 100 000 inhabitants for specialists for Ontario's 49 census divisions or districts and California's 58 counties.<sup>44,45</sup>

We used logistic regression models to estimate the associations of the supply of physicians with indices of care for breast cancer. Age, income and place-adjusted odds ratios and their 95% confidence intervals were estimated from regression statistics.<sup>53</sup> Previous analyses found threshold, rather than linear effects, so we compared each incremental quarter physician supply category with the average effect of the previous categories (7.00, 7.25, 7.50,

etc., PCPs per 10 000 inhabitants). In addition to bolstering statistical power, such reverse Helmert contrasts allowed for the identification of threshold effects.<sup>53,54</sup> The study had the statistical power to detect rate differences of 10% ( $\alpha = 0.05$  and power  $[1-\beta] = 0.80$ ).<sup>55</sup> We then used criteria for optimum physician supply to identify undersupplied and oversupplied places.<sup>56</sup>

This study was approved by the University of Windsor's research ethics committee and the Ontario Cancer Research Network's research ethics board.

## RESULTS

### Supply of PCPs and breast cancer care

The association between supply of PCPs and indices of care for breast cancer in Ontario is shown in Table 1. Protective PCP supply thresholds clustered around 8 PCPs for every 10 000 inhabitants. The odds of 5-year survival among women with breast cancer who resided in Ontario districts with 8.25 or more PCPs per 10 000 inhabitants was 87% greater than among their counterparts of similar age, stage and income who resided in otherwise similar places, but with fewer than 8.25 PCPs per 10 000 inhabitants. Moreover, protective effects of PCPs seemed apparent during pre- and postdiagnostic phases of breast cancer care. Patients in Ontario districts with a supply of physicians at or above 7.75 PCPs per 10 000 inhabitants or 8.00 PCPs per 10 000 inhabitants were significantly more likely to have been diagnosed with node-negative breast cancer or to have received adjuvant radiotherapy, respectively.

There were 5 null findings that may be important in terms of policy-making. First, no level of

**Table 1. Association between supply of primary care physicians and indices of care for breast cancer in Ontario**

Physician density threshold	Index of breast cancer care	
	Odds ratio	95% confidence interval
7.75 PCPs per 10 000 inhabitants	Node-negative disease at diagnosis	
	1.62	1.00-2.63
8.00 PCPs per 10 000 inhabitants	Receipt of adjuvant radiotherapy	
	1.64	1.06-2.55
8.25 PCPs per 10 000 inhabitants	5-year survival	
	1.87	1.09-3.22

PCP = primary care physician.

Notes: All effects were adjusted for age, income, place (large urban, small urban, rural, remote, very remote and extremely remote) and total supply of physicians. Treatment and survival effects were also adjusted for the stage of disease at diagnosis. Fifty-one logistic regression models were run with the California data (17 for each breast cancer care index, quarter physician supply increments from 6.00 to 10.00 PCPs per 10 000 inhabitants). PCP supply was null in them all so they are not shown.

physician supply was associated with the receipt of surgery or chemotherapy, or with any wait times. Second, additional supplies of PCPs above thresholds did not further improve any aspect of care for breast cancer. Third, no aspect of care for breast cancer was further explained by the supply of physicians. Fourth, remoteness was not significantly associated with any aspect of breast cancer care, so rural needs are probably not defined merely by the levels of isolation that can occur in northern Ontario. Finally, no aspect of physician supply was significant when associated with any aspect of breast cancer care in California.

### Cancer care-based estimates of the adequacy of the supply of physicians in Ontario

Ontario physician population parameters within 3 groups of regions that correspond with our analytic strata are displayed in Table 2. Using a criterion of 8 PCPs per 10 000 inhabitants that was associated with optimum care for breast cancer between 1998 and 2006, we estimated that the province of Ontario did not have an overall shortage of PCPs in 2006. With highest-quality care for breast cancer as the criterion, the province as a whole was probably adequately supplied, perhaps even oversupplied, by more than 1500 PCPs. However, nearly half of the province's census divisions or districts seemed inadequately supplied (21 of 49 districts). Ontario's problem with physician supply seems to be one of

inequitable distribution, rather than of inadequate overall supply.

Although we did not find any significant effects related to the supply of specialists, previous studies have observed protective effects in breast cancer care where there are 6 or more Ob-Gyns per 100 000 inhabitants in Ontario.<sup>13,14</sup> The distribution of Ob-Gyns in 2006 is also displayed in Table 2. Again, with provision of highest-quality care for breast cancer as the criterion, the overall supply of Ob-Gyns in urban areas seemed about right, with rural areas modestly undersupplied. The province's aggregate supply discrepancy of 45 Ob-Gyns amounted to additional average needs of only 1 to 2 more Ob-Gyns per district. Again, the real problem seemed to be one of inequitable distribution. Nearly all of Ontario's districts (42 of 49) had less than the optimum supply of Ob-Gyns in 2006, yet the overall provincial supply discrepancy was modest. A small number of districts probably had a relative glut of specialist physicians.

Table 3 groups Ontario physician parameters by places that were either below or above criteria for optimum physician supply in 2006. Slightly more than 40% of the province's population lived in districts that were probably inadequately supplied with PCPs. The aggregate shortage was estimated to be 563 PCPs. The other nearly 60% of the province's population lived in adequately supplied districts that, at least in terms of the provision of optimum care for breast cancer, may have had a surplus of

**Table 2. The supply of physicians in 49 Ontario census divisions in 2006, grouped by urbanity**

Variable	Primary care physicians	Obstetrician-gynecologists
Optimum supply of physicians per inhabitants	8.00/10 000	6.00/100 000
Greater metropolitan Toronto*		
Physician density† (range in census divisions)	9.44/10 000 (6.18–12.42)	6.14/100 000 (2.76–9.79)
No. of inadequately supplied census divisions	3	4
Actual supply – optimum supply	1.44/10 000	0.14/100 000
Supply discrepancy	800	8
Other urban areas‡		
Physician density† (range in census divisions)	9.30/10 000 (6.08–15.57)	5.96/100 000 (0.00–10.43)
No. of inadequately supplied census divisions	9	19
Actual supply – optimum supply	1.30/10 000	–0.04/100 000
Supply discrepancy	698	–2
Rural areas§		
Physician density† (range in census divisions)	8.52/10 000 (5.61–12.99)	1.87/100 000 (0.00–7.76)
No. of inadequately supplied census divisions	9	19
Actual supply – optimum supply	0.52/10 000	–4.13/100 000
Supply discrepancy	64	–51
Provincial supply discrepancy	1562	–45

\*Population: 5 555 912 people in 5 census divisions.

†Physician density (no. of physicians per inhabitant population) was the sum of the physician densities in the census divisions weighted by their populations.

‡Population: 5 371 699 people in 24 census divisions.

§Population: 1 230 449 people in 20 census divisions.

more than 2000 PCPs. The 2 districts that included Toronto and Ottawa accounted for nearly three-quarters of the surplus (1525/2125 = 71.8%). The same pattern was observed for Ob-Gyns, but the distributional problem seemed even more severe. Toronto and Ottawa again accounted for most of the supply surplus (127/157 = 80.9%).

## DISCUSSION

We based this study on the theory that personal economic resources trump community health care resources in the US. Our consistent findings that the supply of physicians was not significantly associated with any aspect of care for breast cancer in California robustly support our theory. Given Canada's access guarantee, our theory alternatively predicted that community resources for health care, including the supply of physicians, matter more here. Our study's consistent results of independent protective associations of the supply of PCPs with breast cancer diagnosis, adjuvant radiotherapy and survival across diverse urban and rural areas in Ontario serve to cross-validate the theory. We estimated a provincial surplus of 1562 PCPs as well as a shortage of 45 Ob-Gyns in 2006. Physician surpluses were most pronounced in Ontario's 2 largest cities. Application of the same criteria to California estimated surpluses of 1825 PCPs and 2920 Ob-Gyns. Californians may not practically benefit more from such seemingly affluent regional health care

service endowments than Ontarians do from their more efficient health care system that puts a greater emphasis on primary care. At the time of this study, PCPs constituted nearly half of Ontario's physicians (47.0%) and just over one-quarter of California's (27.2%).<sup>17</sup> The overall supply of physicians in Ontario seems adequate to provide effective care for breast cancer. However, we estimated that 563 more PCPs and 202 more Ob-Gyns, principally for the primary care they provide, were needed in Ontario's rural and small urban areas.

Policies to functionally redistribute physicians are called for. Merely increasing physician populations is unlikely to positively affect the health of Ontarians. Our study shows that clinically meaningful criteria could be used to rationally inform policy on physician supply. The criterion of breast cancer care used in this study is not the only important indicator of high-quality health care. More population-based studies are needed to cross-validate and systematically replicate this study's findings across other clinically meaningful health outcomes.

## Policy context

The Canadian Medical Association's (CMA's) "More doctors. More care" campaign<sup>1</sup> alleged an enormous physician shortage and argued that the shortage was bound to grow far worse. The association estimated that another 20 000 physicians were needed to keep pace with other member nations of the Organisation

**Table 3. The supply of physicians in 49 Ontario census divisions in 2006, grouped according to inadequate and adequate supply**

Variable	Primary care physicians	Obstetrician-gynecologists
Optimum supply of physicians per inhabitants	8.00/10 000	6.00/100 000
Inadequately supplied places		
Population	5 119 283	7 633 130
No. of census divisions	21	42
Physician density* (range in census divisions)	6.90/10 000 (5.61–7.96)	3.35/100 000 (0.00–5.41)
Actual supply – optimum supply	–1.10/10 000	–2.65/100 000
Supply discrepancy	–563	–202
Adequately supplied places		
Population	7 038 777	4 524 930
No. of census divisions	28	7
Physician density* (range in census divisions)	11.02/10 000 (8.05–15.57)	9.46/100 000 (7.76–10.43)
Actual supply – optimum supply	3.02/10 000	3.46/100 000
Supply discrepancy	2125	157
Provincial supply discrepancy	1562	–45
California supply discrepancy†	1825	2920

\*Physician density (no. of physicians per inhabitant population) was the sum of the physician densities in the census divisions weighted by their populations.

