GUIDELINES AND RECOMMENDATIONS

Smallpox Vaccination Status and Procedures – Guidelines for Grantees using Licensed Undiluted Wyeth Dryvax Vaccine

Background

Among all vaccines/vaccinations, smallpox vaccine/vaccination is unique in that it requires a very small amount of reconstituted vaccine be withdrawn from a vial with a bifurcated needle, placed on the skin and administered into the superficial layers of the skin through multiple punctures. Each step of this procedure provides opportunities for one or more significant errors which can affect whether or not an individual has a successful smallpox vaccination. In addition, some people, primarily those who are 35 years of age and older, have had prior smallpox vaccinations which will in many instances affect the appearance of a current smallpox vaccination reaction. These multiple factors must be considered when observing (reading) the vaccination site reaction at 6-8 days post vaccination.

The reintroduction of smallpox vaccine use in 2003 in the US civilian and military responder populations necessitated extensive education and training of new cadres of health providers in smallpox vaccine handling, administration, and interpretation of vaccination site reactions ('takes"). Several thousands of health providers have received hands on smallpox vaccination training and site reaction education via national, state, military and other venues and more continue to be trained in order to assure maintenance of preparedness. Through the numbers of persons alone trained to administer vaccinations and/or evaluate vaccination site reaction, variability in technique and quality of vaccine administration and interpretation site reactions will occur. Much of this variability is likely to be reduced with continued experience, educational efforts and supervision.

The current policy for determining successful smallpox vaccination ("take assessment") is based on previous experience in the US and in the WHO smallpox eradication program. The procedures outlined are consistent with those followed in the current military vaccination program. The guidelines were developed utilizing input from multiple smallpox eradication experts and recent experience from the current civilian smallpox vaccination program. It is intended for use as guidance for determining if vaccinations are successful, and when not, offers procedures for revaccination.

The current smallpox vaccination program has resulted in slightly lower than expected "take" rates. There may be many reasons for these low rates, such as vaccine potency, improper vaccination technique, or improper reading of the vaccination site. The vaccine has been tested and it has shown to be potent. In addition, there were many facilities delivering the vaccine and many different people reading and evaluating the vaccination site for a "take". With increasing numbers of vaccinators and take readers, there is a potential for wide variation in technique and interpretation of the results. Thus, the current guidance document will allow for better consistency in vaccination technique and appropriate interpretation.

I. Determining prior smallpox vaccination status

1) Factors to consider:
2) Vaccination record,
3) Vaccination scar,

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4) Age of the vaccinee,
5) Prior military service.

Revaccinee:
1) Consider as a revaccinee if:
2) Written record of vaccination, or
3) Visible vaccination scar (determine if foreign born since BCG vaccine also leaves a scar), or
4) Born before 1972, or
5) Served in the military before 1984*.

*If in the military between 1984 and 1990, must show a scar or vaccination record to be considered as revaccinee.

First-time (primary) vaccinee
Has none of the above factors that determine revaccinee status and/or definitive history of not having received a vaccination.

II. Vaccination procedures

For first-time (primary) vaccinees, give three vigorous insertions with potent vaccine and proper technique. If no trace of blood, without reinserting the needle into the vaccine vial, give three additional insertions in the same spot. Even If there is no trace of blood after the additional insertions, proceed with an evaluation of the reaction on day 6, 7, or 8 post vaccination.

For revaccinees, give fifteen vigorous insertions with potent vaccine and proper technique. If no trace of blood, without reinserting the needle into the vaccine vial, give three additional insertions. Even If there is no trace of blood after the additional insertions, proceed with an evaluation of the reaction on day 6, 7, or 8 post vaccination.

For both those vaccinees who were primary vaccinees or revaccinees, if no major reaction, at day 6-8, repeat the vaccination by giving fifteen vigorous insertions with potent vaccine and proper technique. If no trace of blood on revaccination, give three additional insertions. Even If there is no trace of blood after the additional insertions, proceed with an evaluation of the reaction on day 6, 7, or 8 post vaccination. The repeat vaccination should be done on the same day as the take reading so as to not miss an opportunity. In addition, one can use the same arm, one to two centimeters away from the previous vaccination spot.

