One Arm or Two? Concurrent Administration of Meningococcal C Conjugate and Hepatitis B Vaccines in Pre-teens

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ABSTRACT

Background: The purpose of this study was to: a) compare rates of local reactions from meningococcal C conjugate (Neis Vac-C®) and hepatitis B vaccines (Recombivax HB®), and b) compare local reactions when both injections were given in one arm versus one in each arm.

Methods: Schools were randomized to have grade six students receive both vaccines in one arm (One Arm Group), or one vaccine in each arm (Two Arm Group; MCC always given in left arm). Structured telephone interviews of parents were conducted, and respondents were asked about local and systemic reactions, interference with school or other activities, need for medical attention, and lost parental work time.

Findings: The Two Arm Group reported significantly more local redness >46 mm (6.5% vs. 0.5%, $p<0.001$), moderate to severe tenderness (28% vs. 18%, $p<0.05$), and drowsiness (14% vs. 7%, $p<0.05$). When adjusted for sex, ethnicity, and town of residence, report of any tenderness was associated with town of residence only; moderate or severe tenderness was independently associated with the Two Arm Group (OR 1.4, 95% CI 1.1-1.85). There were no statistically significant differences between groups for interference with school attendance or other activities, need for medical attention, or lost parental work time. Among participants of the Two Arm Group (188 students), there was more redness (6% vs. 2%, $p<0.05$) and tenderness (54% vs. 32%, $p<0.001$) experienced with Neis Vac-C® than with Recombivax HB®, respectively.

Conclusions: Injecting two vaccines in one arm did not cause more local reaction than one injection in each arm and remains an option for those who prefer it for logistical reasons. If vaccinating in two arms, Neis Vac-C® should preferentially be given in the non-dominant arm.

Key words: Meningococcal vaccine; hepatitis B vaccine; vaccines administration

La traduction du résumé se trouve à la fin de l'article.

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At the time of the study, British Columbia (BC) was the first Canadian jurisdiction to implement a school-based, universal immunization program providing concurrent administration of meningococcal C conjugate (MCC) vaccine (Neis Vac-C®) and hepatitis B virus (HBV) vaccine (Recombivax HB®). Numerous studies with infants have examined the reactogenicity of these vaccines when administered separately or with other routine infant vaccines.¹⁻⁷ No published studies have systematically assessed the rate of local reactions to concurrent administration of MCC and HBV vaccines when one versus two arms are used for administration in the grade six age group of 11-12 years. The purpose of this randomized, observational study was to: a) compare differences in local and systemic reactions between children having both injections in one arm to those having one injection in separate arms and b) compare local reactions from MCC and HBV vaccination. This study was conducted in response to a call from public health nurse (PHN) immunizers for practical guidance related to these questions.

METHODS

This study received ethical approval from the University of British Columbia Clinical Research Ethics Board.

Sample size considerations

Assuming a binomial distribution, in order to detect a difference in reported reactions of 15% between groups with a beta of 0.8 and alpha of 0.05, 183 participants per group were required. Fifteen percent was deemed an important difference by the study investigators, who are experts in paediatric immunization.

Participants

Eligible participants were children in grade six scheduled to receive MCC and HBV vaccines through the school immunization program. Health units in Quesnel (rural, interior BC) and Cloverdale/Surrey (urban, lower mainland BC) participated. PHNs distributed consent forms to teachers who gave them to students to take home for parental signatures. Within each community, schools were randomized to receive either both vaccines in one arm (One Arm Group), or one vaccine in each

TABLE I

Demographic Characteristics of Participants (n=390)

Characteristic	One Arm (n=202) n (%)	Two Arms (n=188) n (%)
Female sex of child	103 (51)	103 (55)
Mother as respondent	156 (77)	148 (79)
Race of child		
Caucasian	172 (85)	140 (75)
Asian	17 (8)	34 (18)
Other	13 (7)	14 (7)
Education of respondent		
< High school	34 (17)	12 (6)
High school	42 (21)	49 (26)
Post secondary	119 (59)	115 (62)
Declined to answer	7 (3)	12 (6)
Location		
Quesnel	55 (27)	28 (15)
Surrey/Cloverdale	147 (73)	160 (85)
Arm of injection		
Left	181 (90)	NA
Right	21 (10)	

TABLE II

Comparison of Reactions of Children Receiving Both Vaccines in One Arm (n=202) or One Vaccine in Each of Two Arms (n=188)