†Theoretical comparison based on the application of Ontario's criteria for optimum supply.

for Economic Co-operation and Development (OECD). One might fairly wonder about the validity of that criterion. Other policy analysts have convincingly refuted its validity. For example, there seems to be little evidence to support the contention that any meaningful relation exists between physician supply and avoidable mortality among OECD nations.<sup>57</sup> It is well known that more is not necessarily better. Moreover, the per capita supply of all physicians as well as the ratio of PCPs to specialists has remained surprisingly constant over the past 20 years in Canada.<sup>58</sup> Within such a policy context, specific district or regional shortages may be misperceived as provincial or national shortages. This study's findings are consistent with those of policy analysts who have contended the CMA's projections of impending, very large physician shortages. What if, hypothetically, Ontario's share of the CMA's recommended 20 000 physicians were instituted? Where would these additional 7000 physicians practise? Would they rationally fill the gaps that exist throughout Ontario's smaller urban and rural areas? It seems more likely that they would continue to preferentially practise in places that already have physician surpluses. This would only serve to dramatically increase health care costs without producing any health benefits.

### Functional redistribution policies

Simply redistributing physicians, especially specialists, is probably not a sufficient practical solution to the problem of geographic inequity. Even if specialist–population ratios were increased, a number of challenges specific to rural and remote places would remain. Patients in remote areas would still have long distances to travel to visit a physician, and practice volumes in rural and even in certain small urban areas might be so small as to preclude their quality.<sup>59</sup> Rural outreach strategies in Ontario have included the establishment of the Northern Ontario School of Medicine as well as visiting specialist programs that proliferated in the province during this study's time frame.<sup>60,61</sup> These efforts are expected to have beneficial effects.<sup>36,62</sup> Rural practice innovations that integrate telehealth strategies may potentiate the benefits of such efforts, serving to further functionally redistribute physician resources, if not actually redistribute the supply of physicians.<sup>63,64</sup>

### 52 Limitations

The most significant inferences from this study in terms of policy pertain to Canada, but the study's

Ontario samples are not necessarily representative of Canada as a whole. The Ontario samples were randomly selected from a deliberately selected pool of diverse places. Large and small urban and rural places were oversampled; our results are most generalizable to them. However, we think the results are externally robust for the following reasons. Independently, place did not seem to matter in our study's analyses. Physician supply distributions seen in our study seemed consistent with the province's physician populations reported elsewhere.<sup>65,66</sup> This study's findings of ample overall physician supply with identifiable areas of significant undersupply have also been observed in Manitoba.<sup>67</sup> Finally, Ontario ranks close to the bottom of Canadian provinces on the population density of PCPs and close to the top on specialist physician densities.<sup>54</sup> Our study's inferences about surplus PCPs and specialist supply shortages in Ontario may actually be underestimates of the truth across Canada.

Our results converged with the observation of the Canadian Community Health Survey of a very strong association between having a regular doctor and receiving a mammogram within the past 2 years (odds ratio 3.48).<sup>68</sup> A number of potential confounders identified by that study were accounted for by ours. Still, some error probably intruded into our analyses. For example, although physicians play a key roll in mammography referrals, other health care professionals and patients themselves (self-referrals account for 1 of every 5 screening mammograms in Ontario) play an important role that was not assessed in this study.<sup>69</sup> Also, at the time of our study the guidelines for screening mammograms were different in Canada and the US. The Canadian guidelines recommended biennial mammograms beginning at age 50, and the US guidelines recommended annual mammograms beginning at age 40.<sup>70,71</sup> It is unlikely that such prediagnostic processes could confound our study's central within-Ontario results, particularly its results relevant to postdiagnostic care for breast cancer.

Our physician counts were head counts of active physicians that did not allow for estimation of full-time physician equivalents. Head-count data have been shown to result in Canadian physician–population ratios that are overestimates of the truth; however, such overestimation has also been demonstrated to be least problematic in Ontario (5%–10%).<sup>72</sup> Such slight overestimation could easily be accounted for in planning the future supply of physicians. Also, our study's physician supply mea-



asures were community-level aggregates and so did not directly examine individual physician–patient relationships. The measures were conceived as proxies of community-level phenomena; that is, of regional health care service endowments. Therefore, we think that population-level policy inferences can be most appropriately drawn from the findings.

We were not able to resolve clinical versus non-clinical (teaching, research and administration) physician counts. It seems that much of the physician supply surpluses that were identified, particularly in large urban centres of medical education and research such as Toronto and Ottawa, may reflect the much greater prevalence of active, but nonclinical, physicians there. Such confounding seems far less likely in Ontario's small urban and rural areas. Inferences concerning inadequate supply of physicians in small urban and rural areas are probably the most valid inferences of this study.

## CONCLUSION

The supply of physicians matters in Ontario. Rhetoric about gross physician shortages seems a distraction from the probable truths that the adequate supply of physicians is inequitably distributed, that undersupplied places are identifiable and that the magnitude of their shortages is calculable. Functional redistribution policies serving to encourage and support more equitable geographic distributions of physicians are called for in Ontario and across Canada.

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**Competing interests:** None declared.

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## Gallbladder disease in northwestern Ontario: the case for Canada's first rural ERCP program

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**Introduction:** The rate of cholecystectomy in northwestern Ontario is double the provincial rate. This paper explores the demographics of cholecystectomy and the role for rural endoscopic retrograde cholangiopancreatography (ERCP) services in the central part of this region.

**Methods:** We conducted a literature review of ERCP services and cholecystectomy rates, as well as a hospital chart review of patients who underwent laparoscopic cholecystectomies in Sioux Lookout, Ont. We contacted surgeons and gastroenterologists from referral centres in Winnipeg, Man., and Thunder Bay, Ont., for the charts of patients from our catchment area who underwent ERCP.

**Results:** Patients in our region who require urgent and emergent surgery are flown by fixed-wing aircraft to referral centres in Winnipeg and Thunder Bay for assessment and surgery. The rate of ERCP in our population is 150 in 100 000, which is threefold that of other populations, and our cholecystectomy rate is the highest in Ontario.

**Conclusion:** Substantial savings in transportation expenses would offset the development costs of an ERCP program and provide more integrated patient care. The volume of patients would support maintenance of competency. This rural area with a high rate of gallbladder disease would benefit from the development of a rural ERCP program.

**Introduction :** Le taux de cholécystectomie dans le nord-ouest de l'Ontario est deux fois plus élevé que celui de la province dans son ensemble. Cet article explore les caractéristiques démographiques de la cholécystectomie et le rôle des services ruraux de cholangiopancréatographie rétrograde endoscopique (CPRE) dans le centre de cette région.

**Méthodes :** Nous avons effectué une étude documentaire des services de CPRE et des taux de cholécystectomie, ainsi que des dossiers hospitaliers des personnes qui ont subi une cholécystectomie par laparoscopie à Sioux Lookout (Ont.). Nous avons communiqué avec des chirurgiens et des gastroentérologues de centres de référence à Winnipeg (Man.) et Thunder Bay (Ont.) pour obtenir les dossiers des patients de notre bassin qui ont subi une CPRE.

**Résultats :** Les patients de notre région qui ont besoin d'interventions chirurgicales d'urgence et d'extrême urgence sont transportés par avion à des centres de référence à Winnipeg et Thunder Bay pour évaluation et chirurgie. Le taux de CPRE dans notre population s'établit à 150:100 000, ce qui est trois fois plus élevé que celui d'autres populations, et notre taux de cholécystectomie est le plus élevé en Ontario.

**Conclusion :** Des réductions importantes des dépenses en frais de transport compenseraient les coûts d'établissement d'un programme de CPRE et fourniraient aux patients des soins mieux intégrés. Le volume des patients appuierait le maintien de la compétence. Cette région rurale qui a un taux élevé d'affections de la vésicule biliaire bénéficierait de l'établissement d'un programme rural de CPRE.

## INTRODUCTION

This paper explores the demographics of cholecystectomy and the role for a rural endoscopic retrograde cholangiopancreatography (ERCP) service in northwestern Ontario. We hypothesized that it would be economically feasible to establish an ERCP program in our rural hospital based on geography, patient demographics, current and expected surgical volumes, and past referral patterns.

The rate of cholecystectomy in the Kenora–Rainy River District of northwestern Ontario is double the provincial rate.<sup>1</sup> A large part of the Kenora–Rainy River District is served by the Sioux Lookout Meno Ya Win Health Centre, which has a vast service area of 385 000 km<sup>2</sup> (roughly one-third of Ontario's land mass). The 30 000 population served by our catchment area is 82% First Nation,<sup>2</sup> a population known to have high rates of gallbladder disease.<sup>3</sup>

Urgent and emergent surgery involves an airplane medevac from a remote northern community to Sioux Lookout, Ont., for assessment and surgery. If more specialized surgery or anesthesia are required, the patient is flown 300 km to a referral centre in Thunder Bay, Ont., or Winnipeg, Man. We presently have a full complement of 2 general surgeons funded through the Northwestern Ontario Regional Surgical Network who perform laparoscopic cholecystectomies but not ERCPs.

## METHODS

### Literature review

To understand the feasibility of an ERCP service in our area, we undertook a literature search on MEDLINE and Embase, 1950–present, for cholangiopancreatography, endoscopic retrograde; incidence; practice guideline; and quality control. We searched for cholecystectomy rates in publications of the Institute for Clinical Evaluative Sciences.

### Chart reviews

We reviewed the hospital charts of all patients who underwent laparoscopic cholecystectomies in Sioux Lookout in the 2-year period from April 2007 to April 2009. Referral tertiary care surgeons and gastroenterologists in Winnipeg and Thunder Bay were contacted for the charts of ERCP patients from our catchment area, who were identified by postal codes. Ethics approval was granted by the Meno Ya Win Research Review Committee.

## RESULTS

### Literature review

We reviewed a total of 439 abstracts and chose 25 articles based on relevance to our setting.

### *Provincial trends in cholecystectomies*

Historically, laparoscopic cholecystectomies began in Sioux Lookout in 1992, with 100 performed annually, each with an intraoperative cholangiogram.

A 2005 analysis of the global increase in cholecystectomy surgery with the introduction of laparoscopic technique in the 1990s found a subsequent reduction in the rate of acute cholecystitis because of earlier surgical intervention.<sup>4</sup>

The regional rate of laparoscopic cholecystectomies in Sioux Lookout is now the highest in the province (Table 1<sup>5,6</sup>). Since the introduction of laparoscopic cholecystectomies in the 1990s, times have changed again with the development of ERCP. Currently, any suggestion of stone in the duct or cholestatic increase in hepatic enzymes generally warrants an ERCP precholecystectomy, and intraoperative cholangiograms have become dramatically less common.

