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Mass Immunization Programs: Principles and Standards

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Abstract Mass immunization involves delivering immunizations to a large number of people at one or more locations in a short interval of time. Good mass immunization programs apply planning and quality standards that maximize return on resources invested and provide the greatest individual benefits when immunizing many people in a short period of time. These programs can be used to counter contagious outbreaks, adopted as a repeated means of sustained healthcare delivery, or applied where many people move through a specific place in a short interval of time. Relevant quality standards address appropriate facilities and supplies, training of professional and paraprofessional staff, education of potential vaccinees and methods to screen them for contraindications to immunization, safeguards against anaphylaxis and syncope, documentation, safety surveillance, and a quality-improvement program. Successful mass immunization programs require early planning that builds on existing competencies. As the number of available vaccines increases, prioritizing which vaccines to administer during mass campaigns requires consideration of effectiveness, safety, and a cost–benefit equation from both the individual and community perspectives. Mass immunization campaigns aim to maximize the health of a population, but such campaigns need to be customized based on individual contraindications to immunization. Mass immunization programs need to be conducted ethically, with considerations of benefit versus risk and the need for detailed education of healthcare workers and vaccinees.

The views expressed are those of the authors and do not represent the official position of the US Department of Defense or Department of Army.

1
Introduction

Active immunization is the deliberate effort to prevent infection by evoking disease-specific immune responses. Active immunization uses an agent similar to a pathogen, but less risky. The practice of administering whole or subunit microbes as vaccines dates back over 1,000 years, to early efforts to prevent smallpox [1, 2]. In human history, the preeminent forms of infectious disease control have been sanitation and immunization [3–6]

Mass immunization is a term used in diverse ways in the medical literature. The most frequent use of the term, and the definition adopted here, is delivering immunizations to a large number of people at one or more locations in a short interval of time. A common understanding is that mass immunization campaigns involve more people passing through the immunization process than is the usual baseline rate. Similar, but less commonly used terms are pulse immunization, repeated pulse immunization, surge immunization, or cluster immunization [7]. Mass immunization is the technique employed during National Immunization Days conducted in many developing countries as part of the World Health Organization's (WHO) Expanded Program on Immunization (EPI) [2, 8].

This chapter will focus on principles and quality standards that give the greatest return on investment and the greatest individual benefits when immunizing many people in a short period of time. It can be a challenge to apply these standards in austere field situations, but program managers have a responsibility to do their best with the resources available to them. As with most other applications of preventive medicine, immunization reflects a population-based intervention to reduce disease that may have rare adverse consequences for an individual. For that reason, we will discuss contraindication screening and adverse event management.

Mass immunization has been used to refer to the administration of multiple immunizations at the same clinical encounter. In this chapter, we refer to that common practice as simultaneous or concurrent immunization.

We consider the term mass immunization to be misapplied if used to describe immunization recommended for essentially all members of a large cohort, with the cohort typically defined by age, gender, or occupation. We consider that to be a policy of universal immunization for that cohort.

2 Applications for Mass Immunization

The situations in which mass immunization techniques can be applied are summarized in Table 1. The first mass immunization programs occurred when multiple people received variola inoculation or, later, Jenner's smallpox vaccine to prevent smallpox during community outbreaks [1, 2]. Mass immunization in response to outbreaks has been successfully used in the twentieth century to control outbreaks of smallpox [1, 2], measles [2, 9], meningococcal meningitis [10, 11], poliomyelitis [8, 12], diphtheria [13], hepatitis B [14], yellow fever [2, 15], and other infections. Public-health planners debate the

Table 1 Applications of mass immunization

- In response to outbreaks, such as smallpox, measles, meningococcal meningitis, poliomyelitis, or other contagious infections
- As a repeated or iterative means of healthcare delivery, such as where people do not have ready access to routine immunization services
- At gateways, where many people arrive at a specific place in a short interval of time, such as students at a school, military personnel at a training camp, workers at a new job, religious pilgrims, or refugees
- When a new vaccine becomes available or when a new immunization policy is implemented

Definition: Mass immunization – immunizing a large number of people at one or more locations in a short interval of time merits and cost-effectiveness of using mass immunization as a tool to control typhoid fever or cholera outbreaks [16, 17].

