Quality Improvement: Investigation of MMR Vaccine Overuse in Post-Partum Wards

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1. Abstract

Congenital rubella syndrome (CRS) is of substantial concern due to the potential for intrauterine fetal demise and devastating birth defects like deafness. CRS is a result of the trans-placental transit of rubella virions during maternal rubella infection, which can be prevented through widespread vaccination against rubella. Rubella-containing vaccines (MMR and MMRV) are routinely administered to Canadian children in a two-dose schedule, which grants sufficient immunity in most of the population. As such, the National Advisory Committee of Immunizations (NACI) does not recommend any further immunization against rubella beyond two lifetime doses. These live vaccines are contraindicated in pregnancy and instead are administered after birth in susceptible mothers. Recent changes in the standard of care require a review of the vaccination history prior to administration of MMR or MMRV to post-partum mothers, as two prior lifetime doses satisfy the NACI criteria for sufficient rubella immunity regardless of serology. The purpose of this quality improvement project was to assess for redundancy of rubella immunization on post-partum wards in Women's Hospital, Winnipeg and estimate the associated annual cost. A 3-month audit period yielded 16 instances of MMR administration, two of which were redundant based on two prior lifetime doses. The act of observation itself is thought to have acted as an intervention to reinforce previous education about redundant MMR vaccination, with rapidly declining redundancy after the first month. If not for this improvement, a $615 - $733 expense in addition to 4 -5 hours of nursing labour would have been expected annually.

2. Introduction

2.1 Rubella and Congenital Rubella Syndrome

Rubella, colloquially called 'German measles', is caused by rubella virus of the Togaviridae family (1). In adults, symptoms consistent with rubella infection include a sore throat, headache, low-grade fever, and a distinctive erythematous rash that generalizes across the body (2). Young children with rubella experience largely mild respiratory symptoms, and few develop life-threatening sequelae (2). Infection is spread through droplet spread (e.g. sneezing) and direct contact with nasopharyngeal secretions (3). Up to half of all cases are asymptomatic but are nonetheless highly contagious. Even those who develop the characteristic rash may transmit the infection up to a week before its appearance, creating a large window of opportunity for the virus to spread (2).

The primary concern for rubella transmission in the community is the threat posed to pregnant mothers and their unborn children. When pregnant mothers are infected with rubella, the virus may cross the placental barrier and cause congenital rubella syndrome, and the risk of harm to the fetus peaks in first trimester (85%) (2). Congenital rubella syndrome (CRS) is associated with an increased risk of intrauterine fetal demise and serious birth defects such as cataracts and deafness (2). Although CRS has been eliminated in Canada, there is continued risk of imported rubella infection from endemic areas. Vaccination against rubella virus is the best strategy to prevent the occurrence of CRS.

2.2 Vaccination and Immunity

Rubella immunization is routinely completed in Canadian children with the measles-mumps-rubella (MMR) and measles-mumps-rubella-varicella (MMRV) vaccines (3). These vaccines work by introducing a weakened version of the viruses (3). The Society of Obstetrics and Gynecology of Canada recommends that administration of live and live-attenuated vaccines be postponed in pregnant patients until after delivery (4). The reason for this is the entirely theoretical risk of teratogenicity, as wild type rubella is known to cause intrauterine infection, congenital rubella syndrome, and potential fetal demise (3). Importantly, no increased risk to the fetus when rubella vaccination occurs during pregnancy has been established (5). As a precaution, however, mothers found to have insufficient rubella immunity are offered vaccination against rubella only after delivery is complete.

In hospital, mothers are considered susceptible to rubella if they have undetectable blood immunoglobulin titers against the virus (rubella IgG) during the prenatal screen. A significant

proportion of women may be seronegative despite receiving adequate rubella immunization. However, the National Advisory Committee of Immunizations (NACI) have stated that lifelong immunity is established after two lifetime doses of MMR/MMRV, and deem further booster doses as unnecessary (6).

