



ASSOCIATION OF IMMUNIZATION MANAGERS
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June 23, 2008

RADM Anne Schuchat, MD, MPH
Director, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
Mail Stop E-05, Clifton Road, NE
Atlanta, GA 30329-1902

Dear RADM Schuchat,

The Association of Immunization Managers (AIM), representing the sixty-four federally funded state, territorial and urban area immunization programs, is writing to call your attention to the need for national policy and guidelines pertaining to the storage and handling of vaccines. Immunization programs need evidence-based guidance about the best options for managing vaccine storage and vaccine storage failures.

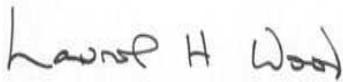
Earlier this year, AIM conducted a survey with its members to obtain information about vaccine storage and handling policies and procedures across immunization programs. The survey had three objectives: to characterize immunization programs' vaccine storage and handling policies, assess the need for uniform, evidence-based standards, and assess the importance of vaccine storage and handling issues to immunization programs. Attached to this letter are four of the most compelling figures from our NIC presentation to illustrate our findings.

Fifty-four of 64 federal immunization grantees (including 48 states) responded to the survey. The results show that immunization programs use a wide range of policies and resources in making decisions about the best equipment to store vaccine and about whether to use or waste improperly stored vaccine. In attached figures #1 and #2, you can see that respondents' beliefs about the damage caused by different types of improper storage on vaccine potency vary widely – these beliefs lead to different decisions about vaccine usability or waste, with major fiscal implications. Even for programs that strictly follow manufacturers' advice, discarding thousands of dollars in vaccines is painful when that advice conflicts with information on temperature stability data published by others, such as the World Health Organization.

It is clear that evidence-based national guidance is needed for programs to make scientifically sound, defensible and consistent decisions. Respondents indicated a critical need for national policy and guidelines pertaining to appropriate vaccine storage equipment, vaccine storage failures and compromised vaccine, and vaccine viability (see figure #3). Most vaccines are highly sensitive to freezing temperatures, which contributes to the need for equipment and monitoring guidelines that help programs and providers minimize the risk of freezing. Slightly more than half of programs that responded to the survey are concerned about legal liability issues when making a decision as to whether vaccine is usable following exposure to out of range temperatures. Specific written guidelines are needed to determine if re-vaccination is recommended in the event that vaccine is found to be compromised (see figure #4).

We urge you to work with AIM and other appropriate partners to develop uniform vaccine storage and handling guidelines. The World Health Organization has produced “Immunization in Practice” and “Temperature Sensitivity of Vaccines,” which provide detailed information about the appropriate storage and handling of vaccines. These documents could be a starting point upon which to develop some additional guidelines. We appreciate your guidance and leadership in immunization and look forward to continued partnership to protect our population from vaccine-preventable disease.

Sincerely,



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Laurel Wood, MPA
Chair

Claire Hannan, MPH
Executive Director

Attachments selected slides NIC presentation

cc: Julie Louise Gerberding, MD, MPH, Director, Centers for Disease Control and Prevention
Lance Rodewald, MD, MPH, Director, Immunization Services Division, National Center for Immunization and Respiratory Diseases
Andrew Kroger, MD, Immunization Services Division
Larry Pickering, MD, Senior Advisor to the Director, National Center for Immunization and Respiratory Diseases
Dale Morse, MD, Chair, Advisory Committee on Immunization Practices
Gregory Wallace, MD, Vaccine Supply and Assurance Branch Chief, National Center for Immunization and respiratory Diseases
Kelly Moore, MD, MPH, Medical Director, Tennessee Immunization Program and Chair AIM Storage and Handling Work Group

Figure 1: Respondents' perception of the impact of common out-of-range temperatures (≤ 24 hours) on vaccine potency (n=52 of 54)

