Canadian Journal of Rural Medicine

Journal canadien de la médecine rurale

The official journal of the Society of Rural Physicians of Canada

Le journal officiel de la Société de la médecine rurale du Canada

VOLUME 16, NO. 4, FALL 2011

VOLUME 16, Nº 4, AUTOMNE 2011

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Canadian Journal of Rural Medicine
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Journal canadien de la médecine rurale

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Les médecins s'expriment

La parole aux médecins — Lettres à la rédaction — Éditoriaux

Nous invitons les médecins à commenter les questions qui les intéressent. Faites parvenir vos textes à Suzanne Kingsmill, rédactrice administrative, *JCMR*, 45, boul. Overlea, C. P. 22015, Toronto (Ontario) M4H 1N9; cjrm@cjrm.net

Canadian Journal of Rural Medicine | Journal canadien de la médecine rurale

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Higher education versus higher learning for rural practice

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It's that time of year again: new medical students in the mill. In the past, rural doctors could have been excused for not noticing; now, it seems that the ivory tower has moved closer to the country. We in "rural" are getting more exposure, particularly to undergraduate students. Perhaps born of necessity, with not enough space on the "main" campus, distributed medical education is in. What an opportunity — both for us and for them.

Now, for some students this opportunity may be nothing more than a tourist trip into cottage country. However, with the reduction in career flexibility among specialists, distributed education may be the only opportunity that the future ophthalmologist will have to experience the rural side of the telephone. Other students are going rural regardless of what the ivory tower could do to them. However, there are some students who had never thought of rural medicine as a career choice whose eyes will be opened. Rural doctors do things. They are something. They can make a difference.

Postgraduate learners present opportunities for higher-quality rural education. Ignore The College of Family Physicians of Canada's "red book" of standards for a moment, and we can do, and should do, so much better. Recently, my general practitioner obstetrician colleague learned that his first-year resident was interested in rural obstetrics. He started teaching her how to cut, and after about 6 weeks (among a few other things that might be taught in a busy general practice) she was the primary surgeon on a cesarean delivery.

Thirty or more years back in the heyday of rotating internships, teaching procedural skills, including cesareans, was not a huge challenge. The challenge in 2011 is not in teaching procedural skills (although this is important for rural practice) but in keeping the "can do" attitude — in both preceptors and learners — warm during the rest of the learner's rotation.

That is the next step. Now that we have the learners among us we are proving that distributed education is as effective as (and, I dare say, in some ways more effective than) conventional medical education. However, the same old training curriculum for family practice that requires just an overall pass is not good enough for us. With the attitudinal agenda that is taught that general practitioners don't do, say, cesareans, that general surgeons don't pin hips (or do cesareans) and that even (cough) emergency medicine requires additional training, we are setting ourselves up over the generations to be able to do less and less with more and more training. It might be fine for the city (I lack the knowledge to make an informed opinion of that setting), but it serves the rural public poorly.

To counter this, we need to define core skills and abilities. There are specific competencies that every rural doctor needs at the outset. We need a rural medicine postgraduate training curriculum that can train to that higher standard and a few family practice programs that can lead by example. Let's demand it and let's do it. We are ready.

Enseignement supérieur ou apprentissage supérieur pour la pratique rurale

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L'heure de la rentrée a sonné et de nouveaux étudiants en médecine ont franchi les portes des universités. Par le passé, on aurait pu pardonner aux médecins ruraux de ne pas avoir remarqué cette rentrée. Maintenant, il semble que la tour d'ivoire se soit rapprochée de la campagne. On entend de plus en plus parler de nous, du milieu rural, en particulier chez les étudiants de premier cycle. Nécessité oblige — sans doute en raison du manque de place dans les « principaux » campus — l'éducation médicale hors les murs ou « distribuée » est à la mode. C'est une bonne chose d'ailleurs, autant pour nous que pour les étudiants.

Pour certains étudiants, il ne s'agira de rien de plus qu'un séjour à la campagne. Cependant, vu la flexibilité réduite des choix de carrière pour les spécialistes, l'éducation « régionalisée » peut être la seule occasion pour un futur ophtalmologue de découvrir la réalité rurale de sa profession. Certains étudiants choisissent le milieu rural sans égard à ce que la tour d'ivoire pourrait leur apporter. D'autres, toutefois, qui n'avaient jamais envisagé la médecine rurale comme choix de carrière, découvriront cette possibilité. La médecine rurale, ce n'est pas rien. Les médecins en milieu rural ont une pratique dynamique et ils peuvent changer les choses.

La formation des apprenants au niveau postdoctoral offre l'occasion d'offrir un enseignement de haute qualité en milieu rural. Mettez de côté pour le moment le « livre rouge » des normes du Collège des médecins de famille du Canada, et vous verrez que nous pouvons et nous devons faire beaucoup mieux. Récemment, un de mes collègues, un omnipraticien obstétricien, a appris que l'obstétrique en milieu rural intéressait sa résidente de première année. Il a commencé par lui apprendre comment faire une incision (parmi les quelques techniques que l'on peut enseigner à une résidente dans une pratique générale achalandée). Après environ six semaines, elle est devenue la chirurgienne principale pour un accouchement par césarienne.

Voilà une trentaine d'années ou plus, à l'âge d'or des internats par rotation, l'enseignement des techniques d'intervention, y compris les césariennes, ne présentait pas un énorme défi. En 2011, le défi ne réside pas dans l'enseignement des techniques d'intervention (bien que cela soit important pour la pratique en milieu rural), mais dans le maintien de l'attitude du « je peux le faire » — tant chez le précepteur que l'apprenant — tout au long du stage.

C'est là la prochaine étape. Maintenant que nous accueillons des apprenants, nous prouvons que la formation régionalisée est aussi efficace (et j'ose dire, à certains égards, plus efficace) que la formation médicale conventionnelle. Néanmoins, le bon vieux programme de formation en médecine familiale, qui ne demande qu'une note globale de passage, ne nous suffit pas. Vu l'attitude qui prévaut dans l'enseignement, à savoir que les omnipraticiens ne font pas, disons, de césariennes,

que les chirurgiens généraux ne brochent pas les hanches (ou ne font pas de césariennes) et que même (toussotement) la médecine d'urgence nécessite une formation supplémentaire, nous préparons le terrain pour qu'au fil des générations, les médecins soient capables de faire de moins en moins d'interventions avec de plus en plus de formation. Ce modèle peut fort bien être adéquat pour la ville (je n'ai pas les connaissances nécessaires pour émettre une opinion informée à ce sujet), mais il ne convient nullement au milieu rural.

Pour contrer cette lacune, nous devons définir les compétences et les aptitudes de base nécessaires. Un médecin en milieu rural doit posséder, dès le départ, des compétences particulières. Nous avons besoin d'un programme de formation postdoctorale en médecine rurale qui peut former les médecins pour qu'ils atteignent ce niveau supérieur de compétences et de quelques programmes de médecine familiale qui peuvent donner l'exemple. C'est ce que nous devons exiger et ce que nous devons faire. Nous sommes prêts.

Directives aux auteurs

Le *Journal canadien de la médecine rurale (JCMR)* est un trimestriel critiqué par les pairs disponible sur papier et sur Internet. Le *JCMR* est le premier journal de médecine rural au monde à être inscrit dans

Index Medicus et dans les bases de données MEDLINE et PubMed.

Le *JCMR* vise à promouvoir la recherche sur les questions de santé rurale, à promouvoir la santé des communautés rurales et éloignées, à appuyer et informer les praticiens en milieu rural, à offrir une tribune de débat et de discussion sur la médecine rurale, ainsi qu'à fournir de l'information clinique pratique aux praticiens en milieu rural et à agir sur la politique de santé rurale en publiant des articles qui éclairent les décideurs.

On étudiera la possibilité de publier des documents dans les catégories suivantes.

Articles originaux : études de recherche, rapports de cas et analyses critiques d'écrits en médecine rurale (3500 mots ou moins)

Commentaires : éditoriaux, analyses régionales et articles d'opinion (1500 mots ou moins)

Articles cliniques : articles pratiques pertinents pour la pratique en milieu rural. On encourage la présentation d'illustrations et de photos (2000 mots ou moins)

Autres : documents d'intérêt général pour les médecins ruraux (p. ex., voyages, réflexions sur la vie rurale, dissertations). (1500 mots ou moins)

Couverture : œuvre d'art à thème rural

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Les copies papier du manuscrit doivent être dactylographiées à double interligne et doivent comporter une page titre distincte portant le nom et le titre des auteurs et un compte de mots, un résumé d'au plus 200 mots (pour la catégorie articles originaux), suivi du texte, des références complètes et des tableaux (chaque tableau sur une page distincte). Pour les références : inscrire les appels de notes dans le texte entre crochets et énumérer les références à la fin du texte dans l'ordre de leur parution dans le texte. Il ne faut pas utiliser les fonctions Endnotes (notes en fin de texte) ou Footnotes (notes en pied de page) des logiciels. Pour la préparation du manuscrit, suivre le guide stylistique approuvé, soit les «Exigences uniformes pour les manuscrits présentés aux revues biomédicales» (voir www.cmaj.ca/misc/ifora.shtml).

Joindre une lettre d'accompagnement signée par l'auteur correspondant et indiquant que le texte n'a pas été publié ni soumis pour publication ailleurs, et précisez la catégorie dans laquelle il faut étudier l'article. Veuillez produire le nom et les coordonnées d'un éventuel examinateur indépendant de votre travail.

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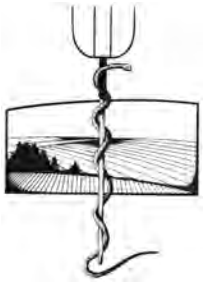

President's message. What if somebody cared?

John Wootton, MD
Shawville, Que.

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Imagine if the following article were to appear in *The New England Journal of Medicine*: "Mortality in Canadian university hospitals higher than in their US counterparts." It would be news! Questions would be asked of the minister of health in the House of Commons. *As it Happens* would interview hospital CEOs. In short, people would care. Excuses would be made. Investments would follow.

This past summer, US rural hospitals were the target of an article published in the *Journal of the American Medical Association* (*JAMA*) with a similar message.[1] Although no comparison between countries was made or implied, the Canadian media quickly made the facile assumption that the findings must also hold true here. The research was done in another country and context of funding and resources, but the findings were extrapolated without scrutiny by Canadian commentators.[2]

Briefly, the study showed that for a number of common conditions (i.e., acute myocardial infarction, pneumonia and congestive heart failure) patients who received treatment at rural critical access hospitals did worse than those who received treatment in a comparison group of hospitals, many of which were larger, urban hospitals with better resources. Critical access hospitals are small hospitals (< 25 acute care beds) that are given this designation to allow them to access cost-based funding rather than diagnosis-related group-based funding. This designation has allowed many such rural hospitals to remain open that otherwise would have been headed for insolvency. The statistical analysis in the *JAMA* article is complex, and critical assessment of its validity is beyond the skills of this writer, but that is not the point.

The point is that the Canadian media assumed the research to be true and, furthermore, assumed it to apply equally to Canadian rural hospitals. The SRPC's staff wondered if we should issue a press release on the issue. We waited for a reaction ... but there was none. There was no outcry from the press or politicians. Why did it seem that nobody cared? Was it perhaps because the quality of care enjoyed by rural Canadians is no one's priority?

Even though an identical study has not been done in Canada, we should care, and we should be asking the hard questions. What research there is in Canada seems to show the opposite: that maternity care, for example, if appropriately organized, is as safe or safer than the same service provided in more centralized settings.[3] But the picture is fragmented and the research in need of updating.