2.3 MMR in the Post-Partum Ward

Currently, a new standard of care is in place within the post-partum ward at Women's Hospital in HSC requiring a review of the vaccination record in conjunction with serological status prior to MMR administration. This is intended to limit redundant rubella vaccination beyond two lifetime doses, according to the NACI recommendations. However, the compliance with this protocol is unknown, and patients may continue to receive MMR vaccination based on serological status alone, without consultation of the immunization record.

We hypothesized that mothers continue to be over-vaccinated against rubella on post-partum wards in Winnipeg based on the Canadian criteria for rubella immunity, despite an established workflow process to prevent vaccine redundancy. Such redundancy would produce unnecessary expenses in the form of nursing labor, medical supplies, and MMR doses. Additionally, redundant MMR vaccination would mean unnecessary patient discomfort and risk of side effects. If true, the current process would require adjustment to address the redundancy associated with non-compliance.

2.4 Purpose of this Study

To date, adherence to the existing standard for MMR administration on the post-partum wards in Women's Hospital has not been evaluated.

The intention of this quality improvement project was to assess the current rate of MMR vaccine redundancy in post-partum patients at Women's Hospital, evaluate associated expenses, and propose interventions to limit vaccine redundancy and optimize resource utilization.

3. Methods

3.1 Approval

Approval for this quality improvement project was obtained from Shared Health Research and Innovation., approval number SH2021:198.

3.2 Data Collection and Storage

Immunization Administration Records (IARs) are routinely photocopied for data entry purposes on the post-partum ward in Women's Hospital at Health Sciences Centre, Winnipeg. Normally, these records are destroyed shortly after data entry is completed. For this project, photocopied IARs of patients from the post-partum ward including evidence of MMR administration were retained by nursing staff over a 3-month period (Nov. 1, 2021 – Jan. 31, 2022) and transcribed onto a master list at the end of the study period. The master list was kept in a locked cabinet in a locked office (WN3478) within a secured administrative area with swipe-card access.

The IARs were reviewed to confirm MMR vaccination on the post-partum ward in Women's Hospital. Then, the immunization record (of patients with confirmed MMR administration on

the ward) was accessed via eChart to assess for lifetime doses of rubella vaccination, which were recorded. Photocopies of IARs will be destroyed as confidential waste at HSC upon completion of a final observation period in Jan. 2023.

Medical equipment and nursing labour invested throughout a typical course of MMR vaccine administration was determined through discussion and observation of nursing staff. For comparison, time invested in a typical review of the vaccination history via eChart was likewise determined. The unit cost of Priorix, the MMR vaccine frequently utilized in Women's Hospital, was estimated through consultation with Manitoba Health, Seniors and Active Living (MHSAL).

3.3 Analysis

Patients who received at least 2 lifetime doses of a rubella vaccine at any time were considered rubella immune, and the MMR dose received on the post-partum ward was considered redundant. The total number of monthly and annual deliveries was determined from the Summary of Delivery Statistics obtained through internal communication (7). This was used to determine the number of redundant doses per 100 deliveries for each month. This was then multiplied by 50-60 to reflect the typical number of annual deliveries at Women's Hospital, 5,000 – 6,000, and estimate the total annual redundant doses (7). Due to rapid improvement after the first month of observation, the November 2021 data was used to further calculate annual costs, to model the 'worst case scenario' before an apparent change in practice took place during the project. The calculated redundant doses per year was then multiplied by the unit cost and time investment of a single MMR dose to estimate the greatest possible annual expense of redundant MMR vaccination.

