Evaluation of rubella screening in pregnant women

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Abstract

Background: The rationale for rubella vaccination in the general population and for screening for rubella in pregnant women is the prevention of congenital rubella syndrome. The objective of this study was to evaluate the effectiveness of the prenatal rubella screening program in Quebec.

Methods: A historical cross-sectional study was designed. Sixteen hospitals with obstetric services were randomly selected, 8 from among the 35 “large” hospitals in the province (500 or more live births/year) and 8 from among the 50 “small” hospitals (fewer than 500 live births/year). A total of 2551 women were randomly selected from all mothers of infants born between Apr. 1, 1993, and Mar. 31, 1994, by means of stratified 2-stage sampling. The proportions of women screened and vaccinated were ascertained from information obtained from the hospital chart, the physician’s office and the patient.

Results: The overall (adjusted) screening rate was 94.0%. The rates were significantly different between large and small hospitals (94.4% v. 89.6%). Five large hospitals and one small hospital had rates above 95.0%. The likelihood of not having been screened was statistically significantly higher for women who had been pregnant previously than for women pregnant for the first time (4.8% v. 1.4%; p < 0.001). Of the 200 women who were seronegative at the time of screening (8.4%), 79 had been vaccinated postpartum, had a positive serological result on subsequent testing or did not require vaccination, and 59 had not been vaccinated postpartum; for 62, subsequent vaccination status was unknown.

Interpretation: Continued improvement in screening practices is needed, especially in small hospitals. Because vaccination rates are unacceptably low, it is crucial that steps be taken to address this issue.

Evidence

From the *Division of Clinical Epidemiology, Montreal General Hospital, the †Department of Epidemiology and Biostatistics, McGill University, the ‡Direction de la santé publique, Régie régionale de la santé et des services sociaux Montréal-Centre, the §Department of Family Medicine, McGill University, and the ¶Laboratoire de santé publique du Québec, Montreal, Que.

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The rationale for rubella vaccination in the general population and for prenatal screening for rubella in pregnant women is the prevention of congenital rubella syndrome. At present, rubella virus continues to circulate in the general population, which creates a risk of infection for susceptible women. If infection occurs during pregnancy before 11 weeks gestational age, the risk of congenital defects is about 90%; the risk approaches zero only after 16 weeks. Among infected symptomatic newborns, the principal effects of congenital rubella syndrome include congenital heart disease, congenital glaucoma and loss of hearing. Congenital infection may be asymptomatic at birth but can have serious effects in the longer term, for example, development of diabetes or glaucoma.

The mean number of cases of congenital rubella syndrome reported annually in Canada (4) is recognized as an underestimate (Dr. Louise Pelletier, Health Protection Branch, Health Canada: personal communication, 1996). Evidence from Quebec hospital data spanning the period 1981 to 1994 suggests that the number of confirmed cases has not declined significantly from an earlier 15-year period (1965–1980), despite a universal rubella vaccination program. Moreover, the Quebec study estimated that the number of cases is underreported by a factor of at least 6.

To reduce the incidence of congenital rubella syndrome, routine prenatal screening and postpartum vaccination have been recommended since the 1970s. Recognizing the enormous financial costs (estimated at $500 000 per affected child, in 1996 dollars) and social burden associated with this condition, the Mumps and Rubella Consensus Conference has set a goal of eliminating indigenous rubella in Canada by the year 2000. The Conference specified 3 objectives related to pregnant women: that all pregnant women undergo screening prenatally or that the date of prior vaccination be ascertained; that postpartum vaccination be achieved in 99% of seronegative women and that such vaccination take place before hospital discharge; and that a seronegative rate of less than 4% among primigravida women be achieved by 1997.

To date, there has been no comprehensive evaluation of prenatal screening for rubella. Our objective was to evaluate the effectiveness of the prenatal screening program for rubella in Quebec and to make recommendations to guide screening and vaccination practice.