### *Trends in ERCP*

Use of ERCP reached its peak in the United States in 1995, with a threefold increase from 1988.<sup>7</sup> It has declined since then. Much of that decline is because of decreased use of ERCP for diagnostic purposes when safer options exist: endoscopic ultrasonography and magnetic resonance cholangiopancreatography (MRCP). Most ERCPs are now done for therapeutic indications.<sup>8,9</sup> From 2002 to 2007, indications for the procedure changed dramatically. Stone retraction accounted for 94% of ERCPs in 2007 but only 38% in 2002.<sup>8,10</sup>

**Table 1. Characteristics of laparoscopic cholecystectomy in Ontario in 1990 and 1994**

Characteristic	1990	1994
Length of stay, d <sup>5</sup>	7.5	2.6
Conversion to open surgery, % <sup>6</sup>	NA	5.3
Bile duct injury, % <sup>6</sup>	NA	1.16
LC rate, Ontario <sup>1</sup>	311/100 000	339/100 000
LC rate, northwestern Ontario <sup>1</sup>	503/100 000	534/100 000

LC = laparoscopic cholecystectomy; NA = data not available.

Presently, the international rate of ERCPs pre-cholecystectomy is between 7% and 17%,<sup>9,11</sup> and the annual US population rate is 50 in 100 000.<sup>7</sup> Rates of post-ERCP pancreatitis vary internationally from 4% to 15%.<sup>12,13</sup>

A 10-year prospective analysis of a rural ERCP program in West Australia<sup>12</sup> was the only program identified as rural. This series of 700 consecutive ERCPs in a catchment area serving a population of 26 000 over 10 years demonstrated a 94% success rate and 4% pancreatitis rate. Seventy-eight percent were done for therapeutic reasons, mostly stone retrieval.<sup>11</sup>

### *Training in ERCP*

ERCP is one of the “most technically demanding and highest risk procedures performed by endoscopists.”<sup>14</sup> Training therefore requires the documented performance of a substantial volume (100<sup>15</sup>–200<sup>14</sup>) of successful (> 80% cannulations<sup>16</sup>) procedures for the training fellow. The present clinical training climate also favours therapeutic over diagnostic procedures.<sup>16</sup> Training benchmarks for an experienced endoscopist for ERCPs are undocumented. Maintenance of competency is felt to require at least 50 procedures annually.<sup>16,17</sup> The proposed competency threshold for sphincterotomies is 40–80 successful procedures.<sup>14,17</sup>

A review of 199 625 inpatient ERCPs in the US from 1998 to 2001 demonstrated that 70% of inpatient ERCPs in the US are done in hospitals that perform fewer than 100 procedures annually, and the mean number of inpatient ERCPs is 48 per hospital per year.<sup>8</sup> Numbers do not tell the whole story. Competence is widely agreed to rely on documented successful procedures and complication records of individual providers.<sup>18</sup>

### *First Nation patients and gallbladder disease*

First Nation patients are known to have high rates of gallbladder disease in many constituencies in North America:<sup>5</sup> Micmac in Nova Scotia,<sup>19</sup> Ojibwa and Cree of Manitoba<sup>20</sup> and Ontario,<sup>5</sup> Chippewa in Minnesota<sup>21</sup> and Pima in Arizona.<sup>22</sup> Genetic and environmental factors are involved. Traditionally, pregnancy, obesity and female sex are associated with gallbladder disease. Biochemical analyses of bile assays in First Nation patients in the 1970s noted “lithogenic bile.”<sup>23,24</sup> Early and increased multiparity in many First Nation women accompanied by a Western diet high in calories and low in fibre also predispose First Nation people to risk for gallblad-

der disease.<sup>24</sup> Metabolic syndrome, a defined constellation of obesity, type 2 diabetes, hypertension and hypercholesterolemia may also play a role.<sup>5</sup>

A 1984 study in Manitoba that compared First Nation people to the general population found that First Nation women with gallbladder disease had a younger mean age (39.9 v. 52 yr).<sup>19</sup> The latter age is consistent with other non-Aboriginal series that identify the mean age of women with gallbladder disease as 46–52 years.<sup>25–28</sup> In 1989, a community-based research initiative in northwestern Ontario and northern Manitoba First Nation communities demonstrated a prevalence of all gallbladder disease of 18.5% in women aged 20–64 years.<sup>5</sup> At that time, the mean age of women with gallbladder disease in Canada was 42.4 years. Interestingly, total cholesterol and low-density lipoprotein were lower in patients with gallbladder disease, compared with patients without gallbladder disease.<sup>5</sup> There was also no association with obesity or diabetes in the 395 cases studied.<sup>5</sup>

### **Chart reviews**

#### *Cholecystectomy and ERCP in Sioux Lookout*

From 2007 to 2009, 74 cholecystectomies were performed annually in Sioux Lookout. Because we have recently recruited our second surgeon to complete our complement, we expect this number will increase. In the first quarter of 2009 we had already performed more than 50 laparoscopic cholecystectomies, and we anticipate we will soon be performing more than 200 procedures annually. Of the patients who underwent cholecystectomy in the 2-year time frame, 14% required an ERCP ( $n = 21$  interventions in 17 patients). Patient characteristics are shown in Tables 2 and 3.

#### *ERCP in patients from our catchment area*

A survey of our referral centres in Winnipeg and Thunder Bay found a 2-year total of 89 ERCPs performed

**Table 2. Sex of 148 patients who underwent laparoscopic cholecystectomy in Sioux Lookout from 2007 to 2009, by age**

Age, yr	Male	Female
< 18	1	8
18–44	15	90
45–64	16	13
≥ 65	4	1
Total	36 (25%)	112 (75%)

on patients from our catchment area, showing an annual rate of 150 in 100 000. This number included the 21 procedures mentioned above and patients who were referred to a tertiary care centre for both ERCP and cholecystectomy.

#### Patient transportation

Medical transportation of patients was important because the 148 patients who underwent cholecystectomies and ERCPs during this 2-year period required an average of 2.2 medevacs per patient. These medevacs are by airplane with air ambulance paramedics in attendance. The 17 ERCP patients alone had an average of 6 medical transportations, because their care was initiated in a northern community and progressed to Sioux Lookout for diagnosis and referral, at an average cost of \$3200 per flight (Dr. Jonathon Morgan, medical director, northern region, Ornge, Sioux Lookout; personal communication: 2010). They were then transferred to and from a tertiary care centre for ERCP and then for a postoperative observation period before their cholecystectomies were performed in Sioux Lookout, often with an intervening trip back to their home community.

## DISCUSSION

The cholecystectomy patients in our catchment area were more numerous and younger than those in all other reported estimates.

The mean age of our female patients was 32 years. This is much younger than a similar population in northern Manitoba studied in 1984, which had a mean female age of 39.4 years.<sup>12</sup> Both of these findings contrast with the generally quoted mean female age of 46 to 52 years.<sup>12,25-28</sup>

The largest demographic age group in our population profile is 10–14 years of age, with 35% of our population under age 15.<sup>2</sup> Because we have no reason to anticipate a decline in multiple parity, obesity

and type 2 diabetes, the incidence of gallbladder disease will likely remain high.

Other than being younger, our patients were similar to those studied in our region by Young and Roche<sup>3</sup> in 1984. Our patients' average total cholesterol was 4.3 mmol/L, which was lower than the values Young and Roche found. This is consistent with Young and Roche's observation that total cholesterol values were inversely correlated with gallbladder disease. They also found high rates of hypertension and diabetes.<sup>3</sup>

Our patients travelled great distances for medical care. Because patients need to be transported to Sioux Lookout for assessment, diagnosis and triage, the provision of complete surgical care at that site would be optimal.

Transportation for ERCP services in our region is very expensive. Simply eliminating 5 of the 6 medevacs our 17 ERCP patients each incurred in the past 2 years could have saved more than \$272 000. The potential savings on 40–50 of the 89 ERCPs done on patients from our region would be greater.

Shorter lengths of stay in hospital, which are now spread between 2 hospitals (including a 3- to 5-day stay awaiting the tertiary care hospital's "ERCP day"), would also decrease global costs.

Global cost savings from each of the above would more than compensate for the training and equipment costs involved in having one of our surgeons learn ERCP skills.

The challenge of a rural ERCP program would be in surgical capacity. For a program to have sufficient volume for maintenance of ERCP competency, we would have to increase our laparoscopic cholecystectomy workload. With a full complement of 2 surgeons for our population of 30 000, we estimate an annual volume of 200 cholecystectomies.

An acceptable ERCP volume (45–50 annually) would be achieved by capturing most of our catchment area's cholecystectomy patients requiring ERCPs as well as referrals from nearby towns in the Northwestern Ontario Surgical Network that presently refer their ERCP patients longer distances to tertiary care centres.

Maintenance of competency would be feasible with an expected annual rate of 45–50 procedures. This compares favourably with the mean volume in US hospitals doing inpatient ERCPs.<sup>8</sup> The only rural program cited in the literature maintained high-quality outcomes and at a higher average of 75 procedures per year.<sup>12</sup>

Training at high-volume tertiary care centres would be required for a rural surgeon to achieve the

**Table 3. Patient profile for laparoscopic cholecystectomies performed in Sioux Lookout from 2007 to 2009**

Characteristic	% of patients*
Mean age, yr	32.2
Female:male ratio	3:1
Type 2 diabetes	16
High blood pressure	18
Total cholesterol, mmol/L	4.3

\*Unless otherwise stated.

required number of procedures and to fit well within the regional network and referral patterns. Additionally, annual updates in higher-volume centres may be required for skill and volume supplementation.

Gallbladder disease requiring ERCP intervention is higher in our region for unknown reasons. Our ERCP population rate of 150 in 100 000 is threefold higher than US inpatient rates and is only partially explained by the higher incidence of gallbladder disease.<sup>7</sup>

Although the rate of precholecystectomy ERCP in patients who received surgery in Sioux Lookout was normal at 14%, the total ERCP population rate is 3 times that seen in other populations. Our laparoscopic cholecystectomy numbers are supplemented by patients referred around us directly for ERCP in other centres. The high number of ERCPs includes some retrieval of retained stones from distant surgeries, but primarily comprises an increased incidence of choledocholithiasis in our region. We wonder if genetic, dietary or other mechanisms lead to gallstones entering the common bile ducts more commonly in our population. A local MRCP service might lower the number of suspected cases, but is not economically feasible.

### Limitations

We were able to get accurate data from manual reviews of our own hospital charts. Data gathered electronically from other sites had less oversight. Identification of patients from our typical referral area was made difficult by the presence of a provincial border and recent changes in surgeon staffing levels. Nonetheless, every effort was made to underestimate rather than overestimate the relevant case burden of ERCP work for our program. Ideally, we would like to have had information on the ERCP findings done in the 3 tertiary centres by 4 providers, but those data were not readily available.

The data cited in the literature changed dramatically depending on the year of the surgeries because this field of surgery has been evolving rapidly. Many studies were therefore not used if they occurred before a shift in procedure adoption. Several studies referenced gallbladder disease and others pure rates of laparoscopic cholecystectomies, making comparisons difficult.