So let's ask the tough questions and challenge the research community to give us some answers. If we don't, we will be the victims of knee-jerk stereotyping, and we will miss an opportunity to advocate for improved resources (if they are found to be needed) or to demonstrate objectively the quality of care that we and our communities know we provide.

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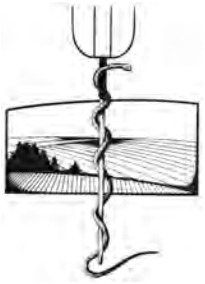

Message du président. Et si la question préoccupait ?

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Imaginez que l'article suivant paraisse dans le *New England Journal of Medicine* : « Les taux de mortalité dans les hôpitaux universitaires sont plus élevés au Canada qu'aux États-Unis. » Voilà qui ferait l'actualité ! On interpellerait la ministre de la Santé à la Chambre des communes. *As it Happens* interviewerait les directeurs généraux des hôpitaux. Autrement dit, la question préoccuperait. Il y aurait des excuses. Des investissements suivraient.

Or, cet été, les hôpitaux ruraux des États-Unis ont été la cible d'un article du *Journal of the American Medical Association (JAMA)* véhiculant un message semblable[1]. Aucune comparaison entre pays n'était faite explicitement ou implicitement dans l'article, mais la presse canadienne a rapidement fait une supposition facile : les constatations devaient être les mêmes de ce côté-ci de la frontière. La recherche avait été effectuée dans un autre pays, dans un différent contexte de financement et de ressources, mais les commentateurs canadiens en ont extrapolé les résultats sans même prendre la peine de les examiner[2].

En deux mots, l'étude montrait que pour un certain nombre de problèmes de santé courants (c.-à-d. infarction aiguë du myocarde, pneumonie et insuffisance cardiaque), les patients traités dans un hôpital rural désigné « d'accès aux soins intensifs » s'en tiraient plus mal que ceux qui avaient été soignés dans un groupe témoin d'hôpitaux urbains, dont un grand nombre étaient plus grands et dotés de meilleures ressources. Les hôpitaux « d'accès aux soins intensifs » sont de petits hôpitaux (moins de 25 lits de soins intensifs) qui sont désignés ainsi pour leur permettre de recevoir du financement en fonction des coûts plutôt qu'en fonction des groupes de diagnostic. La désignation a sauvé un grand nombre de ces hôpitaux ruraux qui se seraient autrement dirigés vers la faillite. L'analyse statistique présentée dans l'article du *JAMA* est complexe et une évaluation critique de la validité des résultats dépasse les compétences de l'auteur du présent message, mais là n'est pas la question.

La question, en l'occurrence, c'est que la presse canadienne a présumé de la validité des résultats de la recherche et a de plus présumé que ces résultats s'appliquaient également aux hôpitaux ruraux canadiens. Le personnel de la SCMR s'est demandé s'il y avait lieu pour la Société de publier un communiqué de presse sur la question. Nous avons attendu une réaction ... mais en vain. Ni la presse ni les politiciens ne sont montés aux barricades. Pourquoi la question semblait-elle laisser tout le monde indifférent ? Était-ce peut-être parce que la qualité des soins dispensés aux Canadiens des régions rurales n'est la priorité de personne ?

Pourtant, même si une étude identique n'a pas été effectuée au Canada, la question devrait nous préoccuper et nous devrions poser les questions difficiles. Le peu de recherche effectué en la matière au Canada semble en fait démontrer le contraire : les soins de maternité en région rurale, par exemple, s'ils sont convenablement organisés, sont aussi sûrs, sinon davantage, que les mêmes services dispensés dans des régions plus centrales[3]. Le portrait

est cependant fragmenté et la recherche a besoin d'une mise à jour.

Prenons donc l'initiative de poser les question difficiles et mettons au défi les chercheurs de nous donner des réponses. Sinon, nous serons victimes de stéréotypes irréfléchis et nous raterons une occasion de préconiser une amélioration des ressources (si elle est justifiée) ou de démontrer objectivement la qualité des soins que nous savons et que nos communautés savent que nous fournissons.

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Original Article
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Accuracy of the Broselow tape in estimating the weight of First Nations children

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Introduction: During resuscitation, the Broselow tape (BT) is the standard method of estimating pediatric weight based on body length. The First Nations population has a higher prevalence of obesity and experiences more injury than the non-First Nations population. The prevalence of obesity has raised the concern that the BT may not accurately estimate weight in this population. The purpose of this study was to validate the BT in 8 First Nations communities.
Methods: We performed a search of the electronic medical records of 2 community health centres that serve 8 local First Nations communities. We searched for the most recent clinic visit during which height and weight had been recorded in the records of patients less than 10 years of age with a postal code indicating residence in a First Nations community. The patients' actual weight was compared with their BT weight estimates using the Bland–Altman method. The Spearman coefficient of rank and percentage error was also calculated.
Results: A total of 243 children were included in the study (119 girls, 124 boys). The mean age was 33.3 months (95% confidence interval [CI] 29.7 to 36.9), mean height was 91.8 cm (95% CI 89.0 to 94.6), mean weight was 16.2 kg (95% CI 15.0 to 17.3) and mean BT weight was 14.0 kg (95% CI 13.1 to 14.8). The Bland–Altman percent difference was 11.9% (95% CI –17.3% to 41.1%). The Spearman coefficient of rank correlation was 0.963 ($p < 0.001$). The BT had a percentage error greater than 10% error 51.8% of the time, with 49.4% being underestimations.
Conclusion: The BT was often not accurate at estimating the weight of children in 8 First Nations communities; it underestimated their weight almost half of the time.

Introduction : Pendant la réanimation, la règle de Broselow est la méthode standard d'estimation du poids de l'enfant en fonction de sa taille. Or, les peuples des Premières Nations présentent une prévalence plus forte de cas d'obésité et sont plus sujets aux blessures, comparativement au reste de la population. Compte tenu de la prévalence de l'obésité, il y a lieu de se demander si la règle de Broselow permet d'estimer avec justesse le poids dans cette population. Cette étude avait pour but de valider la règle de Broselow dans huit communautés autochtones.
Méthodes : Nous avons procédé à une interrogation des dossiers médicaux électroniques de deux centres de santé communautaires desservant huit communautés autochtones locales. Nous avons retracé les visites médicales les plus récentes au cours desquelles la taille et le poids avaient été enregistrés dans les dossiers de patients de moins de dix ans dont le code postal indiquait qu'ils résidaient dans des communautés autochtones. Le poids réel des patients a été comparé aux estimations obtenues selon la règle de Broselow en se basant sur la méthode Bland–Altman. On a également calculé le coefficient de corrélation de Spearman et le pourcentage d'erreur.
Résultats : En tout, l'étude a regroupé 243 enfants (119 filles, 124 garçons). L'âge moyen était de 33,3 mois (intervalle de confiance [IC] à 95 %, 29,7 à 36,9), la taille moyenne était de 91,8 cm (IC à 95 %, 89,0 à 94,6), le poids moyen était de 16,2 kg (IC à 95 %, 15,0 à 17,3) et le poids moyen selon la règle de Broselow était de 14,0 kg (IC à 95 %, 13,1 à

14,8). La différence en pourcentage selon la méthode Bland–Altman était de 11,9 % (IC à 95 %, –17,3 % à 41,1 %). Le coefficient de corrélation de Spearman était de 0,963 (ρ < 0,001). La règle de Broselow affichait un pourcentage d'erreur supérieur à 10 %, dans 51,8 % des cas, dont 49,4 % représentaient des sous-estimations.
Conclusion : La règle de Broselow s'est souvent révélée inexacte lors de l'estimation du poids des enfants de huit communautés autochtones; elle a sous-estimé leur poids près de la moitié du temps.

INTRODUCTION

The Broselow tape (BT) is the standard method for expedient estimation of pediatric weight during resuscitation.[1,2] Accurate measurements of weight are important because appropriate drug doses, energy (joules) used to defibrillate and endotracheal tube sizes are based on weight.[3,4]

Childhood obesity is a growing problem. The World Health Organization has called it a global pandemic and considers it to be a new chronic disease that overshadows all other pediatric diseases.[5,6] The rate of childhood obesity in Canada has been increasing over the past few decades, and up to 1 in 3 children are considered overweight or obese.[7–12]

Multiple studies have attempted to validate the BT in a variety of populations with mixed results.[13–17] A study by Theron and colleagues concluded that the BT underestimates weight for 2 large-for-age ethnic populations, Pacific Islanders and Maoris, the indigenous Polynesian people of New Zealand.[18] The only 2 Canadian studies have shown that the BT underestimates the weight of children living in rural and urban regions.[19,20]

Canada's First Nations population has also been shown to have a higher prevalence of obesity than the non–First Nations population.[21–24] In addition, the First Nations population is more likely to experience traumatic injuries.[25,26] Thus, the BT may underestimate the weight of this high-risk group during resuscitations.

The objective of this study was to determine how accurately the BT estimates the weight of First Nations children in 8 First Nations communities in Ontario.

METHODS

Design and setting

A retrospective chart review was performed using the electronic medical records at 2 health centres that provide medical care to 8 First Nations communities. The Southwest Middlesex Health Centre is located in Mount Bridges and serves the Oneida Nation of the Thames, the Munsee–Delaware Nation and Chippewa of the Thames First Nation. The North Eastern Manitoulin Family Health Team is located on Manitoulin Island. It provides health care to the Wikwemikong, Sheguiandah, Aundeck Omni Kaning, Whitefish River and M'Chigeeng First Nations communities.

Ethics approval was obtained from the University of Western Ontario Health Sciences Research Ethics Board, and band councils consented to the study.

Data collection

Electronic medical records were searched for the most recent clinic visit during which height and weight had been recorded. Inclusion criteria were patients with postal codes matching one of the local First Nations communities and age less than 10 years. Children were excluded if their weight was greater than 35 kg or their length was outside the BT range (< 45.9 cm or > 146.6 cm).

Infants had been weighed in their diapers using an electronic infant scale, and length had been determined using a standard medical measuring tape. Older children had been weighed using a standard beam scale while they were wearing light clothing or underwear, and height had been determined using the same equipment and without shoes.

Statistical analysis

The actual measured weight was compared with the predicted BT weight. A Bland–Altman plot was created to summarize the relation between the 2 methods of measurement, as means with standard deviations. A Spearman coefficient of rank and mean percentage error (PE) was also calculated as a measure of weight discrepancy across all age groups.

Statistical analyses were performed using MedCalc for Windows, version 9.6.0.0.

RESULTS

In total, 243 records were found for children with postal codes belonging to one of the First Nations communities, with age less than 10 years and with body weights and lengths within our inclusion criteria. There were 119 girls (49%) and 124 boys (51%).

The mean age of those included was 33.3 months (95% confidence interval [CI] 29.7 to 36.9), mean height was 91.8 cm (95% CI 89.0 to 94.6), mean actual weight was 16.2 kg (95% CI 15.0 to 17.3) and the mean BT weight was 14.0 kg (95% CI 13.1 to 14.8).

The Bland–Altman mean percentage difference between the BT predicted weight and the actual weight was 11.9% (95% CI –17.3% to 41.1%), indicating an underestimation of the actual weight by the BT (Fig. 1). The Spearman coefficient of rank correlation (rho) was 0.968 ($p < 0.001$), 95% CI 0.959 to 0.975). The BT-estimated weights were within 10% error 43.2% of the time. The percentage error was 10% error or greater 33.3% of the time and was 20% error or greater 18.5% of the time (Table 1). A percentage error of 10% or greater was considered significant.