**Methods**

We designed a historical cross-sectional study of pregnant women in the province of Quebec using a stratified 2-stage sampling procedure. The first stage consisted of a random sampling of hospitals and the second stage, a random sampling of women who gave birth at those hospitals. The source population was obtained from the Canadian Hospital Directory (1992/93) and included the 85 hospitals offering obstetric services and recording more than 10 births in 1991/92. One large hospital was excluded because it had been the site of the preliminary study and had subsequently changed its policy regarding screening and vaccination. We expected, a priori, that the screening rates in small hospitals might be systematically different from those in larger hospitals. Therefore, hospitals were stratified as either small (fewer than 500 recorded births) or large (500 or more recorded births), and 8 hospitals were randomly selected from each stratum. The hospitals were sampled with probability proportional to size (in terms of number of births).

The sampling frame for pregnant women who delivered live infants between Apr. 1, 1993, and Mar. 31, 1994, was provided by a computerized registry of admissions to hospital in Quebec (MED-ECHO) (for 10 of the hospitals) or a chronological listing of eligible women (for 6). A simple random sample of women was obtained from each hospital by means of the SAS program for random sampling (SAS Statistical Software version 6.04; SAS Institute Inc., Cary, NC). In cases in which a selected woman could not be enrolled (e.g., chart was missing or stillbirth had been misclassified as a live birth), the woman with the next chart number was used as a replacement. The sample size calculation was based on the approach for 2-stage random sampling. We assumed, a priori, a 3% standard deviation between hospitals. We also assumed an expected proportion of women screened of 60% in the large hospi-
tals and 40% in the small hospitals. It was estimated that 114 women would have to be selected from each small hospital and 212 from each large hospital to ensure that a 95% confidence interval would estimate the proportion in each stratum with 3% precision.

Data collection

Standard data collection instruments were designed and pretested. Data collection began with a review of the hospital chart. If there was incomplete information in the chart, we contacted the woman's obstetrician or treating physician, from whom information on screening and vaccination was requested. The physician was also given a generic letter and was asked to personalize the letter and send it to the patient if all of the requested information was not available in the physician's office file. This letter invited the woman to participate in our study by returning a reply coupon (which indicated informed consent). We then contacted the woman by telephone to determine her vaccination status.

The study was approved by the Ethics Review Committee at the Montreal General Hospital and by the appropriate committee in each hospital.

Data analysis

Data were entered using the Paradox database program (Paradox for Windows, version 5.0; Borland International Ltd., Scotts Valley, Calif.) and analysed, in part, with SAS software (SAS Statistical Software, version 6.04). A customized Fortran program was written to implement the method proposed by Cochran10 for estimating the mean proportion and its variance in 2-stage sampling designs. Comparisons between subgroups were evaluated with χ² tests and Student's t-test, where appropriate. Ninety-five percent confidence intervals (CIs) were calculated for point estimates. Multivariable analyses were performed on individual patients' data to assess the relative importance of the adjusted effects of the following putative predictors of screening and vaccination, as well as to test their significance: gravidity (dichotomous variable, 1 v. more than 1), age (continuous), hospital size (dichotomous, small v. large) and prenatal care (dichotomous, fewer than 2 visits to a physician v. 2 or more visits). To account for the dependence of the outcomes among patients nested within the same hospital, we used the generalized estimating equations (GEE) approach.11 This type of modelling extends the conventional multiple logistic model to situations where the observed responses may be correlated (e.g., repeated or nested data). Thus, this method allowed us to analyse the adjusted effects of the characteristics of both hospitals and patients on the binary outcomes (for screening and seronegativity) of individual patients, while accounting for clustering of patients within hospitals. In the context of this study, the GEE analysis assumed a constant correlation between the outcomes of any 2 patients from the same hospital. To assess the linearity assumption when estimating the effect of age, we tested the significance of the quadratic effect of age, adjusting for its linear effect and other variables on the GEE model. To test whether the effect of age on screening or vaccination depended on gravidity, the interaction between these 2 variables was included in the model. All tests were performed at the 0.05 significance level. The GEE analyses were carried out with the GENMOD procedure available in SAS version 6.12 software.