Reaction	One Arm (n=202) n (%)	(95% CI)	Two Arms* (n=188) n (%)	(95% CI)	p-value†
Any reaction	123 (61)	(54,67)	118 (63)	(56,69)	NS
Any redness at site	9 (5)	(2,8)	14 (7)	(5,12)	NS
Median hrs duration (IQR)	16 (4-24)		60 (24-95)		<0.005
Size of redness					
<46 mm	8 (4)	(2,8)	11 (6)	(3,10)	NS
>46 mm	1 (0.5)	(0,3)	13 (6.5)	(4,12)	<0.001
Any tenderness at site	112 (55)	(29,62)	111 (59)	(52,66)	NS
Severity					
Mild	75 (37)	(31,44)	58 (31)	(25,38)	NS
Moderate	32 (16)	(12,22)	47 (25)	(19,32)	<0.05
Severe	5 (3)	(1,6)	6 (3)	(2,7)	NS
Any swelling at site	10 (5)	(3,9)	16 (9)	(5,13)	NS
Size of swelling					
<46 mm	7 (3.5)	(2,7)	12 (6)	(4,11)	NS
>46 mm	3 (1.5)	(1,4)	4 (2.5)	(1,5)	NS
Systemic reactions	37 (18)	(14,24)	39 (21)	(16,27)	NS
Fever	8 (4)	(2,8)	6 (3)	(2,7)	NS
Headache	16 (8)	(5,13)	15 (8)	(5,13)	NS
Drowsiness	15 (7)	(5,12)	26 (14)	(10,20)	<0.05
Other	13 (6)	(4,11)	9 (5)	(3,9)	NS

* Where ratings differ between two arms, the most extreme value was used. E.g., if reaction duration was different between two arms, the longer duration was used.

† Each subcategory was tested separately and treated as a binary variable. Chi square was used to test binary variables, and the Kruskal Wallis test was used to compare medians.

arm (Two Arm Group). PHNs were instructed as to which group a particular school was assigned prior to the clinics. Students in all schools randomized to the Two Arm Group received MCC in the left arm and HBV in the right arm.

Vaccine administration

A provincial immunization manual outlines guidelines for vaccine administration.⁸ It is expected that PHNs in both study communities adhered to these guidelines. For the One Arm Group, the injections were given a minimum of 2.5 cm (1 inch) apart, with no pre-determined placement at the injection site. While administration of two vaccines in the same limb is a common immunization practice in BC, it is not known how fre-

quently this is done in comparison to the administration of the same two vaccines in separate limbs.⁸ When students in the Two Arm Group were given a choice, most chose the option of having the vaccines given at the same time by two nurses. For both groups, the same needle length and needle gauge was used (1" 25G). In each community, the same PHNs administered vaccine to both study groups.

Interviews and study questionnaire

Structured telephone interviews were conducted with parents or guardians of immunized children between 48 and 96 hours following the scheduled immunization by a team of trained interviewers. The questionnaire was adapted for this study from a previous, field-tested instrument developed

by Skowronski et al.⁹ Respondents were asked about maximum reactions experienced by their child, including: redness, tenderness, itchiness, swelling, limitation of arm movement, fever, vomiting, loss of appetite, headache, new diarrhea, and drowsiness. Size of redness and swelling was estimated by the following response options using previously validated criteria: smaller than an Oreo™ cookie (46 mm); larger than an Oreo™ cookie, but not the entire upper arm; the entire upper arm (shoulder to elbow); or the entire arm.⁹ Severity of tenderness, swelling, and fever was categorized as mild, moderate, or severe; itchiness and limitation of movement were categorized as mild or marked. These assessments were based on parental report of maximum reaction experienced per arm. Impact was assessed through questions about interference with the child's school or other activities, medical attention-seeking, and parental time lost from work due to reactions.

Data analysis

All analyses were conducted using Splus® 6 for Windows. Chi square and Kruskal Wallis tests were used to compare categorical data and medians, respectively, between groups and between those who did and did not experience specific reactions. Forward stepwise logistic regression was used to model the association between specific reactions (e.g., tenderness, swelling, fever, headache, and drowsiness) and groups and participant characteristics with the odds ratio (OR) being the measure of association. Study group and variables achieving $p < 0.1$ in association with specific reactions were entered into the regression model. For all statistical comparisons otherwise, significance was attributed at $p \leq 0.05$.