4. Results

Table 1. Estimated Total Annual Redundancy Based on Monthly MMR Doses

Observed Month	Total MMR Ward Doses	Known Redundant Doses	Total Monthly Deliveries	Redundant Doses per 100 Deliveries	Annual Redundant Doses
Nov. 2021	9	2	461	0.43	21-25
Dec. 2021	2	0	468	0	0
Jan. 2022	5	0	544	0	0

Total MMR ward doses were determined from IARs. For a dose to be a known redundant dose, there must have been at least 2 prior instances of rubella vaccination documented on eChart. Total monthly deliveries was determined from Summary of Delivery Statistics obtained through internal communication (7). The total number of annual redundant doses was calculated using the typical numbers of total annual deliveries at Women's Hospital, 5,000 – 6,000 (7).

From Nov. 1, 2021 to Jan. 31, 2022, sixteen patients admitted to the post-partum wards at Women's Hospital received post-partum MMR vaccination. In total, 9 doses were given in November, 2 in December, and 5 in January. Two patients receiving MMR in November were already immune to rubella, with documentation of at least 2 prior rubella immunization events in eChart. The remaining 14 MMR doses were medically necessary, based on the NACI criterion. Using the November data alone, the estimated number of annual redundant doses ranges from 21 to 25.

Nine patients had incomplete vaccination histories documented on eChart (Table S1), possibly due to a true absence of these immunizations or their administration in jurisdictions without the use of eChart for documentation.

Table 2. Comparison of Resource Investment for Redundant MMR Administration Vs. Vaccine History Review for November 2021

	Single Dose		Annual	
Resource Invested	Financial (CAD)	Time (mins) ǂ	Financial (CAD)	Time
Redundant MMR Vaccination	$29.32	15	$615 - $733	5h 15m – 6h 15m
Vaccination History Review	$0	2	$0	42m –50m

Financial investment is based upon the cost of MMR vaccine (Priorix) doses, estimated through consultation with MHSAL. The cost of minor medical supplies used in the procedure is excluded. Time investment was determined through discussion with nursing staff. Annual investment was determined by multiplying single dose values by the estimated annual doses, 21-25, calculated in Table 1.

ǂ Variable based on provider skill

The estimated annual cost of redundant MMR vaccination was $615 - $733, based on a range of total deliveries per year. The estimated annual time invested by nursing staff in redundant vaccination was 5hr 15min - 6hr 15min. This equates to $615 - $733 and 4h 25m – 5h 30m of

additional investment when compared to the free alternative of reviewing patient vaccination histories.

5. Discussion

5.1 Risk vs. Benefit of Booster Doses

Table 3. Frequencies of Adverse Events Attributed to Priorix MMR Immunization

	Adverse Event	Frequency	Reference
Risks			
Very Common	Redness[‡] Fever ≥37.5°C oral	≥10%	(8)
	Acute transient arthralgia	≤25%	(3)
	Acute transient arthritis	≤10%	(3)
Common	URTI[*] Rash Pain and swelling[‡] Fever >39°C oral	≥1 and <10%	(8)
Serious or Severe	Including but not limited to: Immune thrombocytopenic purpura Meningitis Guillain Barré syndrome Measles or mumps-like syndromes Anaphylaxis	<1%	(8)

Adverse events associated with Priorix MMR vaccine are shown due to its frequent use in post-partum wards at Women's Hospital.

[‡]At injection site

[*]Upper respiratory tract infection

In Canada, a 2-dose course of rubella immunization has been established in all provinces and territories. MMR or MMRV is scheduled to be given at 12-15 months and 4-6 years of age. As a result of routine vaccination, there have been no cases of CRS for over 20 years in Canada (3).

Various studies have demonstrated 99-100% seropositivity following 2 doses of rubella-containing vaccine (9–12). As a result, the National Advisory Committee of Immunizations (NACI) stated in their 2010 report that "based on the available information, booster dose(s) of MMRV is/are not recommended after the primary series of two doses" (6). The vigorous immune response elicited by the primary doses has been shown to persist, with 100% rubella seropositivity 3 years post-immunization found by Czajka et. al in a review of studies following over 3,000 children (13). More recent studies have raised concern over waning rubella IgG titers in long-term cohorts (14), however the relationship to rubella susceptibility is unclear at this time and the most recent Canada Immunization Guide from the Public Health Agency of Canada (PHAC) states that persons with "documented evidence of immunization with a rubella-containing vaccine on or after the first birthday" are considered rubella immune (3).