### CONCLUSION

The patients in our catchment area who undergo cholecystectomy are young, widely distributed geo-

graphically and require expensive medical transportation for surgical consultations and procedures. These patients require an ERCP intervention at rates several times higher than other populations. From the perspective of both maintenance of surgical competence and best patient care, the volume of ERCPs done on patients in our catchment area of 30 000 justifies the establishment of a rural ERCP program.

**Competing interests:** None declared.

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## The occasional teacher. Part 3: incorporating evidence-based medicine in rural teaching

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*This article has been peer  
reviewed.*

As medical knowledge increases exponentially, it is essential that family physicians develop ways to manage information and base their practices and teaching on the best available evidence. This is easier said than done. Physicians generate many questions in a day's work.<sup>1</sup> The biggest barrier to finding the answers to those questions is time. Even if time is available, the question may remain unanswered because of the way the question is formulated or because the physician does not believe an answer exists.<sup>1,2</sup> However, learners can be a real asset to your practice if you use their information management skills and ask them to find some of those answers for you. Often they will be better at it than you, or, much to your surprise, you may find they are not.

It is acknowledged that for most questions it is unrealistic to go to the original sources. Fortunately, there are many websites and search engines that do the work for us (Table 1). Some of these resources are available online free of charge; others will be accessible through university libraries and professional organizations. For example, the Canadian Medical Association provides its members with access to Ovid MEDLINE, Essential Evidence Plus and The Cochrane Library. Some provincial medical associations also provide free-access websites for information. It will be necessary to obtain user names and passwords to log on to these sites.

It is important to explore the strengths and weaknesses of such resources with students. They should understand that there is a hierarchy of

evidence, with (usually) randomized controlled trials (RCTs) or systematic reviews of RCTs at the top and unsystematic clinical observations at the bottom.<sup>5</sup> You will need to ask the learner where the information came from, what indications of bias there are and if the information pertains to your practice population. Point out that most research originates from tertiary care centres where the patients are highly selected. Rural populations may be poorer, less educated and have different baseline risks than their urban counterparts.

To avoid being swamped by information, make your questions specific. For example, do not ask the student to examine the evidence for screening for cancer, but rather for screening for thyroid cancer in populations living near nuclear power plants. The PICO (Population, Intervention, Comparison, Outcome) structure is a useful tool to formulate a clearly focused clinical question.<sup>4</sup> If possible, the question should pertain to a particular clinical case. Reassure the student that there is no right answer. If you ask a learner to do a search as homework, remember to ask them what they found and if it helped. Neglecting to do this will discourage the student from doing further searches.

If a question comes up in the clinic and you have access to a computer, see if you can answer it using the Internet tools at your disposal. A search on Google and TRIP (Turning Research Into Practice) can often provide a quick answer. Resources that require a little more time to navigate, such as *Clinical Evidence* or Essential Evidence Plus, can

**Table 1. Internet resources for physicians**

Resource	Access
PubMed MEDLINE	Free, pubmed.gov
Ovid MEDLINE	cma.ca, university libraries, subscription
Google/Google Scholar	Free, google.ca, scholar.google.ca
TRIP Database (Turning Research Into Practice)	Free, tripdatabase.com
CMA Infobase: clinical practice guidelines	Free, cma.ca
National Guideline Clearinghouse (US)	Free, guideline.gov
<i>Clinical Evidence</i>	University libraries, subscription
The Cochrane Collaboration	cma.ca, university libraries, subscription
Essential Evidence Plus	cma.ca, university libraries, subscription
UpToDate	University libraries, subscription

CMA = Canadian Medical Association.

also provide quick answers if you are familiar with the resource. Answering questions in the clinic reinforces the relation between learning and daily clinical activities.

Learners are often wedded to guidelines; after all, guidelines can provide rigid solutions to messy situations. Explain the importance of assessing the quality of guidelines — and all the evidence — to your learners. Point out your concerns where guidelines may be misleading or even wrong, and explain your reasoning. Help with assessing the quality of evidence available in several books and websites.<sup>3,4,5</sup> Make your learners aware of the difficulties in applying guidelines to individuals as opposed to populations. One of the most difficult lessons to learn in evidence-based medicine is how to integrate

the best available evidence with clinical expertise and with the patient's preferences and values ... and this is where you can be a valuable role model.

If your local community has evidence-based continuing medical education, such as the Practice Based Small Group (PBSG) Learning Program,<sup>6</sup> be sure to attend with the learner. In witnessing the discussion, the student will come to a fuller understanding of the challenges in applying evidence-based medicine to every patient. This activity will help to set a pattern for lifelong learning.

Although we all aspire to practise evidence-based medicine, reality dictates that sometimes there is no clear answer to our clinical questions. In working with students and enlisting their aid, our practices will become more evidence-based, and the students will see themselves as contributing members of the health care team.

**Competing interests:** None declared.

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## Country cardiograms case 39

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This article has been peer reviewed.

**A** 27-year-old man presents to the emergency department of a rural British Columbia hospital with a 6-hour history of chest pain, preceded by a period of malaise and an upper respiratory infection. He has no significant medical history and has not used cocaine or any other illicit substance. The patient's pain is in the left precordial area and seems to vary with position, so that he prefers to sit bending forward. His vital signs and cardiorespiratory examination are normal.

Results of initial investigations include

a raised troponin-T level of 0.20 µg/L (< 0.03 µg/L: negative for myocardial damage; > 0.10 µg/L: myocardial damage has been detected). The electrocardiogram is shown in Figure 1. The patient is given appropriate treatment, and serial electrocardiograms are taken. One of the electrocardiograms taken the following day is shown in Figure 2.

What is the diagnosis?

**For the answer, see page 70.**

**Competing interests:** None declared.

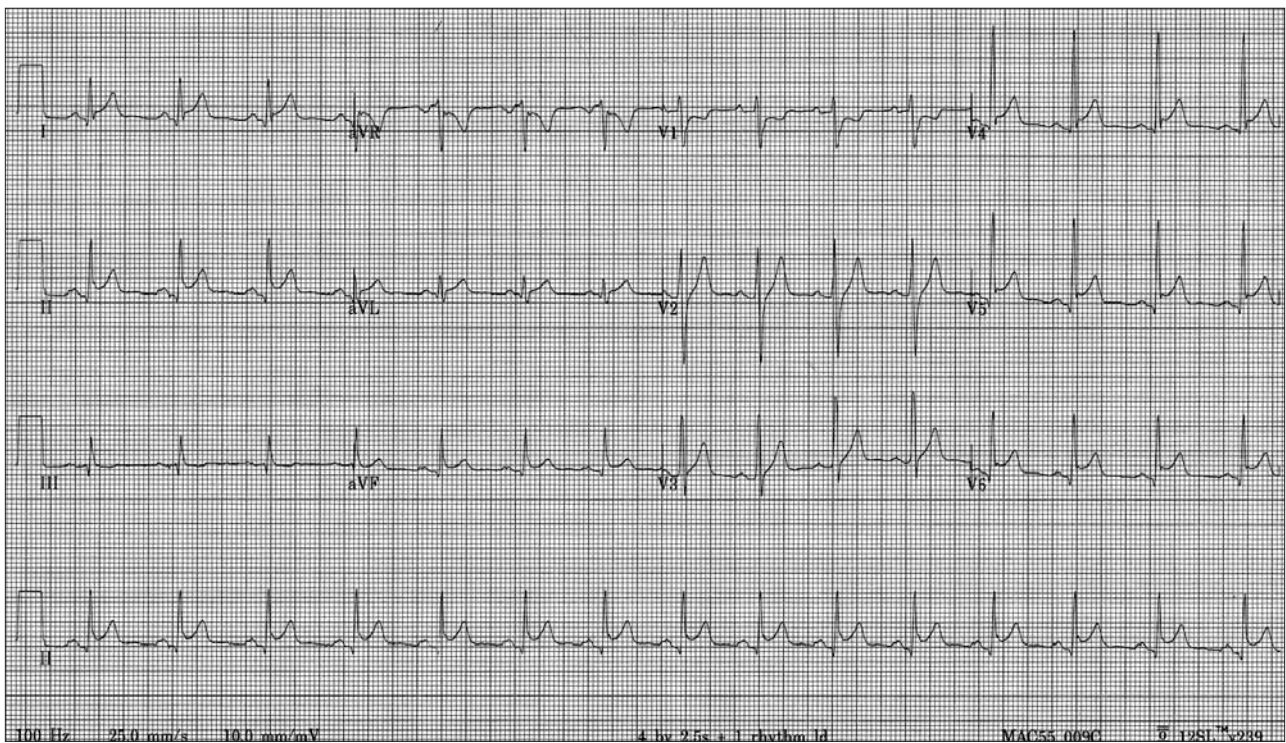


Fig. 1. Electrocardiogram of a 27-year-old man with a 6-hour history of chest pain, preceded by a period of malaise and an upper respiratory infection.

“Country cardiograms” is a regular feature of *CJRM*. We present an electrocardiogram and discuss the case in a rural context. Please submit cases to Suzanne Kingsmill, *CJRM*, 45 Overlea Blvd., P.O. Box 22015, Toronto ON M4H 1N9; cjrm@cjrm.net.