RESULTS

Participation rate

In October and November, 2003, 11 schools in Quesnel (292 total students) and 15 schools in Cloverdale/Surrey (640 total students) were randomized. Six schools in Quesnel were randomized to the One Arm Group (191 students, of whom 186 were immunized and 55 participated in the study) and five to the Two Arm Group (101 students, of whom 97 were immunized and 28 participated). Six

TABLE III

Differences in Local Reactions Between Left Arm (MCC) and Right Arm (HBV) in 188 Children in the Two Arm Group

Reaction	Both Arms Affected n (%) (95% CI)	Left Arm n (%) (95% CI)	Right Arm n (%) (95% CI)	p-value*
Any redness at site	1 (0.5)	12 (6)	3 (2)	<0.05
Median time (hrs) to onset (IQR)		12 (5-14)	2 (1-5)	NS
Median duration (IQR)		36 (24-84)	90 (57-105)	NS
Size of redness				
< Oreo cookie		9 (5)	3 (2)	
> Oreo cookie		2 (1)	0 (0)	
Entire upper arm		1 (0)	0 (0)	
Entire arm		0 (0)	0 (0)	
Any tenderness at site	61 (32)	101 (54)	61 (32)	<0.001
Median time to onset (IQR)		2 (0-6)	2 (0-4)	NS
Median duration (IQR)		24 (20-48)	24 (12-36)	NS
Severity				
Mild		56 (30)	38 (20)	
Moderate		39 (21)	22 (12)	
Severe		6 (3)	1 (0.5)	
Moderate/Severe	15 (8)	45 (24)	23 (12)	<0.01
Any itchiness at site	2 (1)	3 (2)	3 (2)	NS
Median time to onset (IQR)		6 (5-7)	4 (2-5)	NS
Median duration (IQR)		48 (30-60)	24 (18-48)	NS
Severity				
Mild		3 (2)	3 (2)	
Marked		0 (0)	0 (0)	
Any swelling at site	7 (4)	16 (9)	7 (4)	NS
Median time to onset (IQR)		12 (6-21)	4 (2-16)	NS
Median duration (IQR)		51 (24-78)	24 (17-36)	0.08
Size of swelling				
< Oreo cookie		12 (6)	7 (4)	
> Oreo cookie		3 (2)	0 (0)	
Entire upper arm		1 (1)	0 (0)	
Entire arm		0 (0)	0 (0)	
Severity				
Mild		13 (7)	6 (3)	
Moderate		3 (2)	1 (1)	
Severe		0 (0)	0 (0)	
Any limitation of arm movement	17 (9)	27 (14)	17 (9)	NS
Severity				
Mild		20 (11)	13 (7)	
Marked		7 (3)	4 (2)	

* Comparing arms. Note this test violates the assumption of independence (i.e., "arms" are unit of analysis - some children experienced reaction in two arms and others did not). Chi square was used to test binary variables, and the Kruskal Wallis test was used to compare medians.

schools in Cloverdale/Surrey were randomized to the One Arm Group (320 students, of whom 243 were immunized and 147 participated) and nine to the Two Arm Group (290 students, of whom 241 were immunized and 160 participated). The overall participation rate was 51%, which included 307 of 484 (63%) immunized students in Cloverdale/Surrey and 83 of 283 (29%) in Quesnel ($p<0.001$).

Sample characteristics

Participant characteristics are summarized in Table I. A greater proportion of students from Quesnel participated in the One Arm Group, and there was a higher proportion of Caucasian and a lower proportion of Asian students in the One Arm versus Two Arm Group, respectively.

Vaccine-associated reactions

Between Groups

Table II summarizes the main findings related to local and systemic reactions experienced by students in the two groups. Less

than 10% of students in either group reported any local redness, with more students in the Two Arm Group reporting redness greater than 46 mm (6.5% vs. 0.5%, $p<0.001$). Over half of the students in both groups reported any tenderness, and more students in the Two Arm Group rated the tenderness as moderate or severe (28% vs. 18%, $p<0.05$). Although median duration of swelling was greater in the Two Arm group (51 hours vs. 35 hours), this difference was not statistically significant. The most common systemic reactions were drowsiness (7% in One Arm Group vs. 14% in Two Arm Group, $p<0.05$) and headache (8% in both groups).