Because of the emergent nature of contagious outbreaks, mass immunization programs in such settings must be fielded rapidly and may lack intricate planning. In contrast, other mass immunization campaigns are adopted as a repeated means of sustained healthcare delivery, such as in developing regions where people do not have ready access to routine immunization services. In such settings, a mass immunization campaign can benefit from a deliberate planning process.

Other applications of mass immunization procedures occur where a large number of people arrive at or move through a specific place in a short interval of time or on a recurring basis. Examples include new cohorts of students arriving at a school, military trainees arriving at a training camp, workers starting a new job, religious pilgrims [10, 18, 19], refugees, and the public coming to places offering influenza immunization.

Mass immunization may also be employed soon after a new vaccine becomes available or when a new immunization policy is first implemented. For example, when a vaccine is first distributed for a specific geographic area, a larger number of people need to be immunized, compared to the subsequent in-migration of people to that area. When immunization policies change, such as by expanding recommended age ranges for immunization, additional people suddenly need to be immunized. Compared to a routine immunization program or the previous policy, this situation is sometimes referred to as 'catch up' immunization. Mass immunization may be the technique used to get the new cohort caught up to the immunization level of the original cohorts.

Mass immunization is associated with certain occupational or clinical settings, such as training camps, schools, and municipal health clinics. Entering and exiting schools, job sites, refugee camps, and other recognized physical settings offer opportunities to screen immunization adequacy. Similarly, annual influenza immunization programs for the public or for employees can be used as a platform for assessing other immunization needs [18]. Most applications of mass immunization involve humans, but the same practices can be applied for veterinary and community health, such as prevention of rabies in dogs [20].

Immunizations administered via mass campaigns offer either prompt or long-term protection, or both. Prompt protection is needed against contagions that can spread rapidly within coming months (e.g., influenza, measles). Other immunizations can protect against environmental exposures expected to occur later in life (e.g., tetanus, hepatitis A).

3 Policy Making and Planning

Before considering how to implement a mass immunization strategy, policy makers and planners need to determine their public health goals and then decide whether mass immunization is the proper tool to achieve the goals.

Whether immunization is clinically appropriate for an individual is based on benefits expected from avoiding specific infections. Those infections have specific characteristics of incidence, prevalence, endemic level, transmissibility, and incubation period, as well as disease characteristics reflected by the clinical spectrum and duration of morbidity, the case-fatality ratio, availability and effectiveness of treatments, and other factors. The risks of adverse reactions to immunization similarly involve incidence, a clinical spectrum of severity, duration of impaired function, speed and probability of resolution, availability and effectiveness of treatments, and similar factors.

Then, to decide whether mass or routine immunization is the proper approach for a community or cohort, in contrast to sanitation or treatment [2, 9, 12, 16–19, 21–24] planners can model disease transmission dynamics. Such models take into account the degree of preexisting immunity in the population, their access to immunization services, and available resources. Policy makers will consider factors related to available infrastructure, the population's physical and psychological distance from it, the degree of antimicrobial resistance, and other factors. For developing countries, Foege and Eddins describe advantages and disadvantages of organizing mass immunizations based on house-to-house or collecting-point intervention [2]. And policy-makers should consider how to sustain delivery of immunization services over sequential years [2].

In general, the cost per fully immunized child is higher in a mass immunization campaign than in a routine immunization program [2, 7, 25]. The cost of travel and the decreased efficiency of itinerant vaccinators contribute to this calculation. But in rural settings, a mobile immunization team may be one of the only effective ways to deliver immunization services [1, 2, 26]. If the people cannot or will not come to the immunization site, then the immunization team needs to do the traveling. In such cases, the travel cost is a required cost of achieving the public health goal, best amortized by delivering multiple immunizations and other services on the same trip [2].