Adverse reactions must be considered with every medical intervention, as every dose is accompanied by some degree of risk (Table 3). The most common adverse effects associated with rubella vaccination include low-grade fevers, a rash, and injection site redness and pain (8). Additionally, acute arthralgia and arthritis occurs in as many of 25% and 10% of recipients, respectively, and most frequently in post-pubertal women (3). Uncommon reactions include encephalitis, which occurs in 1/1,000,000 doses in North America (3). These adverse reactions are negligible compared to robust rubella immunity gained with the first 2 doses of MMR or MMRV. But, there is no established benefit of additional doses to pre-existing immunity (6), although they carry the risk of adverse events and require the discomfort of the patient during

injection. Any benefit of additional MMR doses in the post-partum period may be restricted further if blood products and antibodies are given perinatally, as these may dampen the immune response to viral vaccines. One such product commonly used in this setting is Rh immunoglobulin. When given perinatally, patients are instructed to follow up with their family physician to complete rubella serology, further exacerbating unnecessary costs due to redundant vaccination.

5.2 Cost Analysis

Throughout the 3-month data collection period, 2 of the 16 patients had already received at least two prior lifetime doses of rubella vaccination, rendering the most recent dose redundant. Both redundant doses occurred in the first month of the project, with all subsequent vaccinations being medically necessary. We hypothesize that this sudden reduction in redundant doses was the result of inadvertent education on the current standard of care, and heightened awareness of staff during a known observation period. In order to model the greatest possible expenditure before this change in practice occurred, the November data alone was used to estimate annual cost and time investment of redundant doses.

Before the change in practice, the annual cost of redundant MMR vaccination would be $615 - $733, an unnecessary expense compared to the free alternative of reviewing vaccination histories. This does not include the cost of other resources used during injection, such as cotton balls, syringes, and needle tips, and so the overall cost may be reasonably expected to exceed $733. This also excludes the cost of unnecessary serological testing, which is only recommended by the PHAC in the absence of previously documented adequate immunization, infection, or positive serology (3). Although not explored in this project, the significant cost associated with redundant serological testing has been demonstrated elsewhere in Canada (15).

In addition to physical materials, skilled labour is required for MMR administration and is typically carried out by nursing staff. Throughout the procedure, time is used to discuss the risks and benefits of the vaccine, to reconstitute and draw that vaccine, clean the site, inject, and monitor for adverse effects post-immunization. This typically requires 15 minutes per injection, when performed by a skilled worker. Comparatively, only 2 minutes is typically required to review the vaccination history, and effectively avoid the need for MMR administration in these patients. Annually, redundant MMR vaccination would consume 4h 25m – 5h 30m more nursing time than eChart review.

During the COVID-19 pandemic, Winnipeg hospitals have become increasingly short-staffed on registered nurses (RNs), increasing the workload of existing nursing staff. Further, a recent surge in delivery volumes at Women's Hospital has exacerbated the time constraints of nursing staff. Now more than ever, it is critical to minimize unnecessary tasks to optimize the use of our RNs, a precious but finite resource.

5.3 Reducing MMR Redundancy

An education session for the post-partum staff took place 1 year ago, where many were unaware of the current NACI standard of two lifetime rubella immunizations. To reflect on the results of this project, a meeting was held between the mentors of the project, nurse managers, and educators. Attendees had not witnessed any conscious change in practice during the study in response to the observation period. Concerns were raised regarding the potential for dwindling compliance in the future, as rates of vaccination history review may have been high in response to regulations prohibiting the coadministration of MMR and COVID-19 immunizations. This

regulation is no longer in practice, and vaccination history review may be more likely to be forgotten. As such, barriers to maintaining the standard of care were identified and potential solutions were discussed. The barriers identified included a lack of patient and provider awareness of the current standard of care, despite a staff educational session last year.