Of the regression models, only tenderness produced statistically significant findings (data not shown for other models). The likelihood of experiencing *any* tenderness was not significantly associated with group after adjustment for sex, ethnicity or town of residence (OR associated with living in Cloverdale/Surrey 1.5, 95% CI

1.14-1.98). However, among those who reported any tenderness, the likelihood of reporting moderate or severe tenderness was independently associated with being in the Two Arm Group (OR 1.4, 95% CI 1.10-1.85) after adjusting for ethnicity, sex, and town of residence.

Between Arms in Two Arm Group

Table III summarizes the local reactions experienced by the Two Arm Group (188 students) stratified by arm. Differences in reports of any redness (6% left vs. 2% right, $p<0.05$), tenderness (54% left vs. 32% right, $p<0.001$), and the rating of tenderness as moderate or severe (24% left vs. 12% right, $p<0.01$) were found.

Impact

Social and health care impacts (interference with the child's school or other activities, medical attention-seeking, and parental time lost from work) were negligible in both study groups with no statistically significant differences found.

DISCUSSION

This study, conducted in response to practical concerns expressed by immunizing nurses, is the first to compare the rate of local reactions following MCC and HBV vaccination when administered in one versus two arms in grade six students.

Participants in the Two Arm group reported more moderate or severe tenderness. Those immunized in one arm only were immunized in the non-dominant arm, which is less used and perhaps less noticed when it comes to evoking discomfort. This detection bias does not likely explain the greater rate of redness reporting also found in the Two Arm Group. Furthermore, Neis Vac-C® was administered in the left arm in the Two Arm Group and was associated with a significantly higher frequency of local reaction reporting overall than Recombivax HB®.

Previous clinical trial data available for HBV vaccine did not separate local reactions according to type (redness, tenderness or swelling).^{10,11} This makes it more difficult to compare our findings with earlier clinical trial data for HBV (Table IV). However, in our study, the rates of reported local tenderness alone (32%) exceed those reported by clinical trials for all local adverse events following HBV vaccine combined (17%). The reason for this is unclear but may reflect differences in methods used to solicit these events. In our study, we used active telephone follow-up to individually probe about each symptom and this may have contributed to higher reporting rates. Despite the possibility of higher reporting rates for HBV in our study compared to clinical trial data for HBV, we still found more local reactions reported in association with Neis Vac-C® than Recombivax HB® in the Two Arm Group. Using the same methods for MCC as for HBV vaccine, we found reported rates of redness, tenderness or swelling associated with MCC that were comparable to those reported among MCC clinical trial participants. Accordingly, available evidence suggests that our findings may reflect the true experience of immunized grade six students with respect to the vaccine reactions associated with HBV versus MCC in one versus two arms.

The study has a number of limitations, including sampling frame and proxy

TABLE IV

Local Adverse Events Following Immunization for MCC and HBV Vaccines: Clinical Trial Versus Current Study Data

Adverse Event	Clinical Trial: MCC*	Clinical Trial: HBV†	Study Findings: MCC	Study Findings: HBV
Local redness, tenderness and/or swelling combined		16.7%		
Redness	5-50%	Not reported	6%	2%
Tenderness	13.7-71.2%	Not reported	54%	32%
Swelling	8.2-31.4%	Not reported	9%	4%

* Shire Biologics. (2004). Product Monograph: Neis Vac-C® Vaccine

† Merck Frosst Canada & Co. (2002).

Product Monograph: Recombivax HB®.

reporting. In a school-based immunization program, it was not feasible to randomize at the level of individual students, and therefore we randomized by schools. This may account for differences in baseline characteristics between groups, including ethnicity, education and geographic location (urban/rural). These differences in study groups may have acted as confounders with independent influence on pain perception and/or reporting. Accumulating evidence describes ethnic differences in the experience of pain and the numerous factors that influence pain perception.¹²⁻¹⁶ As discussed by Gil (2004), each person has preconceptions and personal beliefs about pain that are based on psychological, socio-cultural and ethnic issues. While it is interesting to speculate whether ethnicity may have influenced the study findings, it remains unclear if the difference in the findings can be accounted for, at least in part, by ethnicity. While this did not emerge as a significant explanatory variable in logistic regression, ethnicity was highly correlated with urban versus rural residence.

Proxy interview of parents or guardians, rather than the students, may have introduced additional bias into the study design. It is unclear whether a systematic bias was introduced, nor in which direction it may have skewed results; however, it should be kept in mind in interpreting our results. Despite these possible limitations, the strength of the study design is its reflection of the reality of immunization delivery in a universal, school-based program. Our findings have direct and relevant application to concurrent immunization with these two vaccines, and addressed two important questions for public health practice.