DISCUSSION

In crisis situations, it is often impossible to determine a pediatric patient's weight by traditional methods. An accurate weight is required for appropriate medication dosing, defibrillation energy (joules) and proper endotracheal tube size.[1–4] As such, a variety of methods have been developed to rapidly estimate a child's body weight.[14,27,28] The BT estimates weight based on a child's supine length and has become the standard of care.[2] The BT has been found to be the most accurate method when compared with other methods of weight estimation.[14] However, the BT was formulated based on 50th-percentile data from a 1970s population of European ancestry. Increasing childhood obesity,[7–12] specifically in First Nations people,[21–24] calls into question the validity of the BT, and one recent study questioned its accuracy in Pacific Island and Maori children.[18]

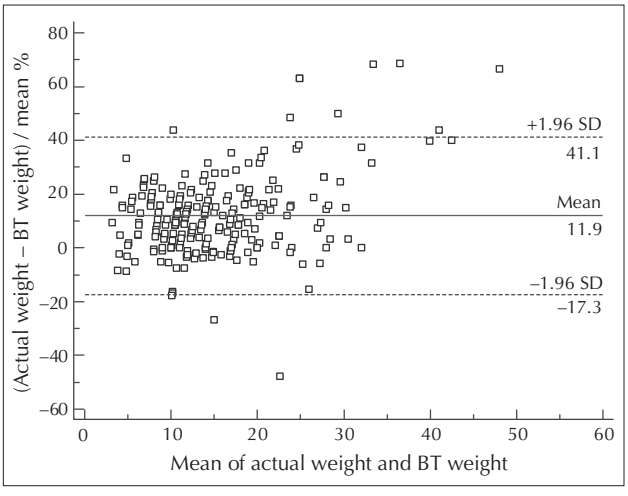

Fig. 1. Bland–Altman graph of percentage differences between actual weight in kilograms and weight in kilograms estimated by the Broselow tape (BT), in 243 children. SD = standard deviation.

Our study found that the BT significantly underestimated the weight of First Nations children almost half (49.4%) of the time. The BT method rarely overestimated the weight of First Nations children (2.4%). This finding is consistent with the results of Theron and colleagues' study, which involved Australia's indigenous populations,[18] and with 2 other Canadian studies that looked at rural and urban populations.[19,20]

This inaccuracy could have serious implications in the care of critically injured or ill First Nations children who present to an emergency department. The doses of resuscitation drugs for children are based on weight. One of the most common errors in pediatric emergency departments is incorrect dosing due to inaccurate weight measurements or estimations.[29] As an example, the Pediatric Advanced Life Support (PALS) guideline recommends a dose of 0.01 mg/kg of adrenaline in certain cases via intravenous or intraosseous infusion.[3] Our study suggests that 49.4% of First Nations children would receive a significantly reduced dose of adrenaline than recommended by the PALS guideline if their weight was estimated using the BT. Although no randomized controlled dosing studies have been done to determine the best dose of adrenaline, it would be best to eliminate any errors if possible. An insufficient drug dose may result in underresuscitation in these children.

Table 1. Percentage error of the Broselow tape in estimating the weight of First Nations children (n = 243)

Percentage error	Under (%)	Over (%)	Total (%)
Exact	—	—	12 (4.9)
< 10%	71 (29.2)	34 (14.0)	105 (43.2)
≥ 10%	77 (31.7)	4 (1.6)	81 (33.3)
≥ 20%	43 (17.7)	2 (0.8)	45 (18.5)
Total	191 (78.6)	40 (16.5)	243 (100.0)

Another life-saving treatment used in the emergency department is defibrillation. The PALS guideline for the amount of joules or energy used in a ventricular fibrillation or pulseless ventricular tachycardia is also a weight-based formula. The PALS manual suggests up to 3 shocks of increasing intensity of 2 J/kg, 2–4 J/kg and 4 J/kg.[3] Our study suggests that one-half of First Nations children would have received lower doses of joules during resuscitation than suggested by the PALS guideline. Although the American Heart Association acknowledges that the safe limits for defibrillation in children are unknown because the evidence is considered poor, the elimination of all potential for errors should be the goal.

A third important resuscitation treatment used in the emergency department is assisted ventilation with the use of endotracheal tubes. The BT method suggests endotracheal tube size based on the estimated weight. Underestimation of a child's weight could result in intubation with an undersized endotracheal tube. It should be noted that the PALS guidelines use an age-based formula for size of endotracheal tubes. Regardless, use of the BT method for selection of endotracheal tubes in First Nations children would lead to an undersized tube size based on our study. Undersized tubes may lead to air leaks, inadequate ventilation and, ultimately, insufficient oxygenation.[13]

The BT was a great advance in standardizing pediatric resuscitation when introduced almost 30 years ago. It reduced the amount of memorization, estimation and calculations needed during critical emergency situations. However, the trend of childhood obesity calls into question the validity of a method based on body length. Various studies in a number of different populations, including those done in Canada, have shown that the BT is not accurate,[19,20] whereas studies done in some specific ethnic populations (India[15] and Korea[16]) have shown the BT still works well. Our results show that the BT underestimates the weight of First Nations children, which is consistent with Theron and colleagues' study involving Australia's indigenous populations.[18] Health professionals should take this into account when faced with the resuscitation of First Nations children.

A study published in 2009 by Yamamoto and colleagues looked at adding a body habitus modifier to the BT.[30] They found this improved accuracy, especially in children over 3 years of age.

One possible solution would be to increase the BT estimates by 12% for the First Nations population. However, a better solution would be to no longer estimate the weight of any children. New technology should be developed that could safely and accurately weigh children who present to the emergency department. This could be combined with computer-assisted algorithms to provide the emergency physician with the correct drug dose, joules for defibrillation and size of endotracheal tube. Then, every child could receive the proper standardized treatment when presenting with a life-threatening illness or critical injury.

Limitations

Limitations of this study include the relatively small sample size compared with other studies. Also, our sample did not involve many children who weighed more than 20 kg. This study assumes that the sample population has the same weight as the population of children who undergo resuscitations, which may or may not be true. In addition, not all First Nations populations may have the same rates of obesity. We looked at 2 medical centres that provided care to 8 First Nations communities, but the external validity to other First Nations communities is not known.

CONCLUSION

Multiple studies have shown that the BT, although the best method currently available for estimating pediatric weight, is not accurate in a variety of populations. Our study adds to the current literature in demonstrating that the BT underestimates weight almost half the time in 8 First Nations communities. Health professionals should consider this information when using the BT for pediatric resuscitation.

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Delivering away from home: the perinatal experiences of First Nations women in northwestern Ontario

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Introduction: Our objective was to understand the perinatal knowledge and experiences of First Nations women from northwestern Ontario who travel away from their remote communities to give birth.
Methods: A systematic review of MEDLINE, HealthSTAR, HAPI, Embase, AMED, PsycINFO and CINAHL was undertaken using Medical Subject Headings and keywords focusing on Canadian Aboriginal (First Nations, Metis and Inuit) prenatal education and care, and maternal health literacy. This qualitative study using semistructured interviews was conducted in a rural hospital and prenatal clinic that serves First Nations women. Thirteen women from remote communities who had travelled to Sioux Lookout, Ont., to give birth participated in the study.
Results: We identified 5 other qualitative studies that explored the birthing experiences of Aboriginal women. The studies documented a negative experience for women who travelled to access intrapartum maternity care. While in Sioux Lookout to give birth, our participants also experienced loneliness and missed their families. They were open to the idea of a culturally appropriate doula program and visits in hospital by First Nations elders, but they were less interested in access to tele-visitation with family members back in their communities. We found that our participants received most of their prenatal information from family members.
Conclusion: First Nations women who travel away from home to give birth often travel great cultural and geographic distances. Hospital-based maternity care programs for these women need to achieve a balance of clinical and cultural safety. Programs should be developed to lessen some of the negative consequences these women experience.

Introduction : Nous voulions chercher à comprendre les connaissances et les expériences périnatales des femmes des Premières nations du Nord-Ouest de l'Ontario qui vont accoucher loin de leur communauté éloignée.
Méthodes : Nous avons effectué une synthèse systématique à partir de MEDLINE, HealthSTAR, HAPI, Embase, AMED, PsycINFO et CINAHL en utilisant les sujets MeSH (*medical subject headings*) et des mots clés portant sur l'éducation prénatale des Canadiennes autochtones (Premières nations, Métisses et Inuites) et la littératie en soins et en santé de la mère. Cette étude qualitative basée sur des entrevues semi-structurées a été effectuée dans un hôpital rural avec clinique prénatale qui dessert les femmes des Premières nations. Treize femmes de communautés éloignées qui s'étaient rendues accoucher à Sioux Lookout (Ont.) ont participé à l'étude.
Résultats : Nous avons trouvé 5 autres études qualitatives explorant les expériences périnatales des femmes autochtones. Les études ont décrit une expérience négative pour les femmes qui se sont déplacées afin d'avoir accès à des soins de maternité intrapartum. Pendant qu'elles étaient à Sioux Lookout pour accoucher, nos participantes ont aussi ressenti de la solitude et leur famille leur manquait. Elles étaient ouvertes à l'idée d'un programme culturellement adapté de doula et de visites à l'hôpital par des aînées des Premières nations, mais les télévisites avec des membres de leur famille dans

leur communauté les intéressaient moins. Nous avons constaté que nos participantes ont reçu la majeure partie de leur information prénatale de membres de leur famille.
Conclusion : Les femmes des Premières nations qui vont accoucher loin de chez elles parcourent souvent de grandes distances culturelles et géographiques. Les programmes de soins de maternité dispensés à ces femmes en milieu hospitalier doivent établir un équilibre entre la sécurité clinique et la sécurité culturelle. Il faut élaborer des programmes pour atténuer certaines des expériences négatives que vivent ces femmes.

INTRODUCTION

Hospital-based maternity care has become the norm in Canada. Because maternity services require many resources, many small rural hospitals can no longer provide maternity care. These closures affect rural women and, in particular, Aboriginal women, who tend to live in remote areas.

Travel to a distant centre, referred to in the literature as "medical evacuation," is controversial for many reasons. For many Aboriginal women, the loss of the community experience of birth is seen as a cultural loss, and forced evacuation is associated with colonial practices.

The return of the birthing experience to remote Inuit communities has been very successful since 1986,[1] and excellent outcomes have been demonstrated in the 3 existing birthing centres without the capability for cesarean delivery.[2] The return of local birthing goes hand in hand with the development of an Aboriginal, community-based midwifery program and appropriate risk assessment and triaging. Inuit women have long been known to have low rates of shoulder dystocia and a rate of cesarean deliveries between 2% and 4%.[2,3]

The experience of First Nations women is not as well explored as that of the Inuit.[4] In northwestern Ontario, we see a rate of cesarean deliveries of 24% (lower than the provincial rate of 28%), the highest rate of smoking in the province and high rates of type 2 diabetes, gestational diabetes and large-for-gestational-age babies in our First Nations population.[5]

The Society of Obstetricians and Gynaecologists of Canada supports the return of the birthing experience to all remote and rural Aboriginal communities "to the extent it is practical and safe."[6] The Sioux Lookout Meno Ya Win Health Centre offers a regional maternity program and strives to be a centre of excellence of Aboriginal health care.[5,7] In conducting this study, we sought to understand the experiences and needs of First Nations women who have travelled for maternity services. A goal of the Sioux Lookout Meno Ya Win Health Centre is to mitigate some of the hardships experienced by these women where possible and provide a culturally safe environment for maternity services.

METHODS

Data sources

We conducted a review of the literature using the following databases: MEDLINE (1966–2010), HealthSTAR (1966–2010), HAPI (1985–2010), Embase (1996–2010), AMED (1985–2010), PsycINFO (1987–2010) and CINAHL (1985–2010). We also searched the *Journal of Aboriginal Health* and the *Journal of Obstetrics and Gynecology*. We used the following Medical Subject Headings: "Indians, North American," "Prenatal care (education/organization and administration/utilization)," "cultural competence," "Inuits" and "Canada." We used the following keywords to better structure the search: "prenatal," "prenatal education," "First Nations," "Aboriginal," "antenatal education" and "maternal health literacy." We searched the *Journal of Aboriginal Health* and the *Journal of Obstetrics and Gynecology* independently, because they are not included in the aforementioned databases.