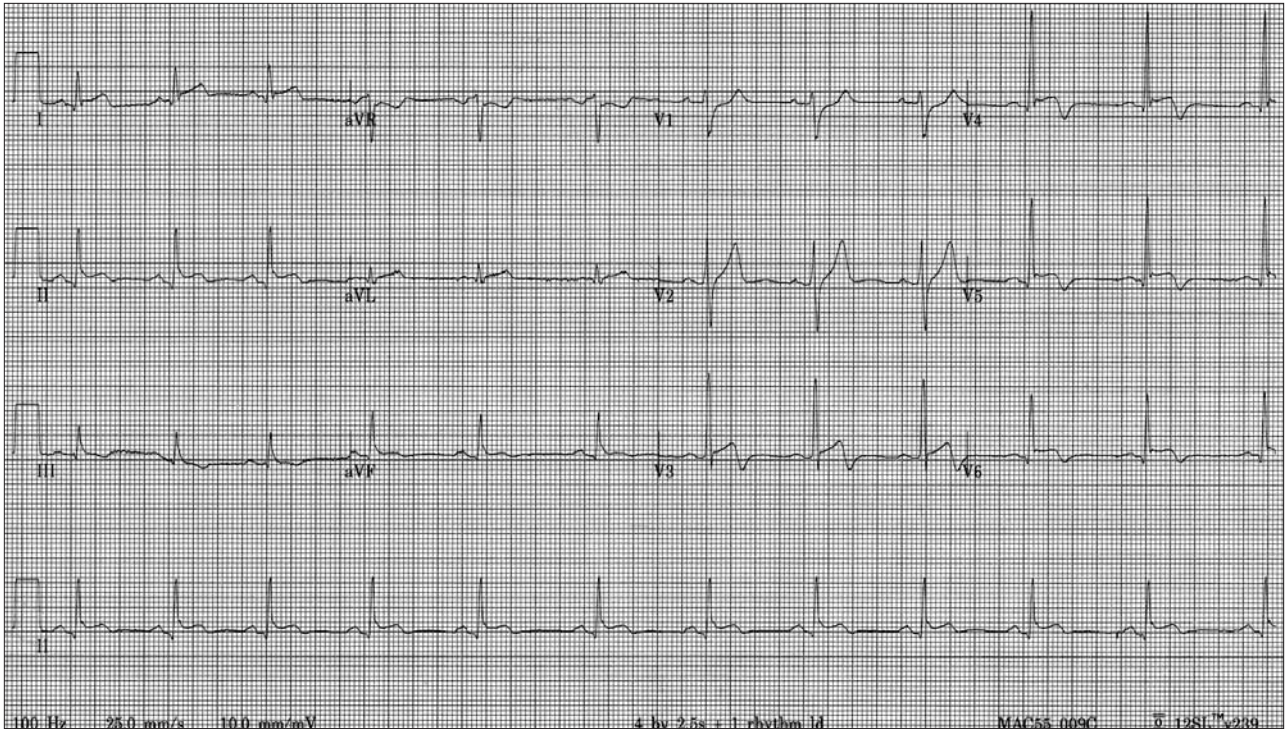


Fig. 2. Electrocardiogram taken the following day.

## Country Cardiograms

Have you encountered a challenging ECG lately?

In most issues of *CJRM* an ECG is presented and questions are asked.

On another page, the case is discussed and the answer is provided.

Please submit cases, including a copy of the ECG, to Suzanne Kingsmill,  
 Managing Editor, *CJRM*, 45 Overlea Blvd., P.O. Box 22015, Toronto ON M4H 1N9;  
 cjrm@cjrm.net

## Cardiogrammes ruraux

Avez-vous eu à décrypter un ECG particulièrement difficile récemment?

Dans la plupart des numéros du *JCMR*, nous présentons un ECG assorti de questions.

Les réponses et une discussion du cas sont affichées sur une autre page.

Veillez présenter les cas, accompagnés d'une copy de l'ECG, à Suzanne Kingsmill, rédactrice  
 administrative, *JCMR*, 45, boul. Overlea, C. P. 22015, Toronto (Ontario) M4H 1N9 ;  
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## Univadis Canada

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Univadis Canada ([www.univadis.ca](http://www.univadis.ca)) is one of a family of physician-oriented websites in different countries sponsored by the Merck pharmaceutical company. Some of the content is uniquely Canadian, whereas some is more international in nature. This article provides a tour of the more useful features of the site.

### HOME PAGE

The home page offers 4 main sections: Search, News, Services and Learning. A Quick Links box (which appears after login) provides rapid access to specific resources. It also displays your local weather forecast.

### SEARCH

The search page allows you to rapidly search all or selected resources on the website. It also searches MEDLINE using PubMed and the Internet using Google. A quick search link is available on the home page. Pull-down menus allow searches to be limited to specific sections. More options are available by clicking on the main Search tab. Both PubMed ([www.pubmed.gov](http://www.pubmed.gov)) and Google ([www.google.ca](http://www.google.ca)) provide more detailed search options than are available on this website.

### ELECTRONIC CPS

Selecting this resource in the search section allows you to search for drug information from the *Compendium of Pharmaceuticals and Specialties* produced by the Canadian Pharmacists Association. In this resource, the search engine recog-

nizes drug names better than medical conditions.

### NEWS

A variety of medical and general news items are displayed on the home page, with Canadian news displayed first. The news display on the home page can be customized by adding and deleting sections, or by changing the order of the sections on the page. If you customize the home page, all news items are still available by clicking on the News tab.

### SERVICES

The Services tab links to the local resources available on the website. Most of these are also available from the Quick Links menu. The most useful links are probably the *Harrison's Principles of Internal Medicine*, the 3D Anatomy and the Image Library.

### LEARNING

This section links to a series of online learning modules from BMJ Learning on a wide range of medical topics. A search window allows you to select courses by specialty, content type or language. Certificates of participation are provided after a module and a posttest case are completed.

### 3D ANATOMY

This resource displays 3-dimensional anatomy images. It is available from the Quick Links or Services menus. It is powerful but complex, so it would be worthwhile to view the introductory

video tutorials provided. Pictures can be printed or saved to a file.

### IMAGE LIBRARY

The Image Library is organized by medical specialty. Pictures can be printed or saved to a PowerPoint slide set. In Windows, individual images can be saved to a local file by right-clicking on the image.

### HARRISON'S PRINCIPLES OF INTERNAL MEDICINE

The full text of this standard textbook is available and can be searched using the Univadis search engine or the search engine provided in the book's home website (AccessMedicine). The AccessMedicine website also provides access to an American drug database, differential diagnoses, clinical practice guidelines and patient education handouts.

### LIBRARY

The Univadis library of online textbooks also contains *Diabetes Mellitus: A fundamental and clinical text* by Derek LeRoith and several Merck manuals. The link to the Merck manuals takes you to the Merck home page. From there, you have to scroll down to the Merck Manuals link at the bottom of the page.

### MEDICAL KNOWLEDGE

This section is a collection of monographs, lectures, clinical cases, electrocardiograms and echocardiograms. The lectures appear to be mainly on diabetes-related topics.

### CONGRESS PLANNER

The Congress Planner searches for conferences by date, specialty, type, country and city. At the time of writing, only 27 Canadian events were listed in the next 3 months. For better Canadian conference information, go to the Doctor's Review website

(www.doctorsreview.com), which listed 96 Canadian conferences for the same period.

### MEDICAL LINKS

The Links section is organized by medical specialty. Precedence is given to the areas of interest specified in a user's registration file.

### TECHNOLOGY CENTRE

This section contains technology information, particularly about using Windows Vista and Microsoft Office 2007 (including Word, PowerPoint and Excel). There was no information about the newer Windows 7 operating system or Microsoft Office 2010.

**Competing interests:** None declared.

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### Resident confidence in obstetrics: Let's get more practice

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It was my fourth shift into a high-volume obstetrics rotation when I finally summoned up the courage to make the big request. Having watched the obstetrician use the Kiwi vacuum twice to deliver reluctant newborns, I was keen to try it myself.

Moir: So, can I try the vacuum?

Obstetrician: Well ... [long pause] I'm not sure how much experience you have. Do you have *any* experience?

Moir: [shorter pause] No, but I've watched at least a dozen (true story).

Obstetrician: Why don't you watch a video we have on vacuum deliveries and then we'll see what happens.

Moir: OK, that sounds great [doing my best to mask dejection and frustration].

Every time I've been asked to step aside in a delivery that requires a vacuum or manoeuvres for a dystocia, I've questioned whether I'll have the courage to do this on my own in 6 months' time. After finding the only VCR in the hospital, I watched the video, and it was helpful. Unfortunately, there were no further vacuum-assisted deliveries that shift.

When I discussed this issue with my fellow residents in the academic days that followed, they echoed similar sentiments. Many had been frustrated when they were asked to step aside during a shoulder dystocia, third-degree repair or vacuum delivery — all important skills we'll require as rural providers of obstetric care. Others worried that they had not participated in enough vaginal deliveries to be proficient. As we neared the end of our residency program, we found we shared our discomfort with certain obstetric skills.

A quick review of the literature

showed that we're not alone. An Ontario-wide study revealed that 69% of graduating family medicine residents felt they had received enough training in intrapartum care.<sup>1</sup> This same study found that only 16% of residents were practising obstetrics 2 years after the end of residency, when 52% had intended to practise it when they began.<sup>1</sup> Given that this study is more than 10 years old, today's reality may be dimmer yet.

As it turned out, I had the good fortune of working with a couple of amazing preceptors who let me use the vacuum and perform a difficult third-degree perineal repair. I'm still on track with my plan to practise obstetrics, and I'm encouraged by the 2009 report *Family Medicine Maternity Care: Implications for the future*.<sup>2</sup> This report addresses many of the above concerns, including a competency-based curriculum that recommends residents complete 50–100 vaginal deliveries during their residency.<sup>2</sup> It also discusses the importance of family medicine residents learning obstetrics from family medicine preceptors. Hopefully, these recommendations are effective in supporting residents interested in obstetrics, and everyone gets a chance to use the vacuum.

**Competing interests:** None declared.

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Please send us your comments and opinions. / Nous serons heureux de recevoir vos commentaires et opinions. Letters to the editor should be addressed to: / Prière de faire parvenir les lettres à la rédaction à l'adresse suivante : *CJRM*, 45 Overlea Blvd., P.O. Box 22015, Toronto ON M4H 1N9; fax 416 961-8271; [cjrm@cjrm.net](mailto:cjrm@cjrm.net)

### THE OCCASIONAL INJECTION FOR TROCHANTERIC BURSTITIS

Thank you for your summary on trochanteric bursitis in the Winter 2011 issue of *CJRM*.<sup>1</sup>

I respectfully submit that evidence is accumulating that injecting corticosteroids for tendinopathies and enthesopathies does not lead to superior outcomes in the long term. In fact, the converse is true. A recent systematic review in *The Lancet* by Coombes and coauthors<sup>2</sup> attests to this.

In the opinion of a growing number of clinicians (myself included), trochanteric “bursitis” as well as other chronic conditions such as Achilles “tendonitis” and supraspinatus “tendonitis” are misnomers. Simply put, there is usually no inflammatory pathophysiology at work (no inflammatory cells are present). The true pathology is degenerative in nature.

Thus, trochanteric bursitis should be seen as an enthesopathy; that is, degeneration of the tendosseous junction of the big hip extensors (such as gluteus maximus) as well as gluteus medius (a hip abductor).

Because there is no true inflammation at work, corticosteroids pose no plausible curative effect in these conditions. What we are observing is short-term gain for (possible) long-term pain as a result of further weakening of collagen fibres in this condition and others.

This was clearly demonstrated in the systematic review by Coombes and colleagues, with poorer outcomes at the 12-month mark compared with other interventions.

Interestingly enough, injections with lidocaine and dextrose (prolotherapy), and sodium hyaluronate were shown to have superior outcomes in the long term.

I can attest to the effectiveness of prolotherapy in my own practice. The curative effects are seen as a result of stimulation of new collagen formation, as well as diminishment of pain because of (postulated) decreases of substance P and calcitonin gene-related peptide.