1. In a stakeholder discussion that brought unit managers, clinical nurse specialists and physicians to the table, five potential practice changes were proposed to maintain a redundancy rate of zero: Implement periodic re-education of RNs regarding the current standard of care.
2. Design of a graphic to be posted on site in the post-partum wards as a daily reminder to review the vaccination history prior to MMR administration. An example of such a graphic was designed for this project and can be found in the appendix (Figure S1).
3. Revise patient education. The current information pamphlet for patients from the Provincial Vaccine Advisory Committee may be updated to include the current NACI recommendations for rubella immunization.
4. Revision of the Manitoba Prenatal Record which is currently underway and will include designated space to record prior rubella immunizations, so that all providers involved in later care are aware of the patient's rubella immunity with the prenatal record alone. This is a great improvement from the previous design, which included space to record rubella serology, but not prior immunizations (Figure S2). This would eliminate the need to access eChart for vaccination history in subsequent care, and so the prenatal record alone could be consulted to determine the need for post-partum MMR.
5. To reduce both redundant MMR dosing and serological studies, the current practice of Rh immunoglobulin and MMR coadministration can be altered. Rather, the MMR dose

could be delayed in the event of Rh immunoglobulin use, and a letter could be sent to the primary care provider to inform them of the need for MMR at a later date. This would eliminate the rubella serology currently being completed after coadministration, as well as the potential second MMR dose if titres are unsatisfactory.

5.4 PAs as a Potential Intervention

A lack of provider awareness of the current standard of care was a recognized barrier to eliminating redundant rubella vaccination. Physician assistants (PAs) have the potential to fill this gap as leaders in the clinical environment, reinforcing the current standard of care within the interprofessional team on post-partum wards. Canadian PAs are trained to meet the standards established by the Canadian Association of Physician Assistants (CAPA) which are encompassed in 12 core entrustable professional activities (EPAs) (16). Notably EPA 12 states that a PA "integrates continuing professional and patient quality improvement, life-long learning, and scholarship" (16). PAs are highly capable clinicians who continue to learn and implement changes in the standard of care into their own practice. As such, PAs are ideal candidates for translating new recommendations into the clinical environment and to fellow healthcare workers, as research continues to change our definition of optimal care.

Additionally, as generalist medical practitioners, PAs are highly capable of providing holistic patient-centred care, including the critical evaluation of the risks and benefits of interventions before they are administered. Because of this, they are well suited to managing post-partum patients and could be entrusted with the prudent use of vaccines and ordering of laboratory tests such as rubella serology. PAs have been shown to improve efficiency of care in a variety of settings, with a positive impact on patient outcomes (17,18).

6. Limitations

A potential limitation is that some lifetime doses of MMR or MMRV cannot be detected if given outside of Manitoba, obscuring the assessment of vaccine redundancy. Nine of the patients in this study had incomplete vaccination histories, including one with no prior vaccinations on record. Additionally, MMR vaccines are provided to Women's Hospital free of charge by the province of Manitoba, and so the unit cost of the vaccine is stated in a legal contract. As this is confidential information, the most current Canadian list price for the Priorix MMR vaccine was provided by MHSAL and used for cost analysis. This value may differ from the true contractual unit price, resulting in over or under-estimation of the annual expense. Lastly, the sudden decrease in vaccine redundancy was likely due to a change in practice as a result of the project itself and may have prevented this observation period from capturing the typical redundancy rate prior to project commencement.

7. Conclusion and Future Direction

This QI project sought to investigate the rate of redundant MMR vaccination, and attributed cost and labour, in post-partum wards at Women's Hospital. Initially, a redundancy rate as high as 0.43 per 100 deliveries was observed but was drastically reduced to zero in subsequent months, likely secondary to unprecedented procedural change in response to the study itself. If the current practice continues, an annual cost of up to $733 and 5 hr of nursing labour can be spared. A meeting was held with the mentors of this project, nursing managers and educators to discuss barriers to immunization record review, and strategies to reduce these barriers, with the goal of maintaining this procedural change for the long-term elimination of redundant MMR vaccination at this site.