Participants

In the summer of 2010, a convenience sample of First Nations women from remote communities who had travelled to the Sioux Lookout Meno Ya Win Health Centre to give birth (at 38 weeks) or who had just delivered at the centre were asked to participate in the study. The centre provides health care services in northwestern Ontario for a population of 30 000, over 80% of which is First Nations. The centre's maternity program has around 320 deliveries annually. Travel is federally funded for family-member escorts to accompany the pregnant woman to Sioux Lookout, Ont., only if there are medical complications or if the expectant mother is under 18 years of age.

Data gathering

Semistructured questions were designed by First Nations and non–First Nations researchers. The audiotaped interviews were undertaken in English, with assistance from Oji-Cree interpreters if needed. The 3 interviewers were female and obtained written consent for the interviews, which took place either on the maternity floor or in the prenatal clinic. Near the end of the interviews, we included several specific questions concerning the development of the maternity and prenatal program at the Sioux Lookout Meno Ya Win Health Centre.

Data analysis

Three researchers coded the interviews and analyzed them for common themes using immersion and crystallization techniques.

Ethics approval

The centre's advisor on First Nations health care participated in the study's design and approved the article's final draft and submission for publication. This study received ethics approval from the centre's research review committee.

RESULTS

Literature review

We retrieved 22 articles and reports that discussed prenatal or maternal care among rural or remote indigenous populations, most of which focused on Canadian Aboriginal populations in the far north. Included were 5 qualitative research studies exploring the birthing experiences of Aboriginal women.

A 1993 study in Moose Factory, Ont., explored "dissatisfaction with medical evacuation for childbirth" as portrayed by avoidance to attend prenatal clinics, refusal to leave the community or an unwilling acceptance of a medial evacuation.[8] The authors found that one of the greatest challenges for pregnant woman was leaving behind other young children. Participants experienced loneliness and boredom in hospital and suggested improvement, which included funding for transportation for the partners of all women who travelled to give birth and apartment-type accommodations. After a discussion of the risk of delivering in their community, most participants expressed a preference for hospital-based deliveries.

In 2000, Chamberlain and Barclay interviewed 20 postpartum Inuit mothers about the psychosocial costs of delivering away from their community.[9] These participants were also preoccupied with the family they left behind. Participants documented the costs associated with a distant delivery, which included long-distance phone calls, babysitters and airfare for their partners' travel. They also noted difficulty reintegrating mother and newborn into the community after their (often) 3-week absence.

In a series of West Coast studies from 2005 to 2010 (including a participatory mixed-method study conducted with members of the West Coast Aboriginal community of Heiltsuk), Kornelson and colleagues examined the effects of closures of rural maternity services on rural and First Nations women.[10–12] Although some participants had positive experiences of medical care and accommodations, they also noted social disruption and loneliness. They described how stressful it was to leave their other children behind and the financial costs incurred. The authors spoke of the "cultural and geographic context of the birth experience": participants noted the importance of support from extended family and community and their historic and emotional ties to the land where they live. Participants pointed out the need for adequate social supports for those who travelled for deliveries.

The Sioux Lookout Meno Ya Win Health Centre seeks to bring culturally competent care closer to home through its regional location, traditional programming and 24-hour interpreting services.[7] The studies described above generally document the experiences of parturient women who travelled to distant centres as negative. Our qualitative study sought to understand whether the development of culturally competent programming could mitigate any of these effects.

Delivering away from home

Participant characteristics

About half of the 13 women who participated in our study were primigravida. The participants' ages ranged from 17 to 34 years.

Experience in Sioux Lookout

Not surprisingly, participants were lonely and missed the families they had left behind: "It's kind of lonely when you have nobody around ... nobody to talk to because I hardly know people around here."

"I always need a person to support me during the pregnancy, and leaving my partner behind ... when I leave him behind, it feels different." "The hardest part is not having my (3-year-old) baby here."

Several participants directly mentioned the absence of funding for family escorts in the region: "Another thing that sucks when you come out here is that they don't allow escorts." "My boyfriend took it really hard, he really wanted to be here ... if you're over 18, you don't get an escort, you just come out here by yourself."

Many participants expressed having fear of pain during labour: "You know you are getting close to the date, and you're feeling more nervous or more scared." "I heard 'it hurts ... you're going to be in pain.' ... I was scared and actually hoping for a c-section." "My cousins and friends told me when the baby is coming out, that's when the pain feels worse, so when it happened to me I just decided to keep on pushing."

They usually recounted a positive experience at the hospital: "I just feel more secure ... I feel safe."

Prenatal knowledge

Most participants learned about how to care for themselves during pregnancy from their immediate and extended family, rather than from nurses or physicians. They learned that a healthy diet, exercise and avoiding alcohol and drugs were important: "I had to cut out drinking, that was one of my big accomplishments." "There's a really big pill problem [oxycodone] ... with pregnant ladies, most of them can't stop ... so I didn't quit for me, I quit for my baby." "They always tell me to eat right and don't go crazy on junk food." "My mom suggested being active during pregnancy ... we usually walk most places, so I get quite a bit of exercise like that."

Breastfeeding was commonly encouraged by family and friends: "My boyfriend's mom wouldn't let me buy formula, because she said that babies don't get sick as much and it would help my body get back to normal." "My mom told me if you breastfeed the baby will grow faster."

Traditional teachings were not something many participants acknowledged receiving. It was attested to by only one participant. However, several participants did know of the traditional importance of keeping the detached stump of the umbilical cord: "The elders take a piece, so the child doesn't have that feeling that something is missing." "Once it comes off the baby you wrap it in leather and keep it with the baby."

Almost all of the participants planned on using the traditional cradleboard, the tikinagan: babies are swaddled to the board in a cocooning fashion. "It's better for the baby because the baby feels secure and sleeps longer." "Like when they are inside you, once they come out they still want to be secure." "It helped my boy a lot with him calming down."

Doulas, elder visits and tele-visitation

We asked directed questions about several areas in which the hospital was exploring program development.

Most participants answered positively about the possibility of having First Nations doulas help them through their labour: "That would be good with your first baby as you don't know what you're doing."

They were also generally in favour of having the option of having First Nations elders visit them while they were in Sioux Lookout and in hospital: "I think the elders are important in the community ... it is important that they are able to teach their kids." "The old ways are kind of interesting; it's supposed to be our heritage." "You could balance the old with the new."

A proposal for establishing tele-visitation with family members back home met with divided responses. Those not in favour expressed a general discomfort with the idea mainly because of shyness: "I tried that with my last child. It was embarrassing seeing someone on TV and then they're looking at me ... my kids were all too shy."

DISCUSSION

The other studies we reviewed found parturient women who travelled for delivery struggled with that model of care. Our patients expressed similar feelings. Although women in our study were generally positive about their medical care, they commonly expressed loneliness being away from their family and community members. This finding is in keeping with the social and emotional disruption documented by Kornelson and colleagues in British Columbia.[10–12] The absence of a funded escort program for mothers over the age of 18 was consistently identified as a difficulty. The Society of Obstetricians and Gynaecologists recommends integrating Aboriginal values into the development of programs.[6]

Participants did not report any difficulty in reintegrating into their communities on their return, as Chamberlain and Barclay found in their far north study.[9] The participants in our study generally noted

positive community support for their pregnancies and motherhood.

Lines of questioning about ideas for improvement were not productive. It is unclear whether this was because there was no glaring change identified or the participants felt uncomfortable expressing ideas for improvement.

Because the Sioux Lookout Meno Ya Win Health Centre looks at all fruitful integration of traditional ways into patient care, we asked participants about having a doula program developed. This generally met with positive responses, as did having an elder drop by occasionally. These are program areas now being explored by the centre.

Questions about providing a tele-visitation program for expectant mothers to contact family members back home revealed a negative attitude toward tele-visitation. Shyness was stated as the main concern. This was surprising to some of the researchers, who generally had more experience and comfort with virtual communication in their own professional and personal lives. This attitude is, however, in keeping with regional cultural norms as best we could discern. This finding may change in coming years when virtual communication becomes more common in our region, especially in remote communities.

Limitations

One of the limitations of this study was the difficulty we often encountered in getting participants to fully engage in the interview process. Despite the offer of interpreters, the young women we spoke to were reticent in sharing their feelings. The 3 interviewers were themselves young women, one of whom brought along her own newborn son. None of the interviewers were First Nations, and that may have contributed to awkward communications at times.

Because we used a convenience sampling of 13 women, our sample may not be representative of the population as a whole. As with all qualitative studies, our ability to identify all of the issues participants felt, but did not want to disclose, was a limiting factor. We did reach saturation of information and themes with our present sample, even though it was small. Our findings are not necessarily applicable to other First Nations regions in Canada. Further study to understand attitudes toward tele-visitation may be prudent.

CONCLUSION

Delivering away from home for women from remote First Nations communities places emotional hardship on the mother and her family. Personnel at the medical facilities caring for these patients should understand the perinatal knowledge and emotional needs of these patients and develop culturally appropriate responses. Some of the negative aspects of this experience may be lessened by successful program innovations, which is the intention at our centre. At the policy level, there is a need to understand the implications of the absence of funding for partners or escorts to be present for birthing.

Competing interests: None declared.

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The occasional teacher. Part 5: the learner in difficulty

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One of the greatest challenges for any preceptor is the problem learner. For a community preceptor this can be doubly challenging, because the learner's issues will reflect on your practice and will have a direct impact on a community with which you are integrated on multiple levels. Furthermore, you and your learner may be at a great distance from the university's usual supports. Residents in difficulty are not uncommon; they make up 9% of the resident population.[1] Therefore, it is important to have an approach should the situation arise.

The difficult student is easier to deal with than the challenging resident. Because a student's work is always reviewed, the opportunity to do harm is minimized. However, because residents are expected to work with greater autonomy, their difficulties need prompt recognition and action. Nevertheless, the approach is similar with residents and students.

When a resident's difficulties become apparent, the first question to ask is, "Is this resident dangerous to the health of the patients?" Unfortunately, the answer is not always straightforward. Does error in the dose of a prescription, once, cause alarm? Probably not. However, repeated errors do. How many repeated errors? Good question. If you have concerns regarding the resident's clinical performance, you need to speak to the postgraduate director immediately and receive some guidance. You will have to increase your level of supervision at the very minimum. You may need to enlist the aid of other community physicians who can validate your concerns and help with the increased supervision.

Problems will usually fall into 3 categories: knowledge, attitudes and skills. If you suspect there is a problem, first try to define it. We have always found the approach of Steinert to be helpful.[2] A similar approach can be found on The Alberta Rural Physician Action Plan website.[3] After defining the problem, ask yourself, whose problem is it? If there is a personality conflict, you may actually be the problem or, at least, may be contributing to it. Are you aware of the appropriate level of knowledge expected of residents at various levels of training? Is your work ethic not in step with the resident's, and are you expecting a level of work outside that prescribed by the existing collective agreement? Are things in your life making you irritable and judgmental?

If you are satisfied your contribution to the problem is minimal or nonexistent, discuss with the learner how the learner sees the situation. There may be factors in the learner's life that contribute to the problem: illness in the learner or family, loneliness or discomfort with the level of responsibility they feel expected to shoulder. As a community preceptor, you may also encounter the reluctant resident, who sees his or her community placement as a form of exile, particularly if he or she has had to leave a spouse or family behind. Although you may work out a compromise that minimizes the learner's distress, you can't compromise on the expectations of the rotation.