Hopefully, we will see more studies published in this interesting field. To continue holding up corticosteroid injections as the gold standard injection for any of these degenerative conditions is not supported by evidence.

**W. Francois Louw, MD, CCFP, ECFMG(USA), DA(SA), MBChB(Pret)**

Chisel Peak Medical Clinic, Invermere, BC

### REFERENCES

1. Kelly L, Minty L. The occasional injection for trochanteric bursitis. *Can J Rural Med* 2011;16:20-2.
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### [One of the authors replies:]

We thank Dr. Louw for his comments. We agree with his perspective that “bursitis” is a misnomer. Our paper and those we referenced made it clear that we are injecting an area of function rather than a discrete structure. We also agree that we are very likely dealing at least in part with an enthesopathy.

Whether lidocaine or steroid is the effective agent is unknown. I sometimes do repeat injections with lidocaine alone, but I generally include steroids in the first injection. Some of my colleagues use longer-acting bupivacaine alone or as an adjunct to steroids. Our assessment and injection technique would apply to injections of any ilk.

The November 2010 review by Coombes and colleagues<sup>1</sup> (not published at the time we wrote our article) is very interesting, but does not specifically address the treatment of trochanteric bursitis. It is a systematic review of 3824 studies encompassing 2672 patients with tennis elbow or rotator cuff tendinitis; therefore, a very large series of small studies. The authors concluded that steroid injections were useful in the short term for tennis elbow and lidocaine injections were more useful in the long term for pain reduction. The role of steroids in shoulder injections was deemed unclear.

This review does little to change my practice of using steroids with



a large volume of lidocaine for trochanteric bursitis. I have injected lidocaine alone in the rare patients with persistent symptoms because I see them as unresponsive to steroids.

The assessment and diagnosis of trochanteric bursitis was the thrust of our article. I often see patients who have had unneces-

sary radiographs and even orthopedic referrals for this common condition. Whether the medication used in the injection varies over time because of evolving science is a question that remains to be answered.

**Len Kelly, MD**  
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## REFERENCE

1. Coombes BK, Bisset L, Vicenzino B. Efficacy and safety of corticosteroid injections and other injections for management of tendinopathy: a systematic review of randomised controlled trials. *Lancet* 2010; 376:1751-67.

## INSTRUCTIONS FOR AUTHORS

The *Canadian Journal of Rural Medicine (CJRM)* is a quarterly peer-reviewed journal available in print form and on the Internet. It is the first rural medical journal in the world indexed in Index Medicus, as well as MEDLINE/PubMed databases.

*CJRM* seeks to promote research into rural health issues, promote the health of rural and remote communities, support and inform rural practitioners, provide a forum for debate and discussion of rural medicine, provide practical clinical information to rural practitioners and influence rural health policy by publishing articles that inform decision-makers.

Material in the following categories will be considered for publication.

**Original articles:** research studies, case reports and literature reviews of rural medicine (3500 words or less)

**Commentary:** editorials, regional reviews and opinion pieces (1500 words or less)

**Clinical articles:** practical articles relevant to rural practice. Illustrations and photos are encouraged (2000 words or less)

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**Cover:** artwork with a rural theme

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Hard copies of the manuscript should be double-spaced, with a separate title page containing the authors names and titles and a word count, an abstract of no more than 200 words (for original articles category), followed by the text, full references and tables (each table on a separate page). Reference marks should be typed in the text and enclosed by brackets <1> and listed in the order of appearance at the end of the text and not prepared using electronic EndNotes or Footnotes. The approved style guide for the manuscript is the “Uniform requirements for manuscripts submitted to biomedical journals” (see [www.cmaj.ca/authors/policies.shtml](http://www.cmaj.ca/authors/policies.shtml)).

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## Country cardiograms case 39: Answer

Charles Helm, MD,  
CCFP  
Tumbler Ridge, BC

**F**igure 1 (on page 63) shows a normal sinus rhythm at 90 beats/min. The PR interval, QRS duration, QT interval, QRS axis and P waves are all within normal limits. Slight PR segment depression is present in leads II and V4–V6. Significant ST-segment elevation is seen in leads I, II, aVL, aVF and V4–V6. These raised ST segments have a contour that shows a “concave upwards” pattern. The only leads with ST segment depression are aVR and V1. The T waves appear normal.

Figure 2 (on page 64) shows normal sinus rhythm at a rate of 70 beats/min. The intervals and axis remain normal. ST-segment elevation is still present in the same leads and now includes lead V3. The interval change lies in the T waves, which are now symmetrically inverted in leads V3–V6. QRS morphology is unchanged.

### DISCUSSION

This case displays some of the features of acute pericarditis, along with pitfalls in its diagnosis and potential confusion with the features of acute ST-elevation myocardial infarction (STEMI).

In this case, young age and male sex tend to favour a diagnosis of acute pericarditis (the male to female ratio is about 2:1). So do the history of a possible viral infection and the nature of the pain, which in cases of acute pericarditis typically varies with position (often worse when supine, better when leaning forward). However, this history is not always present, and ischemic pain may also sometimes seem to vary with position. The character of the chest pain is therefore worth enquiring about, but is not diagnostic.

A pericardial friction rub, if heard, is highly specific for acute pericarditis, but may not be present, as in this case. It may also be transient, and may be missed unless frequent auscultation is performed.

Acute pericarditis is one of the causes of elevated troponin levels, which therefore are not of much use in distinguishing it from myocardial damage associated with acute STEMI.

Electrocardiographic changes are consequently of great diagnostic importance, but they are not as straightforward as is sometimes believed.

The presence of ST-segment elevation in many leads, known as the “concave upwards” pattern, is one of the hallmarks of acute pericarditis. This is contrasted with the findings in acute STEMI, in which the pattern of ST-segment elevation corresponds with the area of the affected myocardium, and is typically coved or “convex upwards.” However, the ST-segment elevation in acute pericarditis is often confined to just a few leads.

The absence of reciprocal changes of ST-segment depression in acute pericarditis is another useful distinguishing feature. In contrast, these are often present in an acute STEMI (ST-segment elevation in the inferior leads being matched by reciprocal ST-segment depression in leads I and aVL, and vice versa). However, ST-segment depression is often seen in lead aVR in acute pericarditis, less frequently seen in lead V1 and sometimes seen in lead III; these changes can be safely ignored.

Figure 1 provides an illustration of these changes of acute pericarditis: widespread ST-segment elevation, with the characteristic contour and no reciprocal changes (just ST-segment depression in

leads aVR and VI, which can be discounted).

Downsloping PR-segment depression is often viewed as a further distinguishing feature of acute pericarditis, but may not be present, or may be present to a mild or equivocal degree, as in Figure 1. Acute pericarditis is often best appreciated by looking for PR-segment *elevation* in lead aVR.

The classic sequence of changes in acute pericarditis is then as follows: the ST segments normalize (also known as the phase of pseudonormalization), after which T-wave inversion develops, followed by the final, true normalization phase. However, the phase of T-wave inversion is frequently not noted.

Furthermore, Figure 2 illustrates that even when T-wave inversion is recorded, this typical sequence does not invariably occur: in this case, ST-segment elevation is seen in conjunction with T-wave inversion. Seen in isolation, and in the context of the raised troponin levels, it would be extremely easy to interpret this electrocardiogram as representing an anterolateral STEMI pattern. Only the concomitant ST-segment elevation in leads II and aVF suggests acute pericarditis.

Finally, the absence of evolving Q-wave changes is a feature of acute pericarditis, whereas the devel-

opment of Q waves is typical of an evolving acute STEMI. However, such changes are usually apparent only over a period of time, and thus allow a retrospective diagnosis.

The dangers of misdiagnosing acute pericarditis as acute STEMI are significant. They include the risks in a rural or remote setting of giving thrombolytic therapy to a patient with acute pericarditis. This may lead to the dreaded complication of pericardial effusion developing into a fatal hemorrhagic tamponade.

A complete blood count, testing for levels of C-reactive protein (or other inflammatory markers), chest radiography and echocardiography are recommended in the further workup of a patient with acute pericarditis. Rest and acetylsalicylic acid or non-steroidal anti-inflammatory agents form the only necessary treatment in uncomplicated cases, although colchicine may be effective in symptom management and in decreasing the risks of recurrence.

This patient was observed, treated with rest and ibuprofen, and went on to make a full recovery. Four days after the initial presentation, electrocardiogram results had returned to normal.

**For the question, see page 63.**

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**[Quadrivalent Human Papillomavirus  
(Types 6, 11, 16, 18) Recombinant Vaccine]**

## **i Prescribing Summary**

## **g Patient Selection Criteria**

### **THERAPEUTIC CLASSIFICATION**

Active Immunizing Agent (Suspension for injection)

### **INDICATIONS AND CLINICAL USE**

GARDASIL® is a vaccine indicated in girls and women 9 through 26 years of age for the prevention of infection caused by the Human Papillomavirus (HPV) types 6, 11, 16, and 18 and the following diseases associated with these HPV types:

- Cervical cancer
- Vulvar and vaginal cancers
- Genital warts (condyloma acuminata)
- Cervical adenocarcinoma *in situ* (AIS)
- Cervical intraepithelial neoplasia (CIN) grade 2 and grade 3
- Vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3
- Vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3
- Cervical intraepithelial neoplasia (CIN) grade 1

GARDASIL® is indicated in boys and men 9 through 26 years of age for the prevention of infection caused by HPV types 6, 11, 16, and 18 and genital warts caused by HPV types 6 and 11.

### **Pediatrics (<9 years of age) / Geriatrics (>65 years of age)**

The safety and efficacy of GARDASIL® have not been evaluated in children younger than 9 years and in adults above the age of 26 years.

### **CONTRAINDICATIONS**

- Patients who are hypersensitive to the active substances or to any of the excipients of the vaccine. For a complete listing, see the DOSAGE FORMS, COMPOSITION AND PACKAGING in the Supplemental Product Information.
- Individuals who develop symptoms indicative of hypersensitivity after receiving a dose of GARDASIL® should not receive further doses of GARDASIL®.

### **SPECIAL POPULATIONS**

For use in special populations, see WARNINGS AND PRECAUTIONS, Special Populations.

## **h Safety Information**

### **WARNINGS AND PRECAUTIONS**

#### **General**

As for any vaccine, vaccination with GARDASIL® may not result in protection in all vaccine recipients.

This vaccine is not intended to be used for treatment of active external genital lesions; cervical, vulvar, and vaginal cancers; CIN; VIN; or VaIN.

This vaccine will not protect against diseases that are not caused by HPV.

GARDASIL® has not been shown to protect against diseases due to all HPV types.

As with all injectable vaccines, appropriate medical treatment should always be readily available in case of rare anaphylactic reactions following the administration of the vaccine.