Results

Study population

The study began in October 1994 and was completed in May 1996. Two large hospitals refused to participate and were replaced. In addition, one large hospital selected for inclusion in our study proved to be a small hospital (because of a recording error in the Canadian Hospital Directory). This hospital was also replaced. In one small hospital the total number of births in fiscal year 1993/94 was less than the required sample size of 114. Therefore, a random sample of 37 women (half the required number) was selected. The total number of women included in the study was 2551; 1696 from the large hospitals and 855 from the small hospitals. Over 99% of the women had received prenatal care (defined as evidence in the hospital chart of a minimum of 2 prenatal visits to a physician, including visits for ultrasoundography and laboratory testing).

Screening rates

The hospital, stratum and overall (adjusted) screening rates are shown in Table 1. For the current pregnancy, the following evidence from the hospital chart was considered to indicate that screening had taken place: presence of a laboratory requisition indicating the date and result of the testing or a written note on the DOEG form (dossier obstétrical evolution de grossesse, a standardized pregnancy follow-up form) indicating that the woman was immunized or had had a negative or positive result on screening. Among the large hospitals, the overall screening rate was 94.4%; 2.8% of women were known not to have undergone screening, and for a further 2.8% of women the screening status was unknown. The range in screening rates among the large hospitals was 87.7% to 98.6%. Among the small hospitals, the overall screening rate was
Evidence of screening obtained from the hospital charts consisted of a requisition in 59.9% of charts in large hospitals and 61.5% of charts in small hospitals. Additional information was sought from a total of 189 physicians, of whom 161 (85.2%) responded. This additional information resulted in an increase in the estimated screening rates that ranged from 0.9% to 9.9% in large hospitals and from 0% to 29.8% in small hospitals.

In bivariate analyses in which women with unknown screening status were omitted from the calculations, the likelihood of not having been screened was statistically significantly higher for women who had been pregnant previously than for women pregnant for the first time (4.8% vs. 1.4%; \( p < 0.001 \)). This difference was greater when the women with unknown screening status were included in the denominator (8.9% vs. 3.8%). Information on screening was recovered in similar proportions from the documented sources (i.e., requisition in the hospital chart, written note in the hospital chart and physician’s office chart) for primigravid and multigravid women. The screening rates were not related to a woman’s age (\( p = 0.13 \)) nor to prenatal care (\( p = 0.18 \)). Women underwent screening on average 180 (standard deviation 40) days before delivery.

In multivariate GEE analyses with screening as a binary dependent variable, the adjusted effect of age showed a statistically significant departure from linearity (\( p = 0.03 \) for the quadratic term). The estimated curvilinear effect of age suggested a U-shaped association, the probability of being screened being lowest at about 25 years and increasing for both younger and older women. After we adjusted for patients’ characteristics and accounted for clustering of patients within hospitals, the patients in smaller hospitals