Also, although the problem may irritate you, consider whether it truly

needs to be resolved. For example, the resident or student may not be as efficient as you would like, but if his or her methodical approach does not endanger the patients, do you need to act, other than to point out that such inefficiency will have a direct impact on future income?

Most issues with learners can be dealt with through day-to-day feedback. However, if you find that a learner is causing you serious concern to the point where they need remediation, contact the postgraduate or undergraduate director immediately. They should be able to provide you with direction on how to proceed and an opportunity to reflect on the issues and their gravity. Remember, if you feel the learner should fail, there are rules in place at the university that must be followed, or the failure will be disallowed. Be aware of your role. You are the student's preceptor; you are not the student's psychotherapist and should not be drawn into counselling the student except where it pertains to education.

Often, difficult learners leave university departments scrambling to devise remediation. Community preceptors may be asked to perform this role. If you are called upon to take a resident or student who has failed a previous rotation, you should first feel comfortable assuming this role. You should read some papers on the difficult learner to develop an approach to the task. Ask the university how they intend to support you in supervising this learner. It is not your responsibility to devise the remedial intervention in solitude.[4] As well, you should be aware of the past difficulties encountered, what remediation has been devised, how this should be implemented and who to contact if things aren't working out. Difficult learners require more time out of your day: Do you have it and can you afford it?

The approach to a learner in serious difficulty requires support at the university level. A community preceptor should not be expected to face this challenge alone but with the support and guidance of the full-time faculty members of the department.

This article is the last in our series on the occasional teacher. Although learners may present the rare challenge, the vast majority are competent, enthusiastic people who will enhance your day and improve care in your community. By hosting learners you will open their eyes to the skills necessary for rural practice. If they eventually practise in an urban setting, they will have an understanding of the challenges of rural physicians. If they choose rural practice, their time with you will have prepared them for their career. And remember, that urban medical student just might become your colleague, because rural student placements are an excellent source for rural physician recruitment.

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Country cardiograms case 41

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A 16-year-old girl who is otherwise healthy reports several episodes of palpitations. She describes a heart rate that is "too fast to count" as well as occasional associated shortness of breath and nausea. The episodes occurred during both rest and activity and ranged from 3 to 10 minutes in duration. Physical examination is normal, and the patient reports taking only oral contraceptive medication (not new) and denies abusing drugs. Results of routine laboratory investigations are normal, including tests of thyroid function. A 24-hour Holter monitor fails to record any episodes. The patient did not have an electrocardiogram (ECG) during any of the episodes; however, a routine ECG has been obtained (Fig. 1). What is the ECG diagnosis?

For the answer, see page 141.

Competing interests: None declared.

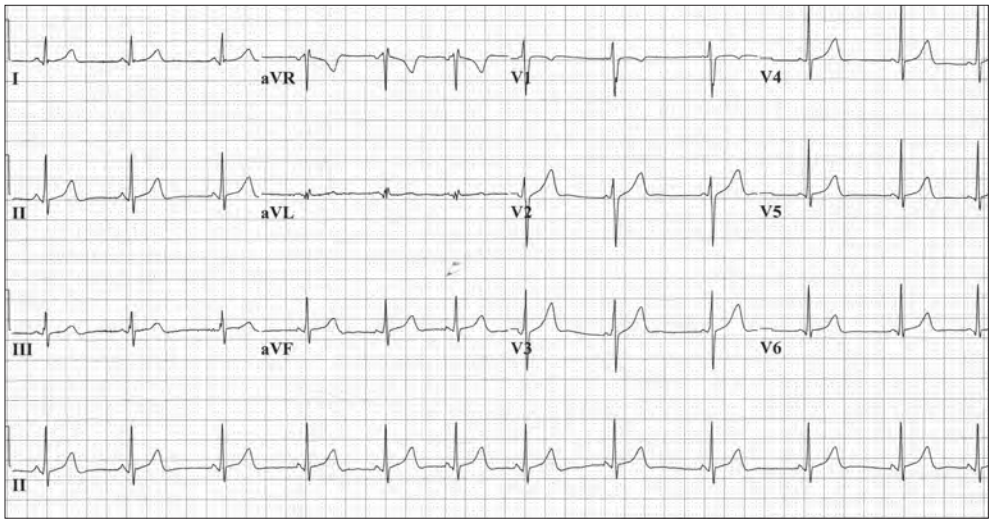

Fig. 1. Routine electrocardiogram of a 16-year-old girl who reports several self-limited episodes of a racing heart rate.

"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.

The Rural Care Needs Index: a potential tool for "have-not" communities

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Since the early 1990s, researchers have attempted to define and measure "rurality" in the context of rural and remote medical care. At a general level, Wootton raised the question of the fit, or lack thereof, between the training of physicians and the dynamics of rural practice.[1] Larsen Soles described the challenge posed by the rural "continuum" (that diversity of places between what we understand to be remote and what we understand to be urban) and how it influences the availability of tools and supports, as well as how one practises.[2] Training and practice were key to Helm's observations about the intimacy of rural practice;[3] Montgomery's review of the personal, community and professional factors that support successful rural practice;[4] and MacLellan's description of how rural Canada "needs the generalist with defined competencies, constantly fluctuating between primary, secondary and tertiary levels of care."[5]

Attempts at measuring rurality from a health care or delivery perspective are similarly important and complex. Pong and Pitblado highlighted how descriptions of over- or underserviced rural areas are challenged by the lack of an objective "optimal ratio" of physicians to patients in different settings.[6] Aird and Kerr critiqued the Rurality Index for Ontario by raising a number of factors not addressed in that ranking system, such as the ability to provide general surgery, obtain locums and access needed equipment.[7]

A benchmark in measuring rurality across British Columbia is the work done by Leduc, who argued for the need "to provide a standard of comparison that can be used by researchers, educators, administrators and rural physicians."[8] Leduc's General Practice Rurality Index comprises a host of variables, including health facilities, staff and equipment; number of general practitioners and specialists; remoteness; availability of transportation; presence and level of training of a range of paramedical support services and staff; community social and economic characteristics; and population levels and characteristics.[8] Olatunde and colleagues' Simplified General Practice Rurality Index focuses on just 3 factors: remoteness from an advanced referral centre, remoteness from a basic referral centre and drawing population.[9]

These authors' work was supported by research at Montana State University that had already concluded how just 2 variables, population and distance to the nearest emergency care facility, were adequate for developing a rurality index.[10] The simplicity of the Montana State University Rurality Index meant that its results were easy to comprehend and readily explained to local residents and decision-makers alike.

EXPECTATION OR NEED FOR RURAL SERVICES

In reviewing the literature, we realized that for all of the complexity found within individual places, these studies had one feature in common: a smaller population conferred a higher degree of rurality. The circumstances we faced in our remote community of Tumbler Ridge, BC, required something different. Our goal was not to measure rurality, but rather to describe a measure that links

the scale of local demand with what services one could expect a community to support — in other words, its need for services. The greater the distance of the rural or remote community from the referral centre and the greater its population, the greater would be such expectation, or need. Thus, population, although inversely proportional to rurality, is directly proportional to the need for rural care in a community of a given remoteness. Our focus on the "demand" aspect of health care needs mirrors earlier articles in *CJRM* on the "supply" aspect of rural practice.[3–6,9]

WHY WERE WE DOING THIS?

Tumbler Ridge, created in 1981, was purpose-built to serve the massive Northeast Coal Project. For its first 2 decades, it was virtually a one-industry town. In 2000, the collapse of the coal industry threatened the community with extinction. Its subsequent survival, reinvention and economic diversification is a success story.

However, this was achieved through what were probably the most intense demographic changes to affect any community in BC in the past decade. Not only were there large fluctuations in population, but owing to a massive housing sale, the influx of retirees and the aging workforce, the proportions of seniors and residents aged 50–65 years rose dramatically. Yet, like many other northern communities, Tumbler Ridge had been designed and built for young families.

Residents and professionals who stayed through these changes noted that the decline in population had led to health service cuts. Despite arguments made by the community, no steps were taken by the regional health authority to address the increases in population and demographic aging. The overall effect was the erosion of services over time.

The Tumbler Ridge Mayor's Task Force on Seniors' Needs recognized that objective evidence was required if the case for enhanced services was to be made. However, the evidence to support the concerns was not readily available. The Community Development Institute at the University of Northern British Columbia was engaged to provide the necessary data and was requested to undertake a comparative study that compared services available in Tumbler Ridge with those in similar communities.[11]

The conclusions and recommendations of this study were to be targeted at local residents, elected officials and administrative staff, and the regional health authority. A simple measure that was easy to comprehend and readily explained was required.

THE RURAL CARE NEEDS INDEX

Consequently, we developed the Rural Care Needs Index (RCNI), which employs just 2 determinants: distance from basic referral centre (km/100) and population size (no./1000).

A community that is 120 km from the nearest referral centre, with a population of 3100, would thus yield an RCNI of 3.72 (1.2×3.1). This index implies that a small, remote community will have a similar RCNI to a community that is larger but proportionately closer to a basic referral centre. Once data were collected for rural communities in northern BC, it became a straightforward process to compare services offered in these communities with reference to their respective RCNIs and to cluster communities with similar RCNIs for comparative purposes.

We recognized that multiple levels may exist at which a rural community could be disadvantaged in Canada. Our comparative study simply attempted to compare "like with like" within the area served by the Northern Health Authority (roughly, the northern two-thirds of the province's land base).

COMPILING THE DATA

The first element in amassing the data involved calculating distance to referral centre and population size to enable the calculation of the RCNI. The second element involved focusing on a comparison of selected care attributes. Combined with the RCNI, this enabled the identification of communities that were underserviced. We selected the following straightforward measurables, believing they were broad in scope and easy to access and comprehend:

- number of physicians
- number of emergency department nurses
- availability of public health nursing
- availability of dentistry
- ability to manage maternity care locally
- level of palliative care provision
- level of emergency care provision
- availability of assisted living services
- availability of local home care services
- level of local ambulance service
- type of medevac transportation service available
- ability of local health facilities to accommodate overnight stays
- availability of social worker services
- availability of counselling services

The entire list of communities was sorted for RCNI, then we examined the cluster of communities with an RCNI immediately above and below

that of Tumbler Ridge. The results portrayed what we had feared: our community appeared to be significantly disadvantaged compared with others of similar population and remoteness. We realized that the RCNI could potentially be used as a tool for other similarly disadvantaged communities.

THE OFFICIAL RESPONSE

The results, conclusions and recommendations were published[11] and presented to the regional health authority. During the study, we had attempted to establish meaningful contact with this authority for data-gathering purposes but had been unsuccessful. The study had, therefore, become more challenging, time-consuming and expensive. After submission of the report, the community waited 20 months for the official response, by which time the data in our comparative study could be criticized for no longer being current.

The official response simply acknowledged receipt of the study and listed services provided to the community. It made no mention of the RCNI, the "like with like" comparison or any comparative data, although these concepts formed the essential theme of the information we had presented.

In this sense, our effort could be construed as a failure. However, we succeeded in obtaining verifiable data that showed significant inequalities in services, and we demonstrated one way by which communities can react to diminishing health services (although our evidence-based approach did not guarantee a positive outcome). Our experience provides a model, through the Tumbler Ridge Mayor's Task Force on Seniors' Needs, of the successful cooperation of elected officials, professionals and community volunteers.

THE RCNI'S POTENTIAL

Rurality is an important concept in rural health care, but it is distinct from the equally relevant concept of rural need. The RCNI has the potential to address this concept. The index addresses equality and fairness, ideas which we think resonate with Canadians. There may be examples of communities with similar RCNIs that merit different levels of service because of specific demographics or unique local factors. However, an acceptance of the RCNI as a measuring tool would mean that such considerations would need to be justified. We suggest that the default position be that communities with similar RCNIs are entitled to similar services and facilities. The required changes may take time, but having such concepts accepted in principle would provide a promising beginning.