Syncope (fainting) may follow any vaccination, especially in adolescents and young adults. Syncope, sometimes associated with falling, has occurred after vaccination with GARDASIL®. Therefore, vaccinees should be carefully observed for approximately 15 minutes after administration of GARDASIL® (See ADVERSE REACTIONS, Post-Market Adverse Drug Reactions).

Routine monitoring and Pap test should continue to be performed as indicated, regardless of GARDASIL® administration.

### **Febrile Illness**

The decision to administer or delay vaccination because of a current or recent febrile illness depends largely on the severity of the symptoms and their etiology. Low-grade fever itself and mild upper respiratory infection are not generally contraindications to vaccination.

### **Immunocompromised individuals**

Individuals with impaired immune responsiveness, whether due to the use of immunosuppressive therapy, a genetic defect, Human Immunodeficiency Virus (HIV) infection, or other causes, may have reduced antibody response to active immunization (see DRUG INTERACTIONS in the Supplemental Product Information). No specific data are available from the use of GARDASIL® in these individuals.

### **Individuals with Bleeding Disorders**

This vaccine should be given with caution to individuals with thrombocytopenia or any coagulation disorder only if the benefit clearly outweighs the risk of bleeding following an intramuscular administration in these individuals.

### **Special Populations**

The safety, immunogenicity, and efficacy of GARDASIL® have not been evaluated in HIV-infected individuals.

**Pregnant Women:** There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, pregnancy should be avoided during the vaccination regimen for GARDASIL®. For more details see WARNINGS AND PRECAUTIONS, Special Populations in the product monograph.

Merck Frost Canada Ltd. maintains a Pregnancy Registry to monitor fetal outcomes of pregnant women exposed to GARDASIL® vaccine. Patients and health-care providers are encouraged to report any exposure to GARDASIL® vaccine during pregnancy by calling 1-800-567-2594.

**Nursing Women:** It is not known whether vaccine antigens or antibodies induced by the vaccine are excreted in human milk. GARDASIL® may be administered to lactating women. For more details see WARNINGS AND PRECAUTIONS, Special Populations in the product monograph.

### **ADVERSE REACTIONS**

(see Supplemental Product Information for full listing)  
**Adverse Drug Reaction Overview**

In clinical trials, GARDASIL® was generally well tolerated when compared to placebo (Amorphous Aluminum Hydroxyphosphate Sulfate (AAHS) Adjuvant or saline).

#### **Clinical Trial Adverse Drug Reactions**

The most commonly reported vaccine-related injection-site adverse experiences (reported at a greater frequency than that observed among placebo recipients) 1 to 5 days postvaccination, in females 9 through 26 years of age in clinical trials with GARDASIL® (n = 5,088), AAHS Adjuvant-containing placebo (n = 3,470) and saline placebo (n = 320), respectively, were pain (83.9%, 75.4%, 48.6%), swelling (25.4%, 15.8%, 7.3%), erythema (24.7%, 18.4%, 12.1%), pruritus (3.2%, 2.8%, 0.6%) and bruising (2.8%, 3.2%, 1.6%). The most commonly reported vaccine-related systemic adverse experiences (reported at a greater frequency than that observed among placebo recipients) 1 to 15 days postvaccination, in females in clinical trials with GARDASIL® (n = 5,088) and for AAHS Adjuvant and non-AAHS Adjuvant-containing placebo (n = 3,790), respectively, were fever (10.3%, 8.6%), nausea (4.2%, 4.1%) and dizziness (2.8%, 2.6%).

The most commonly reported vaccine-related injection-site adverse experiences (reported at a greater frequency than that observed among placebo recipients) 1 to 5 days postvaccination, in males 9 through 26 years of age in clinical trials with GARDASIL® (n = 3,092), AAHS adjuvant-containing placebo (n = 2,029) and saline placebo (n = 274), respectively, were pain (61.5%, 50.8%, 41.6%), erythema (16.7%, 14.1%, 14.5%) and swelling (13.9%, 9.6%, 8.2%). The most commonly reported vaccine-related systemic adverse experiences (reported at a greater frequency than that observed among placebo recipients) 1 to 15 days postvaccination, in males in clinical trials with GARDASIL® (n = 3,092) and for AAHS

adjuvant- and non-AAHS adjuvant-containing placebo (n = 2,303), respectively, were headache (7.5%, 6.7%) and fever (6.2%, 5.1%). For more details on adverse events reported during clinical trials, see ADVERSE REACTIONS in the Supplemental Product Information.

To report a suspected adverse reaction, please contact Merck Frost Canada Ltd. by:

Toll-free telephone: 1-800-567-2594

Toll-free fax: 1-877-428-8675

By regular mail: Merck Frost Canada Ltd., P.O. Box 1005, Pointe-Claire – Dorval, QC H9R 4P8

## **Administration**

### **DOSAGE AND ADMINISTRATION**

#### **Recommended Dose and Dosage Adjustment**

GARDASIL® should be administered intramuscularly as 3 separate 0.5 mL-doses according to the following schedule:

- First dose: at elected date
- Second dose: 2 months after the first dose
- Third dose: 6 months after the first dose

Individuals are encouraged to adhere to the 0, 2, and 6 months vaccination schedule. However, in clinical studies, efficacy has been demonstrated in individuals who received all 3 doses within a 1-year period. If an alternate vaccination schedule is necessary, the second dose should be administered at least 1 month after the first dose, and the third dose should be administered at least 3 months after the second dose (see CLINICAL TRIALS, Schedule flexibility in the product monograph).

#### **Administration**

GARDASIL® should be administered intramuscularly in the deltoid region of the upper arm or in the higher anterolateral area of the thigh.

GARDASIL® must not be injected intravascularly. Neither subcutaneous nor intradermal administration has been studied. These methods of administration are not recommended.

The prefilled syringe is for single use only and should not be used for more than one individual. For single-use vials, a separate sterile syringe and needle must be used for each individual.

The vaccine should be used as supplied; no dilution or reconstitution is necessary. The full recommended dose of the vaccine should be used.

**Shake well before use:** Thorough agitation immediately before administration is necessary to maintain suspension of the vaccine. After thorough agitation, GARDASIL® is a white, cloudy liquid. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Discard the product if particulates are present or if it appears discolored.

#### **Instructions for Use**

**Single-dose Vial Use:** Withdraw the 0.5 mL dose of vaccine from the single-dose vial using a sterile needle and syringe free of preservatives, antiseptics, and detergents. Once the single-dose vial has been penetrated, the withdrawn vaccine should be used promptly, and the vial must be discarded.

**Prefilled Syringe Use:** Inject the entire contents of the syringe.

For instructions for using the prefilled single-dose syringes preassembled with needle guard (safety) device, see DOSAGE AND ADMINISTRATION, Instructions for Use in the product monograph.

#### **STORAGE AND STABILITY**

Store refrigerated at 2°C to 8°C. Do not freeze. Protect from light. GARDASIL® should be administered as soon as possible after being removed from refrigeration. GARDASIL® can be administered provided total (cumulative multiple excursion) time out of refrigeration (at temperatures between 8°C and 25°C) does not exceed 72 hours. Cumulative multiple excursions between 0°C and 2°C are also permitted as long as the total time between 0°C and 2°C does not exceed 72 hours. These are not, however, recommendations for storage. Discard the product if it is frozen, particulates are present, or if it appears discoloured.

## Supplemental Product Information

### DESCRIPTION

GARDASIL® (Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine) is a recombinant, quadrivalent vaccine that protects against Human Papillomavirus (HPV). It is a sterile liquid suspension prepared from the highly purified virus-like particles (VLPs) of the recombinant major capsid (L1) protein of HPV Types 6, 11, 16, and 18. The L1 proteins are produced by separate fermentations in recombinant *Saccharomyces cerevisiae* (yeast) CANADE 3C-5 (Strain 1895) and self-assembled into VLPs.

### ADVERSE REACTIONS

#### Clinical Trial Adverse Drug Reactions

In 6 clinical trials (5 placebo-controlled), individuals were administered GARDASIL® (n = 13,798) or placebo (n = 11,715) on the day of enrollment, and approximately 2 and 6 months thereafter. GARDASIL® demonstrated a favorable safety profile when compared with placebo (AAHS adjuvant or saline). Few individuals (0.2%) discontinued due to adverse experiences. In all except one of the clinical trials, safety was evaluated using vaccination report card (VRC)-aided surveillance for 14 days after each injection of GARDASIL® or placebo.

The vaccine-related adverse experiences that were observed among recipients of GARDASIL® at a frequency of at least 1.0% and also at a greater frequency than that observed among placebo recipients, in the male and/or female population, are shown in Table 1 and Table 2 of the product monograph.

Of those girls and women who reported an injection site reaction, 94.3% judged their injection-site adverse experience to be mild or moderate in intensity.

Of those boys and men who reported an injection site reaction, 96.4% judged their injection-site adverse reaction to be mild or moderate in intensity.

In addition, bronchospasm was reported very rarely as a serious adverse experience.

#### All-cause Common Systemic Adverse Experiences

All-cause systemic adverse experiences for 9 through 26-year-old recipients of GARDASIL®, that were observed at a frequency of greater than or equal to 1% where the incidence in the vaccine group was greater than or equal to the incidence in the placebo group are shown in ADVERSE REACTIONS, Tables 3-4 of the product monograph.

#### Serious Adverse Experiences in the Entire Study Population

A total of 229 individuals out of 25,513 total individuals (9 through 26-year-old girls and women and 9 through 26-year-old boys and men) who received both GARDASIL® and placebo reported a serious systemic adverse experience following any vaccination visit during the clinical trials for GARDASIL®. Out of the entire study population (25,513 individuals), only 0.04% of the reported serious systemic adverse experiences were judged to be vaccine related by the study investigator. The most frequently reported serious systemic adverse experiences for GARDASIL® compared to placebo and regardless of causality were:

- Headache (0.02% GARDASIL® [3 cases] vs. 0.02% placebo [2 cases]),
- Gastroenteritis (0.02% GARDASIL® [3 cases] vs. 0.01% placebo [1 case]),
- Appendicitis (0.04% GARDASIL® [5 cases] vs. 0.01% placebo [1 case]),
- Pelvic inflammatory disease (0.01% GARDASIL® [2 cases] vs. 0.02% placebo [2 cases]),
- Urinary tract infection (0.01% GARDASIL® [2 cases] vs. 0.02% placebo [2 cases]).

One case (0.01% GARDASIL®; 0.0% placebo) of bronchospasm and 2 cases (0.01% GARDASIL®; 0.0% placebo) of asthma were reported as serious systemic adverse experiences that occurred following any vaccination visit.

