SUBJECT: Cold Chain Management of Measles, Mumps, Rubella Vaccine

1. Overview. The most critical element for the management of the measles, mumps, rubella (M-M-R® II) vaccine is appropriate storage and handling. The exposure to temperatures outside of the manufacturers recommendations will result in the reduction of the M-M-R® II vaccine’s effectiveness.

2. Background.
   a. M-M-R® II is a live virus vaccine for vaccination against measles, mumps, and rubella (German measles). M-M-R® II vaccine is supplied as a box of 10 single-dose vials of lyophilized vaccine with a box of 10 vials of diluent.
   b. Per the manufacturer’s package insert to maintain potency the lyophilized (freeze-dried) M-M-R® II vaccine must be stored in a refrigerator at 35°F to 46°F (2–8°C) or in the freezer at -58°F to +5°F (-50°C to -15°C). The diluent must be stored in a refrigerator or at room temperature; the diluent cannot be stored in the freezer.
   c. The M-M-R® II vaccine has no loss of potency when exposed to freezing temperatures; but when exposed to temperatures above 8°C, even for a short period of time, the vaccine loses potency.
   d. The National Center for Immunization and Respiratory Diseases recommends keeping M-M-R® II in the freezer along with ProQuad® (MMRV), if adequate space is available. This may reduce the risk of inadvertent storage of ProQuad® (MMRV) in the refrigerator instead of the freezer.
   e. IHB reviewed 583 DoD and Coast Guard vaccine compromise events submitted to the U.S. Army Medical Material Agency, Distribution Operations Center, for fiscal years 2012-2016 (data for FY 2016 is through 31 Mar 2016). A summary is below:
      (1) 113 ($221,915) of the 583 vaccine compromise events, reflected the loss of M-M-R® II vaccine due to storage temperatures above the recommended range.
      (2) 90 ($173,045) of the 113 M-M-R® II loss events were the result of the refrigerator temperatures being above 8°C for a period of time.
      (3) 23 ($48,870) of the 113 M-M-R® II loss events were the result of the vaccines being left out of the refrigerator at room temperature.
      (4) 23 ($80,141) of the 583 vaccine compromise events involved the refrigerator temperature dropping below freezing; in these incidences the M-M-R® II vaccine was, many times, the only recoverable vaccine.

   a. Unlike most vaccines there is no loss of potency when M-M-R® II is exposed to freezing temperatures. The manufacturer recommends freezer storage as an option for M-M-R® II vaccine.
b. Routine freezer storage of M-M-R® II vaccine from 2012-2016 would have averted >$173,000 in vaccine losses during that time.

4. Recommendations. After reviewing the M-M-R® II vaccine loss data, IHB recommends that M-M-R® II vaccine be stored in the freezer whenever possible. This will help minimize vaccine loss during refrigerator temperature excursion events.

5. References.


   b. Centers for Disease Control and Prevention, Vaccine Storage and Handling Toolkit. May 2014