We propose 3 caveats to the use of the index:

- We promote the RCNI as a potential tool for "have-not" communities. However, for "have" communities, maintenance of the status quo may be a desirable goal.
- There is more than one type of equality, and, rather than raise the services in communities like Tumbler Ridge to the required RCNI level, a potentially negative outcome or "solution" may be to reduce services in the privileged communities.
- Accepting the concept of the RCNI and thus exposing inequalities in health care delivery will be an unpleasant task for health authorities and may be resisted unless pressure is exerted by groups such as the Society of Rural Physicians of Canada.

CONCLUSION

We believe that the simple formula of the RCNI makes it easily exportable to rural and remote communities across Canada. In order for it to be a relevant, useful tool for disadvantaged communities, we suggest it receive further attention. Leduc's assertion on the need for "a standard of comparison that can be used by researchers, educators, administrators and rural physicians"[8] seems as applicable to rural care needs as to rurality.

Competing interests: None declared.

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Is your computer secure?

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Personal computers are frequently attacked by unwanted software (malware) such as viruses, worms, spyware and Trojan horses that try to load themselves onto your computer without your permission. The best defence is to practise safe computing and to make sure that your security software is up to date.

SAFE EMAIL PRACTICES

User carelessness makes it difficult for even the best security software to function effectively. Most of us have learned to ignore email messages from banks we've never used and from African princes wanting to share their money with us. But malware can also be hidden in messages that seem to come from friends or relatives.

SAFE INTERNET BROWSING

Most browsing programs offer limited protection by blocking some pop-up windows, but some websites have developed ways to display them anyway. If this happens, do not click on anything inside the unwanted window, but try to remove it by clicking the browser's Back control, or clicking on the X in the upper right of the window. If that fails, you may have to shut down your browser or restart your computer

IS YOUR SECURITY SOFTWARE UP TO DATE?

Until recently, I had used the McAfee antivirus program and had it set to update automatically. A recent article in *Consumer Reports* gave it a low rating, so I checked to see if it was up to date. To my surprise, it was 13 months out of date and had not given any warning that my computer was at risk. To check the currency of your own security program, click on its icon on your computer screen. If no icon is available, search in your computer's list of installed programs. In Microsoft Windows, this is available by clicking on the Start button.

GET PROFESSIONAL HELP

I was lucky to be able to get assistance from my university's information technology (IT) department. With my permission, they were able to take over my computer remotely and install new antiviral software and several tools that would scan my computer and repair any existing problems. The IT department in your local health region may be able to provide similar support. This article discusses some of the tools that they used.

SPYBOT

Spybot (www.safer-networking.org/en/index.html) is a free tool that the IT technician recommended to check my computer for malware. It detected and removed a number of unwanted and out-dated items.

CCLEANER

CCleaner (www.piriform.com/ccleaner) is a free tool that can check and clean up your system files, data files and Internet-related files. It can also check and repair your main Registry

file, which may be cluttered with bits left over from old programs that you have long ago deleted. In my case, it found over 800 items that could be deleted from the registry.

MICROSOFT SECURITY ESSENTIALS

The IT technician recommended this free security program from Microsoft (www.microsoft.com/en-us/security_essentials/default.aspx), but my computer refused to install it. This may be because I still have some undetected malware program that is blocking it, or there may have been some conflict with my existing security software. I've since read a review that suggested that it is not as effective as other free programs in detecting and removing threats.

MICROSOFT SAFETY SCANNER

Microsoft has recently provided this tool (www.microsoft.com/security/scanner/en-us/default.aspx) that scanned every file on my computer for threats. The full scan took more than 3 hours, but it detected several Trojan horse threats.

AVG ANTI-VIRUS

After my computer refused to load the Microsoft program, I installed the free version of the AVG antivirus software (free.avg.com/ca-en/homepage). I selected it because it had been highly rated in a recent *Consumer Reports* article and a friend has been happy with the commercial version. My computer is now secure but runs more slowly at times.

AVIRA

Avira is another free antiviral program (www.avira.com/en/avira-free-antivirus) that was scored slightly higher than AVG by *Consumer Reports*. I have not tried it personally.

THE BOTTOM LINE

After you finish reading this article, go to your own computer and check to see if your security software has been updated recently.

Competing interests: None declared.

Rural medicine goes wild

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In the summer of 2007, along with 24 other medical students from McMaster University, I embarked on an adventure — the third annual Wilderness Medicine Elective hosted by the Wilderness Medical Associates.[1] The experience was novel in terms of what I had been exposed to thus far in my medical education. It focused on providing students with the ability to function as physicians with limited resources when encountering patients in austere settings and a delayed time to definitive care.

Three elements — austere environment, sparse resource availability and an extended time to definitive care — serve to identify the field of wilderness medicine.[2–4] Although this branch of medicine is still evolving, it is relevant to those involved in medical rescue, expedition or remote medicine, disaster relief, the military and rural practice. In fact, I view wilderness medicine as an extension of rural medicine. It is a specialized form of medicine that works beyond the boundaries of conventional medical settings (hospitals, outpatient clinics, etc.) and acts more like an advanced form of paramedicine.[5]

Wilderness medicine brings the generalist skill set and knowledge of rural medicine to patients in unconventional settings. This generalist approach, familiar to both wilderness and rural medicine, can be viewed on a spectrum that is differentiated by the availability of resources. On one end we have wilderness medicine, which includes the knowledge and skills of a physician tempered by extremely limited resources. Examples include providing care at the scene of a motor vehicle collision or acting as an expedition physician. On the opposite end of the spectrum is rural medicine, which includes the knowledge and skills of a physician aided by the availability of a greater number of resources. Rural practice in much of the developed world does offer laboratory investigations, radiography and ultrasonography, and casting material, among other resources.

Wilderness medicine, a streamlined form of rural medicine, continues to grow in its appeal to medical professionals.[6] Michael Webster, the executive director of Wilderness Medical Associates, reports that since 2005, 215 medical students have taken part in the annual wilderness medicine elective (personal communication, 2011). This has included medical students from 11 of the 17 Canadian medical schools. In addition, Wilderness Medical Associates has developed a Resident Teaching Program that allows graduates of the elective to develop teaching skills and solidify their knowledge base of wilderness medicine. Beyond these educational opportunities, a number of family medicine residency programs within Canada have offered wilderness medicine training to their residents. These educational experiences typically last for several days and have previously been offered at Memorial University, Queen's University (as outlined during its Canadian Residency Matching Service information session held in February 2010), University of Alberta and University of Calgary.[7–9] This trend in developing educational opportunities in wilderness medicine can complement the skills of rural physicians, giving them greater confidence to tackle patient care in unconventional settings.

As a medical student, my experience with the wilderness medicine elective

solidified my interest in rural family medicine. Furthermore, this experience pushed me toward becoming involved with medical rescue operations, international humanitarian projects and a research initiative focused on exploring the morbidity and mortality associated with outdoor activity within Canadian national parks.

Although wilderness medicine is a relatively unestablished entity in Canada, it is my belief that this field of medicine is relevant to rural medicine, and, in a broader sense, it complements the array of medical care already offered in this country.

Competing interests: None declared.

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Country cardiograms case 41: Answer

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Interpretation of the electrocardiogram (ECG) shown in Figure 1 (on page 133) reveals a sinus arrhythmia — most likely due to changes with respirations — at a rate of about 70 beats/min. Of note is the shortened PR interval (80 [normal 120–200] ms). The QRS is normal in appearance and duration (81 [normal 80–120] ms). The corrected QT interval is also normal (395 ms). No other abnormalities are noted on the ECG.

The clinical presentation and ECG are diagnostic of Lown–Ganong–Levine (LGL) syndrome.[1] Diagnosis of LGL syndrome requires a triad of paroxysmal tachycardia, shortened PR interval and normal QRS duration. It is one of several pre-excitation syndromes, the most common being Wolff–Parkinson–White (WPW) syndrome.[2,3] An isolated short PR interval is relatively common, with a reported prevalence of 2%–4%.[4] In their 1952 study, Lown and colleagues reported tachycardia in 10% of the patients with a shortened PR interval and normal QRS duration.[1] Thus, the frequency of LGL syndrome can be estimated at between 0.2% and 0.4%. It typically occurs in women who are otherwise healthy (71% of cases), who range in age from 10 to 61 years.[1]

The ECG findings in LGL syndrome purportedly result from either an accessory pathway (i.e., para- or extranodal) between atrium and ventricles or an enhanced atrioventricular nodal conduction system (i.e., intranodal). There are several proposed accessory pathways in the syndrome; however, no single anatomic anomaly has been consistently reported. It appears more likely that several distinct structural conduction abnormalities can all lead to this ECG presentation.

Irrespective of the precise location of the accessory pathway, this syndrome differs physiologically from WPW syndrome in the following manner. In LGL syndrome, conduction through the accessory pathway must bypass the intrinsic delay of the atrioventricular node (to produce the shortened PR interval) but it still must activate the ventricles via the bundle of His (to produce a normal QRS complex). In WPW syndrome, the PR interval is shortened by the same mechanism; however, the QRS complex is broad with the classic delta wave. This difference results from the location of the accessory pathway (i.e., the Kent bundle) in WPW syndrome. The Kent bundle bypasses both the atrioventricular node and bundle of His, thus depolarizing the ventricles directly and slightly earlier than the physiologic pathway, producing the delta wave on the ECG. Although they are physiologically different, both syndromes predispose the patient to re-entrant dysrhythmias, including atrioventricular re-entrant tachycardia and atrial fibrillation.

The evidence base is limited with respect to the management of LGL syndrome and associated tachycardia. In patients without atrial fibrillation, some studies have suggested efficacy with β-blockers or calcium channel blockers.[5,6] Cardiac glycosides, including digitalis, have not been shown to be effective.[7] There is theoretical rationale for class I or III antiarrhythmic agents — particularly in the context of atrial fibrillation in a stable patient — but no studies are available. As with WPW

syndrome, cardioversion is the preferred treatment modality in the unstable tachycardiac patient with LGL syndrome. As in WPW syndrome, radiofrequency catheter ablation plays a central role in treatment for patients who are experiencing frequent bothersome or dangerous tachycardia that is unresponsive to pharmacotherapy or for patients who wish to avoid long-term treatment.[8]

Our patient is presently experiencing several episodes of palpitations per month; however, none have been confirmed on ECG. Moreover, none have persisted long enough to enable the patient to present to a local medical clinic or hospital for an ECG. She underwent an exercise stress test to determine whether an event could be precipitated. The patient completed 15 minutes (17.2 MET) of a Bruce protocol and reached target heart rate; however, no dysrhythmia was noted and the patient's symptoms were not reproduced. No further investigation is planned at this time, because the patient's symptoms have become less frequent. However, a reasonable next step would be repeat monitoring with a Holter monitor, a King of Hearts (cardiac event) monitor (Instromedix) or an electrophysiology study. Confirmation and characterization of a tachydysrhythmia is essential before consideration can be given to pharmacologic or ablative treatment. The only report of sudden cardiac death in LGL syndrome was in 2 patients with paroxysmal atrial fibrillation in the original study by Lown and colleagues.[1]

For the question, see page 133.

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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. llustrations and photos are encouraged (2000 words or less)

Off Call articles: a grab-bag of material of general interest to rural doctors (e.g., travel, musings on rural living, essays) (1500 words or less)

Cover: artwork with a rural theme

Manuscript submission

Submit 2 hard copies of the manuscript to the Editor, *Canadian Journal of Rural Medicine,* 45 Overlea Blvd., P.O. Box 22015, Toronto ON M4H 1N9, and an electronic version, preferably by email to cjrm@cjrm.net, or on CD. The preferred electronic version is an older Word format (in doc format such as Word 2003 or older — not docx). Digital art and photos must accompany the manuscript in separate files (see "Electronic figures and illustrations").