Assessing vaccination reaction 6-8 days after vaccination

Vaccination site reactions are classified into two categories, "major reactions" and "equivocal reactions". A major reaction indicates a successful vaccination, and is characterized by a pustular lesion or an area of definite induration or congestion surrounding a central lesion, which might be a scab or an ulcer. All other responses are equivocal reactions and are not successful vaccinations. Equivocal reactions may be due to poor vaccination technique, use of subpotent vaccine, or residual vaccinial immunity in previously vaccinated individuals. Persons with an initial equivocal reaction cannot be presumed to be immune to smallpox and revaccination is recommended. If a second equivocal reaction occurs after revaccination with fresh vaccine and vigorous technique, if a revaccinee, the vaccinee can be considered immune, if a first time vaccinee, a third vaccination should be given. (See criteria for considering a vaccinated person immune for persons with two consecutive equivocal reactions.)

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The World Health Organization (WHO) has recommended that response to vaccination be evaluated on post-vaccination day 6, 7, or 8 (Fenner and Henderson, WHO 1988). These are the days of peak viral replication in primary vaccinees, and the period during which vaccination reaction should be assessed in both first-time vaccinees and re-vaccinees. If the response to vaccination is evaluated too early, <6 days post-vaccination, some equivocal responses will look reactive due to dermal hypersensitivity to vaccinial proteins. These were sometimes called "immediate reactions" but are not caused by viral replication, i.e., not successful vaccination. If the response to vaccination is evaluated too late, >8 days post-vaccination, the major reaction may be missed in those individuals with prior immunity to vaccinia who may experience a more rapid progression of the vaccination lesion. Responses in revaccinees that resolve in fewer than 6 days are not successful vaccinations.

Assessing vaccination reaction more than 8 days after vaccination

If a vaccinee is not seen at 6-8 days post vaccination for an assessment of his/her vaccination site, but shows up at a later time, visually observing that the vaccination site reaction is at that time characteristic of a major reaction (pustule, and/or scab or ulcer surrounded by definitive induration or congestion) confirms it to be a successful vaccination. At even a much later time, if the vaccination site has a scar and the receipt and date of the pertinent dose of vaccine can be documented through the vaccinee's vaccination card, clinic record or PVS, the observer may confirm a successful vaccination. The observer should rely on his/her direct visual observation and not on the vaccinee's history of the evolution of the vaccination site reaction.

Criteria for considering a vaccinated person immune

Revaccinees

If a revaccinee has some degree of visible or palpable erythema or induration and there is an indication of a central lesion at day 6, 7, or 8, it is a major reaction and the vaccinee should be considered immune.

If a revaccinee has had 2 additional vaccinations, both with equivocal reactions, consider that person immune. This person may serve on a smallpox response team.

Smallpox response readiness is an on-going, long-term endeavor. It will require that all smallpox response team members maintain an up-to-date smallpox vaccination status. The appropriate interval for revaccination of response team members is currently under review and will be made available in the near future. In addition, upon confirmation of a smallpox outbreak, a repeat vaccination to boost the immune system response may be indicated for all team members to ensure their greatest protection.

Primary vaccinees

If a first time vaccinee (primary vaccinee) has not had a successful vaccination (major reaction) after two vaccinations (the first with 3 insertions; the 2nd with 15 insertions), a 3rd vaccination should be given with15 insertions using fresh vaccine and vigorous technique.

If the 3rd vaccination is not successful, the vaccinee may not have been a true first time vaccinee. If it can be confirmed that the individual actually was vaccinated prior to the recent vaccinations, this person can be considered immune and can serve on a smallpox response team. However, if it can't be confirmed that the individual is actually a re-vaccinee, then this person should not be considered immune and should not serve on a smallpox response team in a capacity in which exposure to smallpox might occur.

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Bibliography

Fenner F, Henderson DA, Arita I, et al (eds). Smallpox and its eradication. Geneva: World Health Organization, 1988. Chapter 7 – Developments in vaccination and control between 1900 and 1966, pp 294-296. Available on the WHO website:
http://www.who.int/emc/diseases/smallpox/Smallpoxeradication.html

For more information, visit www.cdc.gov/smallpox, or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)