We conclude that during immunization involving concurrent administration of

MCC and HBV vaccine, delivering both vaccines in one arm remains an option for those who prefer it for logistical reasons. If vaccinating in two arms, Neis Vac-C® should preferentially be given in the non-dominant arm, given the statistically significant difference for more redness and tenderness experienced with Neis Vac-C® than with Recombivax HB®, which may be even more apparent if administered in the dominant arm. Parents can be reassured that, regardless of vaccine product or arm(s) of administration, vaccine reactions are minimal, well-tolerated and associated with negligible impact on school, recreation or health care attendance. These findings were communicated to provincial health authorities in BC before the start of the second year of the grade six immunization program in 2004.

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RÉSUMÉ

Contexte : Cette étude visait : a) à comparer les taux de réaction au point d'injection du vaccin conjugué contre le méningocoque du groupe C (Neis Vac-C®) et du vaccin contre l'hépatite B (Recombivax HB®) et b) à comparer les réactions au point d'injection lorsque les deux vaccins sont administrés dans le même bras ou un dans chaque bras.

Méthode : Dans deux groupes d'écoles sélectionnées aléatoirement, des élèves de 6^e année ont reçu les deux vaccins dans le même bras (groupe « un bras ») ou un vaccin dans chaque bras (groupe « deux bras »; le vaccin antiméningococcique était toujours administré dans le bras gauche). Des entrevues téléphoniques structurées ont été menées auprès des parents; les répondants ont été interrogés sur les réactions systémiques et au point d'injection, sur les conflits avec les activités scolaires ou autres, sur la nécessité de recevoir des soins médicaux et sur les heures de travail perdues par les parents.

Résultats : Le groupe « deux bras » a déclaré une proportion significativement plus élevée de rougeur de la peau >46 mm au point d'injection (6,5 % c. 0,5 %, $p<0,001$), de sensibilité modérée à grave au toucher (28 % c. 18 %, $p<0,05$) et de somnolence (14 % c. 7 %, $p<0,05$). En rajustant les données selon le sexe, l'appartenance ethnique et la ville de résidence, les déclarations de sensibilité au toucher n'étaient plus associées qu'à la ville de résidence; une sensibilité modérée à grave était associée de façon indépendante au groupe « deux bras » (RC = 1,4; IC de 95 % = 1,1-1,85). Aucune différence significative n'a été observée entre les groupes pour ce qui est des conflits avec les activités scolaires ou autres, la nécessité de recevoir des soins médicaux ou les heures de travail perdues par les parents. Dans le groupe « deux bras » (188 élèves), on a observé davantage de rougeur (6 % c. 2 %, $p<0,05$) et de sensibilité au toucher (54 % c. 32 %, $p<0,001$), respectivement, avec le vaccin Neis Vac-C® qu'avec le Recombivax HB®.

Conclusion : L'injection des deux vaccins dans le même bras n'a pas provoqué plus de réactions au point d'injection que la vaccination dans les deux bras; cela confirme que c'est une bonne option si on la préfère pour des raisons de logistique. Si l'on vaccine dans les deux bras, il est préférable d'administrer le Neis Vac-C® dans le bras non dominant.

Mots clés : vaccin antiméningococcique; vaccin contre l'hépatite B; administration des vaccins

Preparing for pandemic influenza: What family physicians should know

Family physicians play a major role in planning for and managing pandemic influenza. It is estimated that up to 35% of the population, including your staff and patients, will become clinically ill in the event of pandemic influenza and 0.4% of the clinically ill could die. This document outlines important steps that you should follow to ensure that your practice is prepared for a pandemic outbreak both in terms of infection control and service continuity.

Ask your Medical Officer of Health about your role during a pandemic influenza.

Ce que les médecins de famille doivent savoir en prévision d'une pandémie d'influenza

Les médecins de famille jouent un grand rôle dans la planification et la gestion d'une pandémie d'influenza. On estime que 35 % de la population, y compris parmi vos employés et vos patients, seront cliniquement malades lors d'une telle pandémie, et que 0,4 % des personnes cliniquement malades pourraient en mourir. Voici, dans ses grandes lignes, la marche à suivre pour vous assurer que votre cabinet est prêt à cette éventualité, tant du point de vue du contrôle de l'infection que du maintien des services.

Demandez à votre directeur de la santé publique quel serait votre rôle lors d'une pandémie d'influenza.