In addition, 1 individual in the clinical trials in the group that received GARDASIL® reported two injection-site serious adverse experiences (injection-site pain and injection-site joint movement impairment).

### Deaths

Across the clinical studies, 31 deaths were reported in 25,513 (GARDASIL® N = 13,798; Placebo N = 11,715) male and female individuals 9 through 26 years of age. The events reported were consistent with events expected in healthy adolescent and adult populations. The most common cause of death was motor vehicle accident (5 individuals who received GARDASIL® and 4 individuals who received placebo), followed by drug overdose/suicide (2 individuals who received GARDASIL® and 6 individuals who received placebo), gun shot wound (1 individual who received GARDASIL® and 3 individuals who received placebo), and pulmonary embolus/deep vein thrombosis (1 individual who received GARDASIL® and 1 individual who received placebo). In addition, there were 2 cases of sepsis, 1 case of pancreatic cancer, and 1 case of arrhythmia, and 1 case of traumatic brain injury/cardiac arrest in the group that received GARDASIL®, and 1 case of asphyxia, 1 case of chemical poisoning, and 1 case of myocardial ischaemia in the placebo group.

#### Systemic Autoimmune Disorders

In the clinical studies, male and female individuals ages 9 through 26 were evaluated for new medical conditions that occurred over the course of follow up. New medical conditions potentially indicative of a systemic autoimmune disorder seen in the group that received GARDASIL® or placebo are shown in ADVERSE REACTIONS, Tables 5-6 of the product monograph.

#### Post-Market Adverse Drug Reactions

The following adverse experiences have been spontaneously reported during post-approval use of GARDASIL®. Because these experiences were reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or to establish a causal relationship to vaccine exposure.

Blood and lymphatic system disorders: autoimmune hemolytic anemia, idiopathic thrombocytopenic purpura, lymphadenopathy.

Nervous system disorders: acute disseminated encephalomyelitis, dizziness, Guillain-Barré syndrome, headache, motor neuron disease, paralysis, syncope sometimes accompanied by tonic-clonic movements, transverse myelitis.

Gastrointestinal disorders: nausea, pancreatitis, vomiting.

Musculoskeletal and connective tissue disorders: arthralgia, myalgia.

General disorders and administration site conditions: asthenia, chills, death, fatigue, malaise.

Immune system disorders: hypersensitivity reactions including anaphylactic/anaphylactoid reactions, bronchospasm, and urticaria.

### DRUG INTERACTIONS

#### Drug-Drug Interactions

**Use with Other Vaccines:** Results from clinical studies indicate that GARDASIL® may be administered concomitantly (at a separate injection site) with Menactra® (Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine), Adacel® (Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap)), and RECOMBIVAX HB® (hepatitis B vaccine (recombinant)) (see CLINICAL TRIALS, Studies with Other Vaccines). The frequency of adverse experiences observed, in a placebo-controlled study with concomitant administration with hepatitis B vaccine (recombinant), was similar to the frequency when GARDASIL® was administered alone.

In another placebo-controlled study, there was an increase in injection-site swelling when GARDASIL® was given concomitantly with Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine and Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap). The majority of injection-site swelling adverse experiences were reported as being mild to moderate in intensity.

**Use with Common Medications:** In clinical studies for girls and women (aged 16 to 26 years), 11.9%, 9.5%, 6.9%, and 4.3% of individuals used analgesics, anti-inflammatory drugs, antibiotics, and vitamin preparations, respectively. Conversely in a clinical study in boys and men (aged 16 to 26 years), 10.3%, 7.8%, 6.8%, 3.4% and 2.6% of individuals used analgesics, anti-inflammatory drugs, antibiotics, antihistamines, and vitamin preparations, respectively. The efficacy, immunogenicity, and safety of the vaccine were not impacted by the use of these medications.

**Use with Hormonal Contraceptives:** In clinical studies, 57.5% of women (aged 16 to 26 years) who received GARDASIL® used hormonal contraceptives. Use of hormonal contraceptives did not appear to affect the immune responses to GARDASIL®.

**Use with Steroids:** In clinical studies for girls and women (aged 16 to 26 years), 1.7% (n = 158), 0.6% (n = 56), and 1.0% (n = 89) of individuals used inhaled, topical, and parenteral immunosuppressants, respectively. In a clinical study in boys and men (aged 16 to 26 years), 1.0% (n = 21) used corticosteroids for systemic use. The corticosteroids for all individuals were administered close to the time of administration of a dose of GARDASIL®. These medicines did not appear to affect the immune responses to GARDASIL®. Very few individuals in the clinical studies were taking steroids, and the amount of immunosuppression is presumed to have been low.

**Use with Systemic Immunosuppressive Medications:** There are no data on the concomitant use of potent immunosuppressants with GARDASIL®. Individuals receiving therapy with immunosuppressive agents (systemic doses of corticosteroids, antimetabolites, alkylating agents, cytotoxic agents) may not respond optimally to active immunization (See WARNINGS AND PRECAUTIONS, General).

**Drug-Food and Drug-Herb Interactions:** Interactions with food or herbal products have not been established.

**Drug-Laboratory Interactions:** Interactions with laboratory tests have not been established. There was no evidence from the clinical studies database of impact of GARDASIL® administration on the performance characteristics of the Pap test and some commercially available HPV tests.

### OVERDOSAGE

There have been occasional reports of administration of higher than recommended doses of GARDASIL®. In general, the adverse event profile reported with overdose was comparable to recommended single doses of GARDASIL®. For management of a suspected drug overdose, contact your regional Poison Control Centre.

### DOSAGE FORMS, COMPOSITION AND PACKAGING

GARDASIL® is a sterile preparation for intramuscular administration supplied as a 0.5 mL single-dose vial or a 0.5 mL single-dose prefilled Luer Lock syringe, with or without safety device. After thorough agitation, GARDASIL® is a white, cloudy liquid.

### COMPOSITION

**Active Ingredients:** GARDASIL® is a sterile preparation for intramuscular administration. Each 0.5 mL dose contains approximately 20 µg of HPV 6L1 protein, 40 µg of HPV 11 L1 protein, 40 µg of HPV 16 L1 protein, and 20 µg of HPV 18 L1 protein.

**Inactive Ingredients:** Each 0.5 mL dose of the vaccine contains approximately 225 µg of aluminum (as amorphous aluminum hydroxyphosphate sulphate [AAHS] adjuvant), 9.56 mg of sodium chloride, 0.78 mg of L-histidine, 50 µg of polysorbate 80, 35 µg of sodium borate, and water for injection. The product does not contain a preservative or antibiotics.

### PACKAGING

**Vials:** GARDASIL® is supplied in 3 mL single-dose Type I glass vials containing one 0.5 mL dose of liquid vaccine. GARDASIL® is available in packages of 1 and 10 single-dose vials.

#### Syringes:

• GARDASIL® is supplied in 1.5 mL single-dose Type I glass prefilled Luer Lock syringes, preassembled with an UltraSafe Passive® delivery system, containing one 0.5 mL dose of liquid vaccine in a carton. One needle is provided separately in the carton.

• GARDASIL® is supplied in 1.5 mL single-dose Type I glass prefilled Luer Lock syringes, without safety device, containing one 0.5 mL dose of liquid vaccine in a carton. One needle is provided separately in the carton.

Vials and prefilled syringes components are latex free.

† UltraSafe Passive® delivery system is a Trademark of Safety Syringes, Inc.

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For further information please contact:

**Kerri Balon, Recruitment Coordinator**  
Northern Medical Services  
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Saskatoon, SK S7K 0L4  
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The **ONLY HPV** vaccine indicated for **GENITAL WARTS** in females and males.\*

**INDICATIONS AND CLINICAL USE**

GARDASIL® is a vaccine indicated in girls and women 9-26 years of age, for the prevention of infection caused by the Human Papillomavirus (HPV) types 6, 11, 16 and 18, and the following diseases associated with these HPV types: cervical, vulvar and vaginal cancers, genital warts, cervical adenocarcinoma *in situ* (AIS), cervical intraepithelial neoplasia (CIN) grades 1, 2 and 3, and vulvar and vaginal intraepithelial neoplasia (VIN/VaIN) grades 2 and 3. GARDASIL® is indicated in boys and men 9-26 years of age for the prevention of infection caused by HPV types 6, 11, 16 and 18, and genital warts caused by HPV types 6 and 11.

**SELECTED IMPORTANT SAFETY INFORMATION**

The most commonly reported vaccine-related injection-site adverse experiences in clinical trials with GARDASIL® in females (n = 5,088), amorphous aluminum hydroxyphosphate sulfate (AAHS) adjuvant-containing placebo (n = 3,470) and saline placebo (n = 320), respectively, were pain (83.9%, 75.4%, 48.6%), swelling (25.4%, 15.8%, 7.3%), erythema (24.7%, 18.4%, 12.1%), and pruritus (3.2%, 2.8%, 0.6%). The most commonly reported vaccine-related systemic adverse experience in females was fever: 10.3% for GARDASIL® (n = 5,088) vs 8.6% for AAHS adjuvant- and non-AAHS adjuvant-containing placebo (n = 3,790). The most commonly reported vaccine-related injection-site adverse experiences in clinical trials with GARDASIL® in males (n = 3,092), AAHS adjuvant-containing placebo (n = 2,029) and saline placebo (n = 274), respectively, were pain (61.5%, 50.8%, 41.6%), erythema (16.7%, 14.1%, 14.5%) and swelling (13.9%, 9.6%, 8.2%). The most commonly reported vaccine-related systemic adverse experience in males was headache: 7.5% for GARDASIL® (n = 3,092) vs 6.7% for AAHS adjuvant- and non-AAHS adjuvant-containing placebo (n = 2,303).

This vaccine is not intended to be used for treatment of active external genital lesions; cervical, vulvar or vaginal cancers; CIN, VIN, or VaIN. This vaccine will not protect against diseases that are not caused by HPV. Routine monitoring and Pap test should continue to be performed as indicated, regardless of GARDASIL® administration. Pregnancy should be avoided during the vaccination regimen for GARDASIL®. As for any vaccine, vaccination with GARDASIL® may not result in protection in all vaccine recipients. Syncope (fainting) may follow any vaccination, especially in adolescents and young adults. Syncope, sometimes associated with falling, has occurred after vaccination with GARDASIL®. Therefore, vaccinees should be carefully observed for approximately 15 minutes after administration of GARDASIL®.

PLEASE CONSULT THE ENCLOSED PRESCRIBING INFORMATION FOR INDICATIONS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND DOSING GUIDELINES.

\*Comparative clinical significance has not been established.

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- GENITAL WARTS IN MALES AND FEMALES (only those caused by HPV types 6 and 11 in males)

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See prescribing summary on page 72