SUMMARY
Bifurcated Needle Workshop

A Workshop was held on the use of Bifurcated Needles for administration of smallpox vaccine on Thursday, November 15, 2001 at Johns Hopkins University under the auspices of the Institute for Vaccine Safety. Participants included professionals with experience in administering smallpox vaccine, vaccine manufacturers, injection device manufacturers, and representatives from CDC, OSHA, and the FDA (List of Participants and Agenda attached.)

Objectives

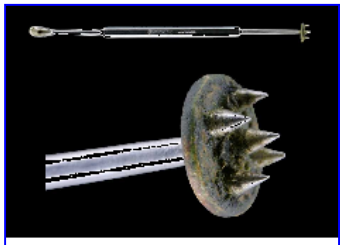
The meeting objectives were:

1. To review the use of bifurcated needles and other devices for the administration of smallpox vaccine,
2. To review guidelines for the use of these devices, and
3. To review proposed design modifications that might enhance functionality and/or decrease needlestick injuries.

Background

The last naturally acquired case of smallpox occurred in 1977; the disease was declared globally eradicated in 1980. In the United States, routine vaccination against smallpox ended in 1972. However, in the face of possible bioterrorism, smallpox has once again become a concern.

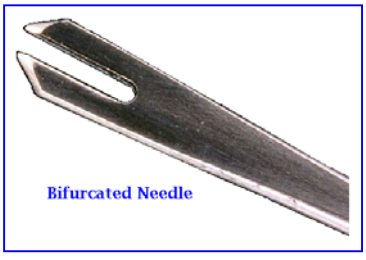
Historically, several devices have been used to administer smallpox vaccine including scarification with sharp, scalpel-like devices, the rotary lancet, a reusable device with sharp points for deep penetration, and straight needles[1]. Current devices licensed for administration of smallpox vaccine in the United States include the bifurcated needle and Mono-Vac, a plastic, single use device with 9 tines[2]. The objective is to penetrate the stratum corneum layer of the skin and deliver a small amount of vaccine to the deep epidermis[1].



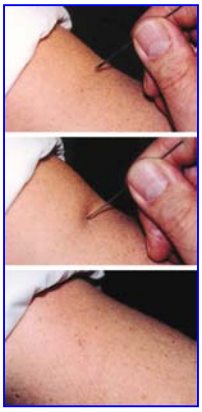
Rotary Lancet
courtesy of S Music

Bifurcated Needle

The development of the bifurcated needle in 1965 by Benjamin Rubin provided a major technical breakthrough in the ability to control smallpox[3]. This simple device is easy to use, uses a very small amount (0.0025 ml) of smallpox vaccine, and provides standardization of vaccine administration. The needle is dipped into reconstituted vaccine and the small volume is held between the two tines by capillary action.

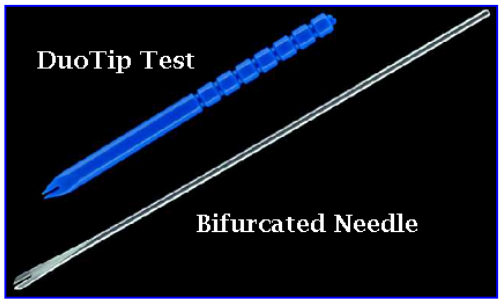


Bifurcated Needle



There were variations in the methods used by different vaccinators, but WHO and CDC guidelines call for the needle to be held at a 90º angle (perpendicular) to the skin and the vaccine administered by 15 strokes to an area of about 5 mm diameter[4]. The strokes should be sufficiently vigorous to produce a trace of blood at the vaccination site. Although individual techniques varied, high 'take' rates of 95-100% were observed in different settings, including vaccine administration by non-professionals with minimal training. Bifurcated needles are made of steel and can be reused after sterilization.