In continuation with this work, IAR collection will continue for the duration of 2022, to monitor for the efficacy of proposed interventions in sustaining a MMR vaccine redundancy rate of zero.

To our knowledge, there are no other studies assessing the translation of the newest NACI recommendations into post-partum care in Canada. This presents a great opportunity for future studies of possible vaccine redundancy and subsequent resource-sparing initiatives in facilities across the province and Canada.

Further work could investigate the costs associated with unnecessary rubella serology, as the SOGC recommends screening for rubella immunity only if there is "no record of rubella past immunity and no proof of immunization against rubella" (19). Although not investigated in this project, a 2009 study by Kearns et. al estimated that $180,000 was lost to redundant rubella serology testing in Alberta from August 2002 to December 2005 (15). Thus, this is a potentially lucrative focus for further studies in Manitoba.

9. Acknowledgements

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Appendix

Table S1. Vaccination Histories of Patients Immunized for Rubella on the Post-Partum Wards

Patient Code	Date of MMR Vaccination on Post-Partum Wards	Year(s) of Prior Rubella Immunization	Known Redundancy
1	Nov. 8, 2021	*	No
2	Nov. 18, 2021	*	No
3	Nov. 20, 2021	2000	No
4	Nov. 21, 2021	-	No
5	Nov. 21, 2021	-	No
6	Nov. 22, 2021	*	No
7	Nov. 25, 2021	1990, 1996	Yes
8	Nov. 25, 2021	*	No
9	Nov. 26, 2021	2004, 2008	Yes
10	Dec. 18, 2021	*	No
11	Dec. 21, 2021	*	No
12	Jan. 7, 2022	1997	No
13	Jan. 7, 2022	1992	No
14	Jan. 7, 2022	*	No
15	Jan. 20, 2022	*	No
16	Jan. 21, 2022	2007 *	No

Patients who received MMR vaccination on the post-partum ward from Nov. 1, 2021 to Jan. 31, 2022 were assigned a code for anonymity and prior vaccination against rubella was determined via eChart. MMR doses received on the post-partum ward are considered redundant if two prior lifetime doses are documented in eChart.

* Incomplete vaccination history, absence of prior rubella vaccinations is uncertain