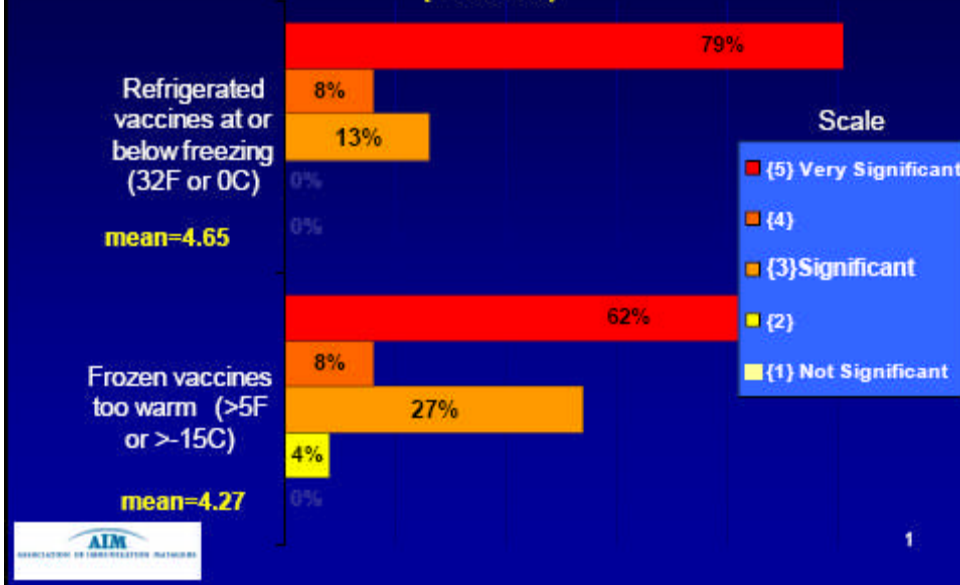


Figure 2: Respondents' perception of the impact of common out-of-range temperatures (≤ 24 hours) on vaccine potency (n=52 of 54)

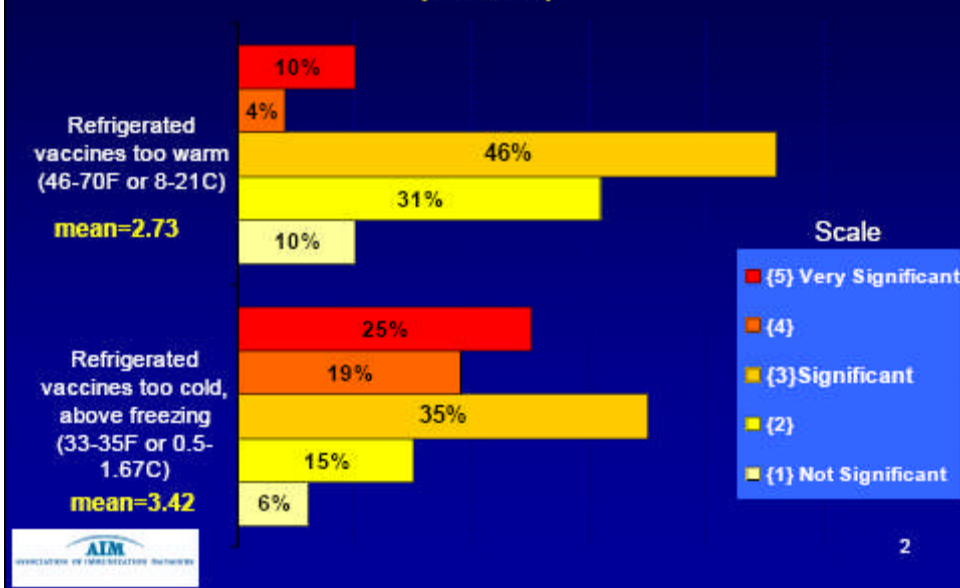


Figure 3: The need for consistent national policy for process of determining vaccine viability (n=54 of 54)

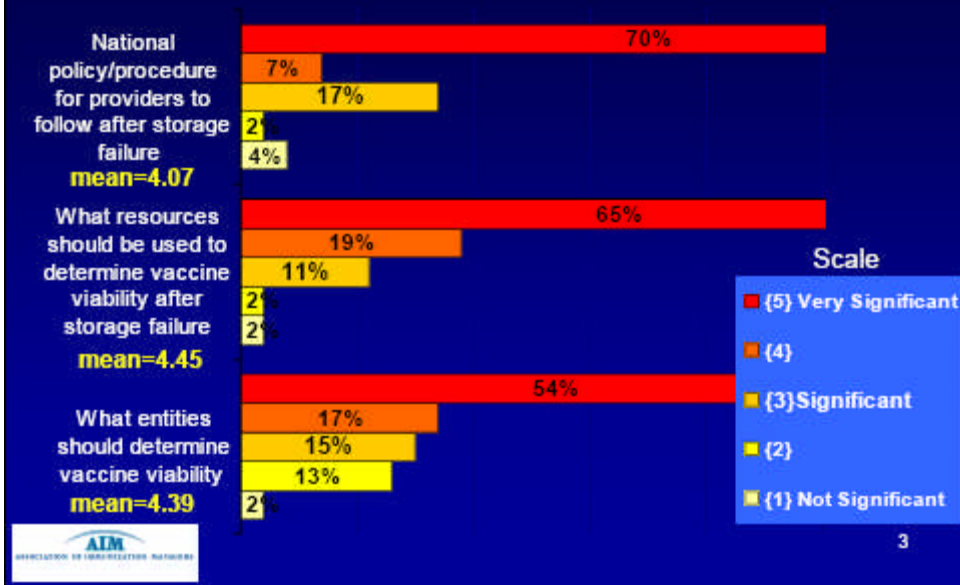


Figure 4: Need for Better Evidence-Base and National Policy for Revaccination (n=54)