Precision Medical Products (www.pmp.net) is the only current manufacturer of bifurcated needles approved by the FDA. Lincoln Diagnostics (www.lincolndiagnostics.com) has developed a modified bifurcated needle called the DuoTip-Test for allergy testing based on the original bifurcated needle. This small plastic device is dipped in skin-test allergens, which are then applied, by either pinprick or rotation, to produce a small standard break in the stratum corneum and deliver a fixed amount of antigen. If there was an immediate demand for devices that could not be fulfilled by manufacturers, these devices could be considered although studies have not been done to demonstrate the effectiveness for administration of smallpox vaccine.



Mono-Vac

The Mono-Vac is a plastic, ring-like device that slips over the thumb and has 9 small points designed to penetrate the stratum corneum[5]. This device is approved for the administration of smallpox vaccine but requires at least 5 times as much smallpox vaccine as the bifurcated needle. A drop of vaccine is placed on the 9 clustered tines and the device is applied with pressure to one site on the upper arm. A similar device with 4 tines was used extensively for tuberculosis skin testing and is known as the "tine test".

Safety

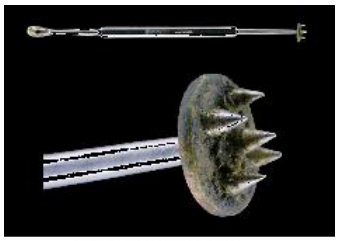
In the late 1960s in the United States, approximately 6 million primary smallpox vaccinations and 9 million revaccinations were administered each year. No reports of injuries associated with bifurcated needles were reported by CDC before 1972 when routine smallpox vaccination was stopped[6-8]. Between 1983 and 2001, more than 8000 laboratory workers received smallpox vaccine and no injuries to vaccinators or others from bifurcated needles were reported by CDC.

Although CDC received no reports of needlestick injuries associated with bifurcated needles, there was no surveillance system in place for needlestick injuries, and all sharps devices are

associated with some rate of needlestick injuries[9]. For instance, a device with similar characteristics is the fingerstick lancet which has an injury rate of 12.5 per 100,000 uses for a conventional lancet. The injury rate was reduced to 0.54 per 100,000 uses for lancets with needlestick protective features[9]. Desirable features for making devices safer include automatic retracting needles, 'autodisable' including needle shielding devices, minimizing the size of the blade surface, single use devices, no reusable parts, and the use of gloves and strict hand hygiene[10]. Additional information can be obtained on the International Health Care Worker Safety Center website (www.med.virginia.edu/epinet).

OSHA Regulations

OSHA's bloodborne pathogen standard (29 CFR 1910.1030, Occupational Exposure to Bloodborne Pathogens) was published in December 1991 and became effective in March 1992. This standard covers all occupational exposure to blood and other potentially infectious material. The Needlestick Safety and Prevention Act, Public Law 106-430, passed in November 2000 clarified and revised the bloodborne pathogen standard. Information regarding the standard and the law can be obtained on OSHA's website (www.osha.gov). Current regulations indicate that employers must: (1) Identify worker exposures to blood or other potentially infectious material, (2) Review all processes and procedures with exposure potential and (3) Re-evaluate when new processes or procedures are used.



Rotary Lancet
courtesy S Music

Employers must select and implement appropriate engineering controls to reduce or eliminate employee exposure. When engineering controls will reduce employee exposure either by removing, eliminating, or isolating the hazard, they must be used. Employers must evaluate available engineering controls for safer devices, train employees on safe use and disposal, implement appropriate engineering control devices and document these procedures in an Exposure Control Plan. Additional information about safer devices is available at ww.tdict.org, www.premierinc.com or www.med.virginia.edu/epinet.

At the present time, there are no FDA approved safety-modified devices for administration of smallpox vaccine. If alternate devices were made available, then employers would be required to review these devices and make a determination regarding their use in their setting.

Potential modifications to bifurcated needles

Smallpox vaccine is administered to the skin and it is impossible to remove all bacteria from the surface of the skin. Studies done without alcohol or acetone cleaning have revealed no differences in the rate of local adverse events. Alcohol use was discouraged during the smallpox eradication program because residual alcohol on the skin could inactivate smallpox vaccine. CDC

is currently using alcohol for administration of smallpox vaccine but allowing the site to dry thoroughly before the vaccine is administered.