In an acute outbreak, a limited window of opportunity to control the disease may tip the balance toward mass immunization. Examples include smallpox and meningitis, where promptly achieving herd immunity (i.e., community immunity) can slow disease transmission and bring an outbreak under control. Immunization policy making is situational. The factors that make mass immunization appropriate for one setting or region may differ from another setting, where a different policy would be appropriate [9]. In some cases, a mixed strategy of both routine and targeted mass immunization may be appropriate [11]. If an outbreak occurs where insufficient vaccine is available, planners may face difficult decisions on prioritizing access to the vaccine [27].

Unlike clinical prescribing decisions, where medication use is customized to individual patients, vaccine policies typically involve a few decisions that lead to medication administration to large populations of people. Vaccines are required to be among the safest of all categories of medications, because vaccines are given primarily to healthy people to keep them healthy. The acceptable side-effect profile of the average vaccine is milder than most other medications.

No medication, however, is 100% safe. So the standard of practice with vaccines is to screen everyone eligible for immunization, to identify the few individuals who should be exempted from that immunization [28]. Exemptions are granted based on medical contraindications or a history of serious adverse events after an earlier immunization. Some contraindications are absolute, but most are relative, where policy makers and clinicians need to weigh the individual benefit–risk ratio of immunization versus no immunization.

With the success of immunization in reducing the incidence of diseases such as poliomyelitis, measles, and rubella, the public-health sector faces increasing concerns about vaccine safety and adverse events experienced after immunization. Even one adverse reaction in thousands of vaccine recipients, if serious or with prolonged health impact, can cause concerns about the safety of an immunization program.

Administration of multiple immunizations on the same day has been practiced for decades in the EPI, as well as in civilian and military healthcare settings around the world. This approach mimics the natural experience of receiving multiple immunologic stimuli from viruses and bacteria in the natural environment. In a March 2004 report, the civilian physicians and scientists who comprise the US Armed Forces Epidemiological Board (AFEB) reviewed the scientific basis for the safety and effectiveness of simultaneous immunization [29]. Scientific panels consistently conclude that scientific studies have not documented any known serious health risk from simultaneous immunizations. To minimize discomfort to immunized personnel, the AFEB recommended strategies for US military personnel to decrease concurrent immunizations, without sacrificing the individual and population benefits of widespread immunization. These strategies included dispersing immunizations into clusters over time, increased use of serologic screening to eliminate redundant immunization, and increasing the frequency of individual immunization reviews. Naturally, discomfort from simultaneous immunizations is less influential in settings were the people have few contacts with organized healthcare [2].

4 Military Cohorts as Examples

High-density cohorts of military personnel have a long history of suffering from disease outbreaks and benefiting from mass immunization campaigns. Smallpox influenced the course of many wars, including the American Revolutionary War [1, 30]. Napoleon vaccinated his troops in 1805 [2], but the policy was later abandoned. By 1869, an estimated 200,000 Frenchmen died of smallpox [1]. During the Franco-Prussian War of 1870–1871, the Prussian Army of 800,000 men vaccinated and revaccinated their personnel and suffered 8,463 cases of smallpox, with a case-fatality ratio of 5.4%. In contrast, the French Army was unvaccinated and suffered 125,000 cases of smallpox, with a fatality rate if infected of 18.7%. Mass immunization programs eventually led to the eradication of natural smallpox from this planet [1, 2].

The first large-scale use of tetanus toxoid, mass administration for American military forces began in 1941. In this case, a change in policy led to the need for a mass immunization program. A record of tetanus toxoid doses administered was stamped on soldiers' identification tags, as well as in paper records. In contrast, the German Army relied on treatment with tetanus antitoxin, and suffered higher rates of morbidity and mortality from tetanus [3, 4].