<table>
<thead>
<tr>
<th>Hospital size</th>
<th>Total screened, no. (and %)</th>
<th>Source of information; no. (and %) of women</th>
<th>Screening status unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Hospital chart</td>
<td>Physician’s office file</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Requisition</td>
<td>Written note</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Large*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>203 (95.8)</td>
<td>194 (91.5)</td>
<td>6 (2.8)</td>
</tr>
<tr>
<td>2</td>
<td>203 (95.8)</td>
<td>158 (74.5)</td>
<td>41 (19.3)</td>
</tr>
<tr>
<td>3</td>
<td>204 (96.2)</td>
<td>179 (84.4)</td>
<td>20 (9.4)</td>
</tr>
<tr>
<td>4</td>
<td>193 (91.0)</td>
<td>23 (10.8)</td>
<td>149 (70.3)</td>
</tr>
<tr>
<td>5</td>
<td>197 (92.9)</td>
<td>175 (82.5)</td>
<td>14 (6.6)</td>
</tr>
<tr>
<td>6</td>
<td>186 (87.7)</td>
<td>144 (67.9)</td>
<td>40 (18.9)</td>
</tr>
<tr>
<td>7</td>
<td>209 (98.6)</td>
<td>4 (1.9)</td>
<td>201 (94.8)</td>
</tr>
<tr>
<td>8</td>
<td>207 (97.6)</td>
<td>140 (66.0)</td>
<td>60 (28.3)</td>
</tr>
<tr>
<td>Subtotal</td>
<td>1602 (94.4)</td>
<td>1017 (60.0)</td>
<td>531 (31.3)</td>
</tr>
<tr>
<td>Small†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9‡</td>
<td>41 (71.9)</td>
<td>37 (64.9)</td>
<td>4 (7.0)</td>
</tr>
<tr>
<td>10</td>
<td>99 (86.8)</td>
<td>2 (1.8)</td>
<td>63 (55.3)</td>
</tr>
<tr>
<td>11</td>
<td>106 (93.0)</td>
<td>77 (67.5)</td>
<td>27 (23.7)</td>
</tr>
<tr>
<td>12</td>
<td>106 (93.0)</td>
<td>74 (64.9)</td>
<td>21 (18.4)</td>
</tr>
<tr>
<td>13</td>
<td>101 (88.6)</td>
<td>86 (75.4)</td>
<td>11 (9.6)</td>
</tr>
<tr>
<td>14</td>
<td>102 (89.5)</td>
<td>76 (66.7)</td>
<td>20 (17.5)</td>
</tr>
<tr>
<td>15</td>
<td>102 (89.5)</td>
<td>78 (68.4)</td>
<td>15 (13.2)</td>
</tr>
<tr>
<td>16</td>
<td>109 (95.6)</td>
<td>96 (84.2)</td>
<td>11 (9.6)</td>
</tr>
<tr>
<td>Subtotal</td>
<td>766 (89.6)</td>
<td>526 (61.5)</td>
<td>172 (20.1)</td>
</tr>
<tr>
<td>Overall total</td>
<td>2368 (92.8)</td>
<td>1543 (60.5)</td>
<td>703 (27.6)</td>
</tr>
</tbody>
</table>

Note: After weighting according to the number of patients in each of the 2 strata, the overall screening rate was 94.0% (see text for further explanation).

*For large hospitals, the required sample size for 2-stage sampling to ensure that a 95% confidence interval would estimate the proportion in each stratum with 1% precision was 212, and percentages reflect this total.

†For small hospitals, the required sample size for 2-stage sampling to ensure that a 95% confidence interval would estimate the proportion in each stratum with 3% precision was 114, and percentages reflect this total (except where indicated otherwise).

‡For hospital 9, the total number of births in fiscal year 1993/94 was less than the required sample size of 114. Therefore, a random sample of 57 women (half the required number) was selected for study.
requisition did not depend on age. Regardless of the patients’ ages, significantly higher proportions of primigravid women underwent screening compared with multigravid women (OR 4.08, 95% CI 1.86 to 8.96; \( p < 0.001 \)). Prenatal care was not associated with the probability of screening (\( p = 0.09 \)). The interaction between age and gravidity was not significant (\( p > 0.30 \)), which indicated that the effect of gravidity on screening did not depend on age.

**Seronegativity**

Excluding the 89 women who were not screened and the 94 women for whom screening status was unknown, a total of 200 women (8.4%) were found to be seronegative (Table 2). Small hospitals had a significantly higher proportion of seronegative women than large hospitals (\( p < 0.001 \)). In most cases (62.5%), the laboratory requisition indicating the test results was found in the hospital chart; however, in 30.0% of cases, the information in the chart was in the form of a written note, and in 7.5%, the information was obtained not from the hospital but from the physician’s office.