- No prior vaccination for rubella despite detailed vaccination history

Figure S1. Poster Reminder of New Standard of Care for Rubella Immunization

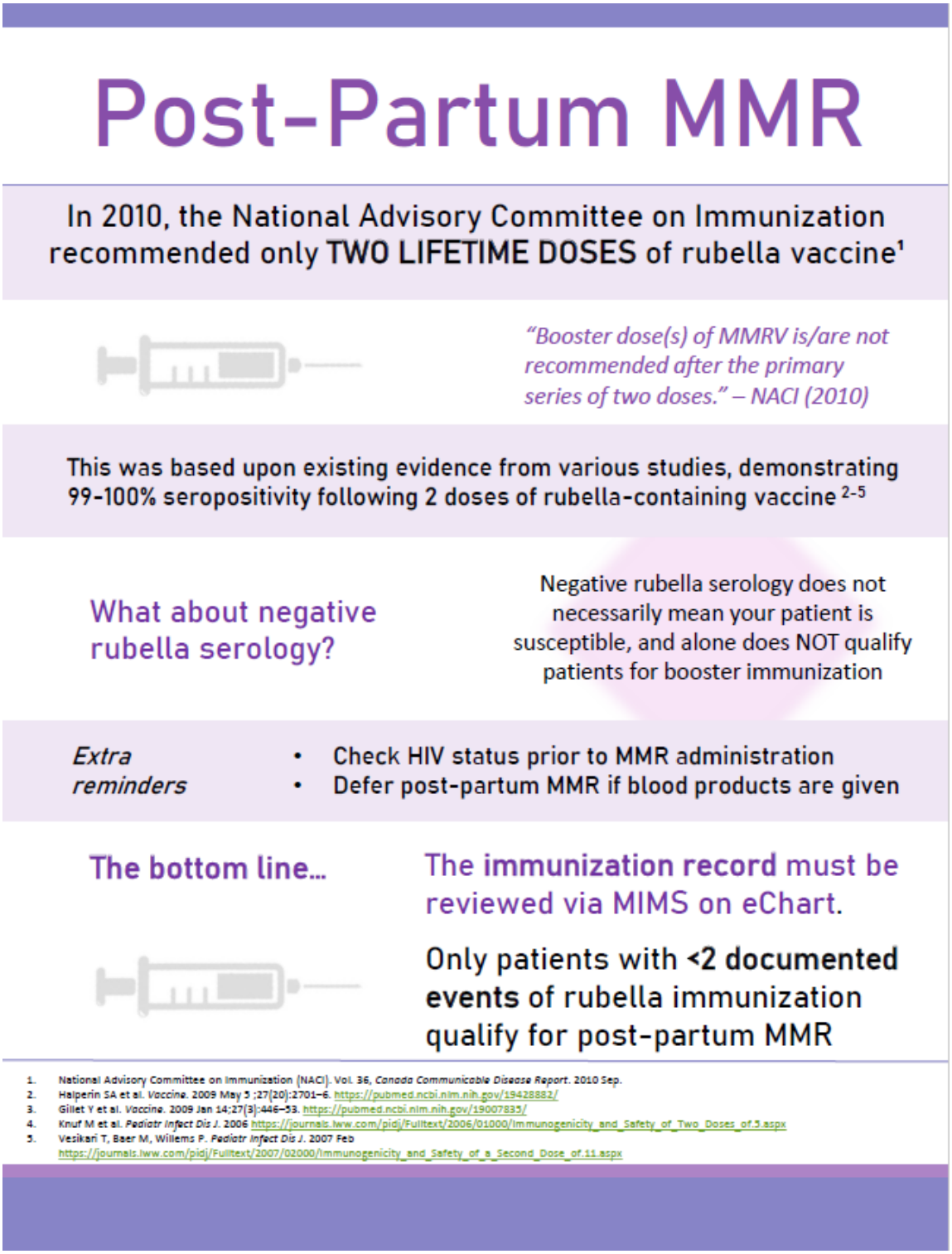
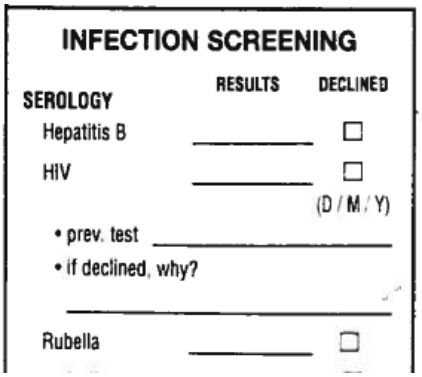


Figure S2. Rubella Documentation on Old and New Prenatal Records



INFECTION SCREENING

SEROLOGY	RESULTS	DECLINED
Hepatitis B	_____	☐
HIV	_____	☐
		(D / M / Y)
• prev. test	_____	
• if declined, why?		
	_____	
Rubella	_____	☐

IMMUNOGLOBULIN AND VACCINES		DATE
TDaP	☐ Accepted ☐ Declined	
Influenza	☐ Accepted ☐ Declined	
MMR	☐ Offer PP	
Varicella	☐ Offer PP	

The old prenatal record design (left) contained space to document rubella serology, but not prior rubella immunizations. The new design (right) will include designated space to record prior dates of rubella immunization, and would eliminate the need to access eChart for vaccine history in subsequent care.