

# Guidance for Adopting Vaccine Protocols

Why are vaccine protocols necessary?

Why not standing orders?

Recently, it has come to light that the use of protocols or standing orders is widely misunderstood in public health immunization programs. Many programs have been using "standing orders" for years -- but standing orders are patient-specific, and the public health orders are not. The MDH Immunization Program has added to this misunderstanding by distributing a one-page document called "Standing Orders for Local Public Health Agencies."

The fact is that patient-specific orders are not an efficient mechanism for holding mass immunization clinics without a physician on site. Public health nurses need another mechanism to do this. That mechanism was added to the Minnesota Nursing Practice Law in 1995. It is called "prescription by protocol." [Minnesota statute section 148.235, Subd.,(8) .] This allows RNs to prescribe and administer legend drugs, including vaccines, based on conditions (as opposed to being based on specific patients.) Subsequently, the law was amended in 2004 to include licensed practical nurses administering vaccines [Subd. (9)].

The Minnesota Board of Nursing has published a series of articles in their newsletter and on their website at [www.nursingboard.state.mn.us](http://www.nursingboard.state.mn.us) since 1995 explaining this law. The Board of Nursing is responsible for interpreting the nursing law -- not MDH.

The bottom line is that our use of "standing orders" in public health immunization programs is not in keeping with the Minnesota nursing practice law. While several local public health agencies in the state are already using separate vaccine protocols (previous called standing orders), most are not. Clearly, it is in the best interest of nurses to work toward compliance with the nursing practice law that has been in effect for a number of years. In short, this is an issue that needs work and we will all need to do our part in correcting it.

Why so many vaccine protocols?

Yes, there are a lot of protocols; however, providing prescriptions is a necessary task of the medical director in order for public health nurses to carry out their duties safely and legally.

The Board of Nursing suggests that vaccines with different schedules, ages, or dose indications need to have separate protocols.

Do protocols need to be re-signed annually?


Legally, no. There is no law requiring that these protocols be re-signed annually by the licensed medical prescriber. However, the Minnesota Board of Nursing suggests, as a standard of practice, that they be reviewed, updated if necessary, and re-signed annually.

Need help developing or modifying your vaccine protocols to meet the legal requirements?

Call Mariclaire England  
Minnesota Board of Nursing  
612-617-2274.

Next steps.

The "Guidance for Adopting Vaccine Protocols" and the protocols completed so far are available on the MDH website at [www.health.state.mn.us/immunize](http://www.health.state.mn.us/immunize), (click on *Vaccine Protocols for Local Public Health* under For Health Care Providers).

As new protocol templates are completed, or when information about a vaccine changes, MDH will update the protocol template and notify local public health by email. To receive these email notifications, please subscribe by clicking on the "Subscribe to this page" or the  icon at the top of the *Vaccine Protocols for Local Public Health* web page.

The following table describes each element of the vaccine protocol template and steps needed by local public health to adapt a protocol.



Immunization Program  
P.O. Box 64975  
St. Paul, MN 55164-0975  
651-201-5503, 1-800-657-3970  
[www.health.state.mn.us/immunize](http://www.health.state.mn.us/immunize)

| Definitions   | Steps to take to adopt protocols   |
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| <p><b>Condition-specific protocol:</b><br/>The disease against which you are vaccinating is the specific condition that is used in each protocol.</p>   | <ul style="list-style-type: none"> <li>• This has already been included in the templates.</li> </ul>   |
| <p><b>Criteria:</b><br/>The parameters/boundaries by which the RN can proceed or not to vaccinate, based on the screening and her assessment. Criteria are organized by indications, contraindications, and precautions.</p>  | <ul style="list-style-type: none"> <li>✓ Review and further delineate the criteria (see below). A licensed prescriber must review the criteria and actions and determine the appropriate action to be prescribed.</li> </ul>   |
| <p><b>Indications:</b><br/>Groups that are or are not recommended for vaccination.</p>  | <ul style="list-style-type: none"> <li>• The ACIP recommended indications are included in the templates.</li> <li>✓ Make sure all the indications for which you give a vaccine are included in the protocols.</li> </ul>   |
| <p><b>Contraindications:</b><br/>Most standard contraindications found in the ACIP recommendations and described in the Guidelines to Contraindications and Precautions are included on the templates. All templates will include the two common contraindications that result in a prescribed action to <i>not vaccinate</i>:</p> <ul style="list-style-type: none"> <li>• anaphylaxis (systemic reaction) to a previous dose and</li> <li>• anaphylaxis (systemic reaction) to a component in the vaccine.</li> </ul> | <ul style="list-style-type: none"> <li>✓ Review this section to determine, according to agency practice, if any additional contraindications need to be added or if any existing contraindications should be further delineated.</li> </ul>  |
| <p><b>Precautions:</b><br/>Conditions that usually result in a temporary or permanent deferral of vaccination. The most common precaution is acute moderate or severe illness.</p>  | <ul style="list-style-type: none"> <li>✓ Based on your nursing assessment skills and your experience determining when to proceed or not with vaccination, work with your medical director to clearly define mild illness and moderate to severe illness.</li> <li>✓ Once defined, include these same definitions in all vaccine protocols your agency adopts.</li> <li>• The following factors influence how the illnesses are defined and what prescribed actions are taken:- <ul style="list-style-type: none"> <li>○ The experience level of the nurses,</li> <li>○ The specialty of the prescriber,</li> <li>○ The availability of immediate medical care in the community,</li> <li>○ Whether the nurses will be able to reach the medical prescriber with questions.</li> </ul> </li> <li>✓ Discuss with your medical director: <ul style="list-style-type: none"> <li>○ What is the temperature threshold for withholding vaccination? And how is it taken: oral-rectal-axillary? Note: The Red Book uses 100.4°F (38°C) or greater as the defining boundary between low grade fever and fever in young children. (AAP. Report of the Committee on Infectious Diseases. 2006)</li> <li>○ If a baby has a cold or a runny nose, what other symptoms should be clarified to differentiate between acute mild and acute moderate to severe illness? (Unchanging symptoms for 1 day, 2</li> </ul> </li> </ul> |