GEE analyses showed a linear relation between age and seronegativity. The risk of seronegativity decreased significantly (\( p < 0.001 \)) with increasing age (OR 0.91 per 1 year, 95% CI 0.87 to 0.95). Gravidity was not associated with risk of seronegativity (OR 0.89, 95% CI 0.65 to 1.22). After adjustment for patients’ characteristics and accounting for clustering of patients within hospitals, seronegativity was more likely to be observed in small rather than large hospitals (OR 1.78, 95% CI 1.06 to 2.98). There was no interaction between age and gravidity (\( p > 0.10 \)).

**Vaccination**

When we accumulated evidence from all 3 sources of information (hospital chart, physician’s office and the women themselves), we ascertained that 67 of the 200 women had been vaccinated postpartum. This number included women for whom a later positive serological result was reported. In 11 other women, vaccination was not required because the woman either had undergone or intended to undergo tubal ligation or hysterectomy, or the woman’s partner had undergone vasectomy, and one woman had been vaccinated during the pregnancy for an unknown reason. Of the remaining 121 women, 59 were considered definitely at risk because they were known not to have been vaccinated and 62 were considered possibly at risk because their vaccination status was unknown.

The information regarding postpartum vaccination of these women indicated that vaccination was rarely achieved outside the hospital setting (Table 3). Only 5 (4.0%) of the 126 women who were not vaccinated in hospital (130 minus the 4 who did not require vaccination) were considered to have been vaccinated appropriately (i.e., within 3 months of delivery) outside the hospital setting. The 62 women whose status was unknown represented an important proportion of women for whom information on vaccination would likely not be known in the event of a subsequent pregnancy. Table 4 lists the reasons why follow-up information was incomplete.

Of a total of 73 letters sent to women to obtain information about postpartum rubella vaccination that was not available from either the hospital chart or the woman’s physician, 31 (42%) reply coupons were returned. Three

### Table 2: Numbers of women who tested seronegative on prenatal rubella screening

<table>
<thead>
<tr>
<th>Hospital size</th>
<th>Hospital chart</th>
<th>Requisition</th>
<th>Written note</th>
<th>Physician’s office file</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large</td>
<td>66</td>
<td>41</td>
<td>2</td>
<td>109</td>
<td></td>
</tr>
<tr>
<td>Small</td>
<td>59</td>
<td>19</td>
<td>13</td>
<td>91</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>125</td>
<td>60</td>
<td>15</td>
<td>200</td>
<td></td>
</tr>
</tbody>
</table>

### Table 3: Postpartum follow-up of the 200 women who tested seronegative on prenatal rubella screening

<table>
<thead>
<tr>
<th>Source of information</th>
<th>Vaccinated</th>
<th>Later positive result</th>
<th>Vaccination not required</th>
<th>Not vaccinated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital chart</td>
<td>54</td>
<td>8</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>Physician’s office file</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>36</td>
</tr>
<tr>
<td>Patient</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>23</td>
</tr>
<tr>
<td>Total</td>
<td>58</td>
<td>9</td>
<td>12</td>
<td>59</td>
</tr>
</tbody>
</table>

*For 62 women, postpartum vaccination status could not be determined.

### Table 4: Reasons for incomplete postpartum follow-up of women who tested seronegative on prenatal rubella screening

- Physician refused to participate
- Physician did not respond to letter of request
- Physician had died
- Physician had moved
- Physician was on maternity leave
- Physician did not have a file for the patient
- Patient had moved
- Address for patient unknown
- Telephone number for patient unlisted
- Foreign patient*
- Reply coupon not returned
- Patient refused to participate

*Gave birth while visiting Canada and left soon after delivery.
women indicated that they would not participate. Of the 28 women who agreed to participate, one could not be reached (unlisted telephone number), one declared a medical procedure such that vaccination would not be required, and 23 indicated that they had not been vaccinated. Reasons given for not undergoing vaccination included not having been informed by the physician, having become newly pregnant or having been told (by the local health service centre) that vaccination was not required (because the woman was breastfeeding or because of previous vaccination history).