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).

Include a covering letter from the corresponding author indicating that the piece has not been published or submitted for publication elsewhere and indicate the category in which the article should be considered. Please provide the name and contact information of a potential independent reviewer for your work.

Electronic figures and illustrations

Illustrations should be in JPG, EPS, TIFF or GIF formats as produced by the camera at a minimal resolution of 300 dpi (typically a 2 mega pixel or better camera for 10 × 15 cm image). Do not correct colour or contrast as our printer will do that. Do not include text or captions in the image. If you need to crop the picture ensure that you save with the highest quality (lowest compression). Do not scan art or reduce the resolution of the photos unless you indicate in the cover letter that you have done so and will also be forwarding high resolution copies on either CD or as camera ready art.

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ZOSTAVAX®

[zoster vaccine live, attenuated (Oka/Merck)]

Prescribing Summary

Patient Selection Criteria

THERAPEUTIC CLASSIFICATION

Live, attenuated virus varicella-zoster vaccine

INDICATIONS AND CLINICAL USE

ZOSTAVAX® is indicated for the prevention of herpes zoster (shingles).

ZOSTAVAX® is indicated for immunization of individuals 50 years of age or older.

SPECIAL POPULATIONS

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

CONTRAINDICATIONS

History of hypersensitivity to any component of the vaccine, including gelatin. History of anaphylactic/anaphylactoid reaction to neomycin (each dose of reconstituted vaccine contains trace quantities of neomycin). Neomycin allergy generally manifests as a contact dermatitis. However, a history of contact dermatitis due to neomycin is not a contraindication to receiving live virus vaccines.

Primary and acquired immunodeficiency states due to conditions such as: acute and chronic leukemias; lymphoma; other conditions affecting the bone marrow or lymphatic system; immunosuppression due to HIV/AIDS; cellular immune deficiencies. Immunosuppressive therapy (including high-dose corticosteroids); however, ZOSTAVAX® is not contraindicated for use in individuals who are receiving topical/inhaled corticosteroids or low-dose systemic corticosteroids or in patients who are receiving corticosteroids as replacement therapy, e.g., for adrenal insufficiency.

Active untreated tuberculosis.

Pregnancy (see WARNINGS AND PRECAUTIONS - Pregnant Women in the Supplemental Product Information).

Safety Information

WARNINGS AND PRECAUTIONS

General

The health care provider should question the patient about reactions to a previous dose of any varicella-zoster virus (VZV)-containing vaccines (see CONTRAINDICATIONS).

As with any vaccine, adequate treatment provisions, including epinephrine injection (1:1000), should be available for immediate use should an anaphylactic/anaphylactoid reaction occur. Deferral of vaccination should be considered in the presence of fever >38.5°C (>101.3°F). ZOSTAVAX® does not protect all individuals against the development of Herpes Zoster or its sequelae. See ACTION AND CLINICAL PHARMACOLOGY and CLINICAL TRIALS in the product monograph.

The duration of protection beyond 4 years after vaccination with ZOSTAVAX® is unknown. The need for revaccination has not been defined.

ZOSTAVAX® has not been studied in individuals who have previously experienced an episode of herpes zoster.

Transmission

In clinical trials with ZOSTAVAX®, transmission of the vaccine virus has not been reported. However, post-marketing experience with varicella vaccines suggests that transmission of vaccine virus may occur rarely between vaccinees who develop a varicella-like rash and susceptible contacts. Transmission of vaccine virus from varicella vaccine recipients who do not develop a varicella-like rash has also been reported and is therefore a theoretical risk for vaccination with ZOSTAVAX®. The risk of transmitting the attenuated vaccine virus to a susceptible individual should be weighted against the risk of developing natural herpes zoster and potentially transmitting wild-type VZV to a susceptible contact.

ADVERSE REACTIONS

Adverse Drug Reaction Overview

In clinical trials, ZOSTAVAX® has been evaluated for general safety in more than 32,000 adults 50 years of age or older. ZOSTAVAX® was generally well tolerated.

ZOSTAVAX® Efficacy and Safety Trial (ZEST) in Subjects 50 to 59 Years of Age

In the ZEST study, subjects received a single dose of either ZOSTAVAX® (n=11,184) or placebo (n=11,212) and were monitored for general safety throughout the study. During the study, a vaccine-related serious adverse experience was reported for 1 subject vaccinated with ZOSTAVAX® (anaphylactic reaction).

All subjects received a vaccination report card (VRC) to record adverse events occurring from Days 1 to 42 postvaccination in addition to undergoing routine safety monitoring throughout the study.

Vaccine-related injection-site and systemic adverse experiences reported at an incidence of ≥1% are shown in Table 1. The overall incidence of vaccine-related injection-site adverse experiences was significantly greater for subjects vaccinated with ZOSTAVAX® versus subjects who received placebo (63.9% for ZOSTAVAX® and 14.4% for placebo).

Table 1: Vaccine-Related Injection-Site and Systemic Adverse Experiences Reported in ≥1% of Adults Who Received ZOSTAVAX® or Placebo (1-42 Days Postvaccination) in the ZOSTAVAX® Efficacy and Safety Trial

Adverse Experience	ZOSTAVAX® (N = 11,094) %	Placebo (N = 11,116) %
Injection-Site		
Pain†	53.9	9.0
Erythema†	48.1	4.3
Swelling†	40.4	2.8
Pruritus	11.3	0.7
Warmth	3.7	0.2
Hematoma	1.6	1.6
Induration	1.1	0.0
Systemic		
Headache	9.4	8.2
Pain in extremity	1.3	0.8

† Designates a solicited adverse experience. Injection-site adverse experiences were solicited only from Days 1-5 postvaccination.

Within the 42-day postvaccination period in the ZEST, noninjection-site zoster-like rashes were reported by 30 subjects (15 for ZOSTAVAX® and 15 for placebo). Of 21 specimens that were adequate for Polymerase Chain Reaction (PCR) testing, wild-type VZV was detected in 10 (3 for ZOSTAVAX®, 7 for placebo) of these specimens. The Oka/Merck strain of VZV was not detected from any of these specimens.

Within the same 42-day postvaccination reporting period in the ZEST, varicella-like rashes were reported by 115 subjects (64 for ZOSTAVAX® and 51 for placebo). Of 21 specimens that were available and adequate for PCR testing, VZV was detected in one of these specimens from the group of subjects who received ZOSTAVAX®; however, the virus strain (wild type or Oka/Merck strain) could not be determined.

Shingles Prevention Study (SPS) in Subjects 60 Years of Age and Older

In the largest of these trials, the Shingles Prevention Study (SPS), 38,546 subjects received a single dose of either ZOSTAVAX® (n=19,270) or placebo (n=19,276) and were monitored for safety throughout the study. During the study, vaccine-related serious adverse experiences were reported for 2 subjects vaccinated with ZOSTAVAX® (asthma exacerbation and polymyalgia rheumatica) and 3 subjects who received placebo (Goodpasture's syndrome, anaphylactic reaction, and polymyalgia rheumatica).

In the Adverse Event Monitoring Substudy, a subgroup of individuals from the SPS (n=3,345 received ZOSTAVAX® and n=3,271 received placebo) were provided vaccination report cards to record adverse events occurring from Days 0 to 42 postvaccination in addition to undergoing routine safety monitoring throughout the study.

Table 2: Number of Subjects with ≥1 Serious Adverse Events (0-42 Days Postvaccination) in the Shingles Prevention Study

Cohort	ZOSTAVAX® n/N %	Placebo n/N %	Relative Risk (95% CI)
Overall Study Cohort			
All ages	255/18671 1.4%	254/18717 1.4%	1.01 (0.85, 1.20)
60-69 years old	113/10100 1.1%	101/10095 1.0%	1.12 (0.86, 1.46)
≥70 years old	142/8571 1.7%	153/8622 1.8%	0.93 (0.74, 1.17)
AE Monitoring Substudy Cohort			
All ages	64/3326 1.9%	41/3249 1.3%	1.53 (1.04, 2.25)
60-69 years old	22/1726 1.3%	18/1709 1.1%	1.21 (0.66, 2.23)
≥70 years old	42/1600 2.6%	23/1540 1.5%	1.76 (1.07, 2.89)

N=number of subjects in cohort with safety follow-up
n=number of subjects reporting an SAE 0-42 Days postvaccination

The incidence of death was similar in the groups receiving ZOSTAVAX® or placebo during the Days 0-42 postvaccination period: 14 deaths occurred in the group of subjects who received ZOSTAVAX® and 16 deaths occurred in the group of subjects who received placebo. The most common reported cause of death was cardiovascular disease (10 in the group of subjects who received ZOSTAVAX®, 8 in the group of subjects who received placebo). The overall incidence of death occurring at any time during the study was similar between vaccination groups: 793 deaths (4.1%) occurred in subjects who received ZOSTAVAX® and 795 deaths (4.1%) in subjects who received placebo.

Vaccine-related injection-site and systemic adverse experiences reported at an incidence ≥1% are shown in Table 3. Most of these adverse experiences were reported as mild in intensity. The overall incidence of vaccine-related injection-site adverse experiences was significantly greater for subjects vaccinated with ZOSTAVAX® versus subjects who received placebo (48% for ZOSTAVAX® and 17% for placebo).

Table 3: Vaccine-Related Injection-Site and Systemic Adverse Experiences Reported in ≥1% of Adults Who Received ZOSTAVAX® or Placebo (0-42 Days Postvaccination) in the Adverse Events Monitoring Substudy of the Shingles Prevention Study

Adverse Experience	ZOSTAVAX® (N = 3345) %	Placebo (N = 3271) %
Injection Site		
Erythema†	35.6	6.9
Pain/tenderness†	34.3	8.6
Swelling†	26.1	4.5
Hematoma	1.6	1.4
Pruritus	7.1	1.0
Warmth	1.7	0.3
Systemic		
Headache	1.4	0.9

† Designates a solicited adverse experience. Injection-site adverse experiences were solicited only from Days 0-4 postvaccination.

The remainder of subjects in the SPS received routine safety monitoring, but were not provided report cards. The types of events reported in these patients were generally similar to the subgroup of patients in the Adverse Event Monitoring Substudy. Within the 42-day postvaccination reporting period in the SPS, the number of reported noninjection-site zoster-like rashes among all subjects was small (17 for ZOSTAVAX®, 36 for placebo; p=0.009). Of these 53 zoster-like rashes, 41 had specimens that were available and adequate for PCR testing. Wild-type VZV was detected in 25 (5 for ZOSTAVAX®, 20 for placebo) of these specimens. The Oka/Merck strain of VZV was not detected from any of these specimens.

The number (n=59) of reported varicella-like rashes was also small. Of these varicella-like rashes, 10 had specimens that were available and adequate for PCR testing. VZV was not detected in any of these specimens. The results of virus testing in subjects with varicella-like and zoster-like rashes should be interpreted with caution due to the number of samples that were not available for testing.

The numbers of subjects with elevated temperature (≥38.3°C [≥101.0°F]) within 7 days postvaccination were similar in the ZOSTAVAX® and the placebo vaccination groups [6 (0.2%) vs. 8 (0.3%), respectively].

Other Studies

In other clinical trials conducted prior to the completion of the SPS, the reported rates of noninjection-site zoster-like and varicella-like rashes within 42 days postvaccination were also low in both zoster vaccine recipients and placebo recipients. Of the 17 reported noninjection-site zoster-like and varicella-like rashes, 10 specimens were available and adequate for PCR testing. The Oka/Merck strain was identified by PCR analysis from the lesion specimens of only two subjects who reported varicella-like rashes (onset on Day 8 and 17).