Currently, bifurcated needles come in dispensers of 100 needles. Once the dispenser is opened, there is a potential for contamination of the unused devices, especially when they are dispensed over a long period of time (ie, months). The need for production of individually wrapped and sterilized devices has been recognized and plans are in place for such production.

Becton Dickinson (www.bd.com) has expressed a willingness to package and sterilize as many as 50 million of these devices as soon as they can be provided using their high speed, automated processes. BD proposes to attach the bifurcated needle to a standard needle hub and place the device in a blister pack with a hard shield around the needle using their existing production line so that the devices would be packaged in a similar manner to standard needles and thereby minimize cost. The addition of a needle hub to the bifurcated needle would provide the user with greater control and ease of handling the needle with a gloved hand. The device would be more comfortable to use and possibly safer as slippage or dropping would be less likely and, if dropped, picking up the needle would be easier.

Becton Dickinson has volunteered to add needle hubs, provide packaging, and sterilize 50 million devices for use free of charge in order to expedite the availability bifurcated needles to meet emergency needs. Becton Dickinson also expressed intent to produce basic bifurcated needles as well as bifurcated needles with safety-engineered features that would reduce the risk of needlestick injuries.

References

1. Fenner F, Henderson DA, Arita I, Jezek Z, Ladnyi ID. Smallpox and its Eradication. Geneva: World Health Organization; 1988. p 293.
2. Smith MHD. Pediatrics, 1963:32;447.
3. Rubin BA. A note on the development of the bifurcated needle for smallpox vaccination. WHO Chronicle 1980;34:180-1.
4. WHO Fact Sheet on Smallpox. October 2001. WHO instructions for vaccine administration using the bifurcated needle (multipuncture technique). (http://www.who.int/emc/diseases/smallpox/factsheet.html#Bifurcated)
5. Kravitz H. A Simplified Technique for Vaccination Against Smallpox. Pediatrics 1961;27:219-26.
6. J Michael Lane, personal communication to T. Stephen Jones. November 14, 2001.
7. Lane JM, Ruben FL, Neff JM, Millar JD. Complications of smallpox vaccination, 1968: results of ten statewide surveys. J Infect DDis 1970;122:303-9.
8. Lane JM, Ruben FL, Neff JM, Millar JD. Complications of smallpox vaccination, 1968: national surveillance in the United States. N Engl J Med 1969;281:1201-8.
9. International Health Care Worker Safety Center website (hsc.virginia.edu/medcntr/centers/epinet/
10. Jagger J. Injury rates from conventional versus self-retracting fingerstick lancets. unpublished data, 1997

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AGENDA
Bifurcated Needle Workshop

8:30	Coffee and Tea
9:00	**Welcome and Introductions**
9:05	**Objectives and brief review of devices for administration of smallpox vaccine** ..... Neal Halsey
9:20	**Proper use of the bifurcated needle** ..... Steve Jones
	Questions
9:45	**Adverse events associated with the bifurcated needle and related devices** ..... Janine Jagger
10:00	Discussion
10:15	**OSHA requirements for injection devices** ..... Amber Hogan
10:30	Discussion
10:45	Break
11:00	**Proposed modifications to the bifurcated needle** ..... Zeil Rosenberg
11:30	Discussion
12:00	Lunch (Sandwiches provided)
1:00	Comments and discussion: FDA Vaccine manufacturers Wyeth-Lederle Merck Acambis GlaxoSmithKline
1:30	**Discussion of Questions**

- Should there be one standardized design?
- Does the device, as is, adequately meet Federal OSHA Needlestick Prevention legislation?
- Are there options to improve safety and functionality that should be recommended? What will the associated costs be?
- How will the FDA assure that the device approval process can meet the urgent timeframes?

4:00 **Adjourn**