Interpretation

These results indicate that screening for rubella is a routine but not universal practice in obstetric hospitals in the province of Quebec. Ten of the 16 study hospitals had screening rates below 95%. Lower screening rates were observed in smaller hospitals compared with larger hospitals and in multigravid women compared with primigravid women. Given the overall adjusted screening rate of 94% and an average of 90 000 births annually in Quebec we estimate that, on average, over 5000 women would not undergo screening or their screening status would be unknown (and they could therefore be presumed not to have undergone screening). Because seronegativity rates among these women are expected to be higher than among women who underwent screening, the overall seronegativity rate would likely exceed the proportion that we observed (8.4%). Therefore, a minimum of 7500 women would be susceptible each year to rubella, of whom more than 4500 would not be vaccinated or would not likely be vaccinated postpartum.

It is uncertain whether our overall rate of seronegativity (8.4%) is high compared with the rate in other countries, given that published reports are dated (e.g., 2.7% in 1984 in Manchester, England; 1.4% in 1991 in the United Kingdom; between 2% and 3% in Europe). Data from the United States indicate that between 10% and 15% of women of reproductive age are susceptible. A local study in one Quebec hospital reported a rate of 5.3%.

When these rates are considered in light of low postpartum vaccination rates, especially in small hospitals, it is clear that measures to redress this situation are urgently required. In-hospital postpartum vaccination is widely recognized as an effective means of vaccinating at-risk women — one that subsequently prevents between one-third to one-half of all cases of congenital rubella syndrome. Berkeley and associates, in 1991, recommended that a central (institution-based) rather than an individual (physician-based) approach be used to ensure postpartum vaccination. Standing orders for vaccination before hospital discharge ensure that the opportunity for vaccination is not missed.

Although it is not recommended that women be vaccinated during pregnancy, there are few contraindications for postpartum vaccination. In circumstances where immune globulin (other than anti-Rh, [anti-D]) has been administered, a delay of 3 months is recommended. Vaccination may not be recommended for women who are immunosuppressed or are hypersensitive to components of the vaccine. The perception that breastfeeding or the administration of anti-Rh immune globulin is a contraindication for postpartum vaccination is incorrect. Misconceptions about vaccine use were noted in our study and are known to contribute to problems in vaccine distribution that affect timely administration and lead to missed opportunities.

Recommendations for prenatal rubella screening and postpartum vaccination

Both Canadian and US public health authorities currently recommend universal prenatal screening for rubella and postpartum vaccination before hospital discharge where the test result is seronegative. The evidence presented in our study indicates that a renewed plan of action is urgently required.

We gratefully acknowledge the collaboration of the participating hospitals: Centre hospitalier Cité de la santé de Laval, Centre hospitalier de Buckingham, Centre hospitalier de Matane, Centre hospitalier Hôtel-Dieu d’Arthabaska, Centre hospitalier Hôtel-Dieu de Saint-Jérôme, Centre hospitalier Pierre-Boucher, Centre hospitalier régional l’Hôtel-Dieu de Gaspé, Centre hospitalier St-Joseph de la Malbaie, Hôpital Chibougamau Ltée, Hôpital du Christ-Roi, Hôpital du Haut-Richelieu, Hôpital du Sacré-Cœur de Montréal, Hôpital Notre-Dame-de-Fatima, Hôpital Notre-Dame de Sainte-Croix, Hôpital Sainte-Juste et Lakeshore General Hospital. Roxane du Berger performed the statistical analyses, and Sylvain Dancausse designed the data entry program.

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References

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