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|   | <p>days, 3 days? Presence of cough? Presence of any fever? Alert, active, eating well? Report of lethargy? Poor appetite?)</p> <ul style="list-style-type: none"> <li>○ What gastrointestinal symptoms should result in deferral of vaccination? The presence of both of vomiting and diarrhea? Vomiting within the past 24 hours? Diarrhea alone that is liquid and occurring more than 6 times per day? Any diarrhea within the past 24 hours?</li> <li>○ When a patient has a chronic illness, how comfortable are the nurses with proceeding to vaccinate? For influenza vaccination it may be clear, but what about other vaccines and their relationship to chronic health conditions? Are there specific conditions that would prompt a referral back to the person’s primary care provider, for example, immune deficiency, cancer, or clotting factor deficiencies? If so, they should be listed as a precaution.</li> </ul>   |
| <p><b>Actions prescribed:</b><br/>Instructions for the nurse when the patient meets or does not meet the criteria. Those listed in the template are suggested actions that might be typical. Those in brackets [like this] may work for some and not for others and are included for consideration.</p> | <ul style="list-style-type: none"> <li>✓ Review the list of prescribed actions with the medical director and determine which are appropriate for your agency.</li> <li>✓ Fill in the blanks.</li> <li>✓ Decide what the nurse should do beyond not vaccinating when there is a contraindication or precaution (e.g., call the medical director first, refer patient to a primary care provider, or set up an appointment with the agency’s doctor or an allergist).</li> <li>✓ Insert this information into each protocol you adopt.</li> <li>✓ Decide prescribed actions based on resources in your community and agency. For example: <ul style="list-style-type: none"> <li>○ You may refer patients with allergies to a primary care provider, an allergy specialist, or to your agency’s own clinic for further evaluation.</li> <li>○ You may need to specify what to do if specific products can or cannot be given, e.g., refer patients who are allergic to thimerosal to a clinic that has thimerosal-free vaccine if your agency doesn’t have these products.</li> </ul> </li> <li>✓ Decide what the nurse should do, besides deferring vaccination until resolution of symptoms, when moderate to severe acute illness has been ascertained. Should the patient be referred to the primary care provider? Urgent care? Should the medical prescriber be called?</li> <li>✓ Decide how chronic conditions identified for referral should be handled. Should they be referred back to a primary care provider? A specialist? Should the medical director be called to determine whether or not to vaccinate?</li> </ul> |
| <p><b>Prescription:</b><br/>Must include all the elements that any prescription would require.</p>  | <ul style="list-style-type: none"> <li>• The templates include this information.</li> <li>✓ Verify that these elements are included in protocol prescriptions: <ul style="list-style-type: none"> <li>○ The name of the drug</li> <li>○ The dosage of the drug</li> <li>○ The route of administration</li> <li>○ The timing (schedule) of the drug</li> <li>○ Any special instructions that apply to the drug</li> </ul> </li> </ul>  |

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| <p><b>Medical emergency or anaphylaxis</b></p>       | <ul style="list-style-type: none"> <li>✓ Determine which of the medical emergency/anaphylaxis directions on the template is most appropriate for your agency:               <ul style="list-style-type: none"> <li>○ If only RNs (PHNs) are giving vaccines, use the first statement.</li> <li>○ If LPNs or unlicensed assistive personnel, such as MAs, are actually giving the vaccines, use the second statement.</li> <li>○ Note: The two options are in separate rows of a table on the protocol template, so you can delete the whole row that you are not going to use.</li> </ul> </li> <li>✓ Fill in the name of your agency’s emergency protocol document.</li> </ul>                             |
| <p><b>Questions or concerns</b></p>                  | <ul style="list-style-type: none"> <li>✓ Fill in the contact information for your medical director (prescriber) or designee.</li> </ul>   |
| <p><b>Signature</b></p>                              | <ul style="list-style-type: none"> <li>✓ Fill in the name of prescriber.</li> <li>✓ Have the licensed medical prescriber sign and date each protocol.</li> </ul>  |
| <p><b>Formatting</b> (header, footer, watermark)</p> | <ul style="list-style-type: none"> <li>✓ To remove the “Sample Protocol” watermark on the protocol template and change the footer:               <ul style="list-style-type: none"> <li>○ Go to View and click on Header and Footer. This takes you to the background text page.</li> <li>○ Click over the “Sample Protocol” text. It will show a text box that you can delete.</li> <li>○ Next, scroll down until you see the footer. Type in the date of review and update and delete the words “sample protocol.”</li> <li>○ Once you are finished, click the “close” button from the header and footer toolbox that popped up. It will take you to the main text of the article.</li> </ul> </li> </ul> |