To address concerns for individuals with an unknown history of vaccination with ZOSTAVAX®, the safety and tolerability of a second dose of ZOSTAVAX® was evaluated. In a placebo-controlled, double-blind study, 98 adults 60 years of age or older received a second dose of ZOSTAVAX® 42 days following the initial dose; the vaccine was generally well tolerated. The frequency of vaccine-related adverse experiences after the second dose of ZOSTAVAX® was generally similar to that seen with the first dose.

Post-Marketing Adverse Drug Reactions

The following additional adverse reactions have been identified during post-marketing use of ZOSTAVAX®. Because these reactions are reported voluntarily from a population of uncertain size, it is generally not possible to reliably estimate their frequency or establish a causal relationship to the vaccine.

Skin and subcutaneous tissue disorders: rash.

Musculoskeletal and connective tissue disorders: arthralgia; myalgia.

General disorders and administration site conditions: injection-site rash; injection-site urticaria; pyrexia; injection-site lymphadenopathy.

Immune system disorders: hypersensitivity reactions including anaphylactic reactions.

To report a suspected adverse reaction, please contact Merck Canada Inc. by:
Toll-free telephone: 1-800-567-2594
Toll-free fax: 1-877-428-8675
By regular mail: Merck Canada Inc., P.O. Box 1005, Pointe-Claire – Dorval, QC H9R 4P8

DRUG INTERACTIONS

Overview

ZOSTAVAX® must not be mixed with any other medicinal product in the same syringe. Other medicinal products must be given as separate injections and at different body sites.

Concurrent administration of ZOSTAVAX® and antiviral medications known to be effective against VZV has not been evaluated.

Use with Other Vaccines

ZOSTAVAX® and PNEUMOVAX® 23 (pneumococcal vaccine, polyvalent, MSD Std.) should not be given concomitantly because concomitant use resulted in reduced immunogenicity of ZOSTAVAX® (see CLINICAL TRIALS in the product monograph).

Administration

DOSAGE AND ADMINISTRATION

(see Product Monograph for complete information)
Recommended Dose and Dosage Adjustment
FOR SUBCUTANEOUS ADMINISTRATION.

Do not inject intravascularly.

Individuals should receive a single dose consisting of the entire content of the vial (approximately 0.65 mL).

ZOSTAVAX® is not a treatment for zoster or postherpetic neuraligia (PHN). If an individual develops herpes zoster despite vaccination, active current standard of care treatment for herpes zoster should be considered.

At present, the duration of protection after vaccination with ZOSTAVAX® is unknown. In the Shingles Prevention Study (SPS), protection was demonstrated through 4 years of follow-up. The need for revaccination has not yet been defined.

Reconstitute immediately upon removal from the freezer.

To reconstitute the vaccine, use only the diluent supplied, since it is free of preservatives or other antiviral substances which might inactivate the vaccine virus.

Vial of diluent:

To reconstitute the vaccine, first withdraw the entire contents of the diluent vial into a syringe.

To avoid excessive foaming, slowly inject all of the diluent in the syringe into the vial of lyophilized vaccine and gently agitate to mix thoroughly. Withdraw the entire contents into a syringe, and using a new needle, inject the total volume of reconstituted vaccine subcutaneously, preferably into the upper arm - deltoid region.

IT IS RECOMMENDED THAT THE VACCINE BE ADMINISTERED IMMEDIATELY AFTER RECONSTITUTION, TO MINIMIZE LOSS OF POTENCY. DISCARD RECONSTITUTED VACCINE IF IT IS NOT USED WITHIN 30 MINUTES.

Do not freeze reconstituted vaccine.

CAUTION: A sterile syringe free of preservatives, antiseptics, and detergents should be used for each injection and/or reconstitution of ZOSTAVAX® because these substances may inactivate the vaccine virus.

It is important to use a separate sterile needle and syringe for each patient to prevent transfer of infectious agents from one individual to another.

Needles should be disposed of properly.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. ZOSTAVAX® when reconstituted is a semi-hazy to translucent, off white to pale yellow liquid.

OVERDOSAGE

There are no data with regard to overdose.

For management of a suspected drug overdose, contact your regional Poison Control Center.

STORAGE AND STABILITY

Storage

ZOSTAVAX® **SHOULD BE STORED FROZEN** at an average temperature of -15°C or colder until it is reconstituted for **injection** (see DOSAGE AND ADMINISTRATION). Any freezer, including frost-free, that has a separate sealed freezer door and reliably maintains an average temperature of -15°C or colder is acceptable for storing ZOSTAVAX®. The diluent should be stored separately at room temperature (20 to 25°C) or in the refrigerator (2 to 8°C). Do not store the diluent in a freezer.

Before reconstitution, protect from light.

DISCARD IF RECONSTITUTED VACCINE IS NOT USED WITHIN 30 MINUTES.

DO NOT FREEZE THE RECONSTITUTED VACCINE.

Study References

References:

1. National Advisory Committee on Immunization. Update on varicella. CCDR 2004;30(ACS-1):1-28.
2. Oxman MN. Clinical manifestations of herpes zoster. In: Arvin AM, Gershon AA, editors. Varicella-zoster virus virology and clinical management. Cambridge Press 2000:246-75.
3. Data on file, Merck Canada Inc.: Product Monograph. ZOSTAVAX®, 2011.

Supplemental Product Information

WARNINGS AND PRECAUTIONS

Special Populations

Geriatric: The mean age of subjects enrolled in the largest (N=38,546) clinical study of ZOSTAVAX® was 69 years (range 59-99 years). Of the 19,270 subjects who received ZOSTAVAX®, 10,378 were 60-69 years of age, 7,629 were 70-79 years of age, and 1,263 were 80 years of age or older. ZOSTAVAX® was demonstrated to be generally safe and effective in this population.

Pregnant Women: There are no studies in pregnant women. It is also not known whether ZOSTAVAX® can cause foetal harm when administered to a pregnant woman or can affect reproduction capacity. However naturally-occurring varicella-zoster virus infection is known to sometimes cause foetal harm. Therefore, ZOSTAVAX® should not be administered to pregnant women; furthermore, pregnancy should be avoided for three months following vaccination (see CONTRAINDICATIONS).

Nursing Women: It is not known whether VZV is secreted in human milk. Therefore, because some viruses are secreted in human milk, caution should be exercised if ZOSTAVAX® is administered to a nursing woman.

Pediatrics: ZOSTAVAX® is not recommended for use in this age group.

HIV-AIDS Patients: The safety and efficacy of ZOSTAVAX® have not been established in adults who are known to be infected with HIV with or without evidence of immunosuppression (see CONTRAINDICATIONS).

Immunocompromised Subjects: Data are not available regarding the use of ZOSTAVAX® in immunocompromised subjects (see CONTRAINDICATIONS).

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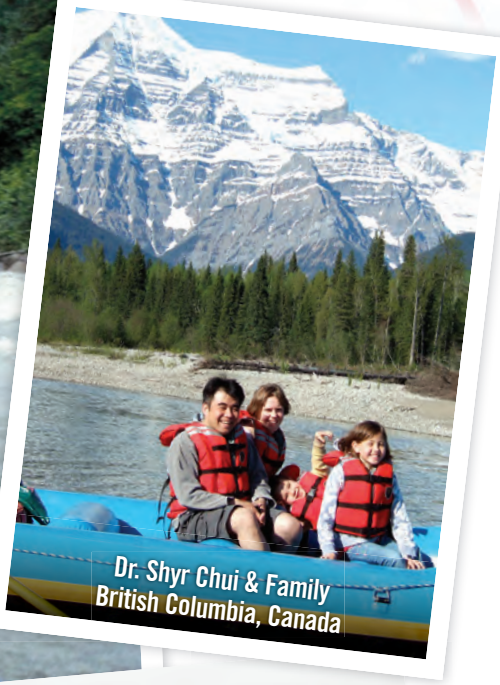

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Approximately 95% of Canadian adults have had chickenpox and are therefore at risk for herpes zoster[1]

A DISEASE THAT MAY CAUSE BURNING, STABBING, SEARING PAIN[2]*

And there is no way to predict who will develop herpes zoster[3]

INDICATIONS AND CLINICAL USE

ZOSTAVAX® is indicated for the prevention of herpes zoster (shingles) in individuals 50 years of age or older.

SELECTED IMPORTANT SAFETY INFORMATION

ZOSTAVAX® is not a treatment for zoster or postherpetic neuralgia (PHN). If an individual develops herpes zoster despite vaccination, active current standard of care treatment for herpes zoster should be considered. Vaccination with ZOSTAVAX® may not result in protection of all vaccine recipients. ZOSTAVAX® is contraindicated in patients with a history of hypersensitivity to any component of the vaccine, including gelatin; a history of anaphylactic/anaphylactoid reaction to neomycin; primary and acquired immunodeficiency states due to conditions such as: acute and chronic leukemias; lymphoma; other conditions affecting the bone marrow or lymphatic system; immunosuppression due to HIV/AIDS, cellular immune deficiencies; immunosuppressive therapy (including high-dose corticosteroids); active untreated tuberculosis; pregnancy. In clinical trials, ZOSTAVAX® has been evaluated for general safety in more than 32,000 adults 50 years of age or older. ZOSTAVAX® was generally well tolerated. Vaccine-related injection-site and systemic adverse experiences reported at an incidence ≥1% are shown below. The overall incidence of vaccine-related injection-site adverse experiences was significantly greater for subjects vaccinated with ZOSTAVAX® versus subjects who received placebo (48% for ZOSTAVAX® and 17% for placebo among recipients aged ≥60 (Shingles Prevention Study [SPS]) and 63.9% for ZOSTAVAX® and 14.4% for placebo among recipients aged 50-59) (ZOSTAVAX® Efficacy and Safety Trial [ZEST]). Vaccine-related injection-site and systemic adverse experiences reported in ≥1% of adults who received ZOSTAVAX® (N=3,345) or placebo (N=3,271) (0-42 Days Postvaccination) in the Adverse Event Monitoring Substudy of the SPS were: erythema† (35.6%, 6.9%), pain/tenderness† (34.3%, 8.6%), swelling† (26.1%, 4.5%), hematoma (1.6%, 1.4%), pruritus (7.1%, 1.0%), warmth (1.7%, 0.3%), headache (1.4%, 0.9%). Most of these adverse experiences were reported as mild in intensity. The remainder of subjects in the SPS received routine safety monitoring, but were not provided report cards. The types of events reported in these patients were generally similar to the SPS subgroup of patients in the Adverse Event Monitoring Substudy. Vaccine-related injection-site and systemic adverse experiences reported in ≥1% of adults who received ZOSTAVAX® (N=11,094) or placebo (N=11,116) (1-42 Days Postvaccination) in the ZEST were: pain† (53.9%, 9.0%), erythema† (48.1%, 4.3%), swelling† (40.4%, 2.8%), pruritus (11.3%, 0.7%), warmth (3.7%, 0.2%), hematoma (1.6%, 1.6%), induration (1.1%, 0.0%), headache (9.4%, 8.2%), pain in extremity (1.3%, 0.8%).

ZOSTAVAX®

[zoster vaccine live, attenuated (Oka/Merck)]

THE FIRST AND ONLY VACCINE INDICATED TO HELP PREVENT HERPES ZOSTER IN INDIVIDUALS 50 YEARS OF AGE OR OLDER

* ZOSTAVAX® is not indicated to reduce the morbidity and complications associated with herpes zoster.

† Designates a solicited adverse experience. Injection-site adverse experiences were solicited only from Days 0-4 postvaccination in SPS and from Days 1-5 postvaccination in ZEST.

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See prescribing summary on page 144