Typhoid fever was a major scourge of the Spanish–American War of 1898 and the Boer War of 1899 [3–6]. Mass administration of various typhoid vaccine formulations during World War I and World War II decreased its toll substantially.

The devastating 1918–1919 influenza pandemic caused the greatest loss of life from any cause in a short period of time in history [3–6, 31]. The extraordinary loss of fighting strength led to the US Army's research program to develop viral influenza vaccines in the 1940s. Since then, US military forces are routinely immunized against influenza A and B using mass immunization techniques.

Meningococcal meningitis is a life-threatening bacterial infection that can spread rapidly in dense populations, including military training camps. In 1968, scientists at the Walter Reed Army Institute of Research (WRAIR) developed a successful meningococcal serogroup C vaccine and later a serogroup A vaccine. A few years later, colleagues at the Institut Mérieux in France manufactured similar vaccines using the WRAIR formulation [32]. The work of both teams permitted a massive response to meningococcal serogroup A epidemics that swept Finland and Saõ Paulo, Brazil. In 1973, the entire population of Finland, more than four million people, was immunized against group A at a series of mass immunization clinics to control an epidemic. The Brazilian epidemic of 1974 produced 150,000 cases of meningococcal disease and 11,000 deaths. In one of the most dramatic mass immunization efforts ever, 100 million doses of serogroup A vaccine were administered during the Brazilian epidemic. These and successor vaccines are now used to prevent disease outbreaks among military trainees and in other settings [3, 4, 6, 15, 33]. The military success with meningococcal immunization among repeated iterations of newly assembled cohorts was cited when recognition of elevated rates of meningococcal disease among college freshman and dormitory residents led to calls for immunization in those populations [34].

Today, military units in the US conduct mass immunization programs at training camps, before overseas deployments, and annually during influenza immunization campaigns. The vaccines selected for these programs protect against infections during training, as well as during later military service. The vaccines of most acute need during military training protect against pathogens that represent an imminent risk of contagious disease in settings of close contact: influenza, meningococcal, measles, mumps, rubella, and varicella. Other vaccines are given to prevent infections more likely to occur later, during international travel or during extended periods of military service. These immunizations include: hepatitis A, hepatitis B, influenza, poliovirus, and tetanus–diphtheria–pertussis.

One of the more remarkable instances of mass customized immunization occurred in early 2003, as more than 400,000 service members being deployed to southwest Asia were screened for smallpox immunization [35]. The mission to thoroughly educate both providers and recipients about the idiosyncrasies of smallpox vaccination, identify those with atopic dermatitis or other reasons not to be immunized, safely administer the vaccine, and care for the vaccination site was performed with standardized education materials, concise screening forms, bandages, and thoroughly prepared medical staff who performed vaccinations at hundreds of clinics on four continents and dozens of warships at sea.

5
Implementation Issues

The pragmatic aspects of implementing a mass immunization campaign can be grouped into a series of planning topics. The planning domains and quality standards are summarized in Tables 2 and 3.

Table 2 Planning domains for mass immunization

1. Identify campaign goals
2. Prepare facility and order supplies. Set up multiple lanes
3. Prepare staff
4. Issue information to vaccine candidates
5. Customize procedures to the session's unique circumstances
6. Educate vaccine candidates
7. Screen for contraindications
8. Double-check safeguards
9. Administer immunizations
10. Observe for anaphylaxis
11. Document immunizations
12. Evaluate and assess quality

Table 3 Standards for mass immunization

Inform and educate	Train vaccine providers in vaccine administration, storage and handling, screening for contraindications, education of vaccinees, injection and related techniques, clinical ability to respond to adverse reactions
Vaccine storage and handling	Maintain cold chain, refrigeration or freezing, as appropriate to the specific vaccine. Large stocks of vaccine inventories should be connected to recording thermometers and alarm systems
Assess immunization histories	Identify earlier immunizations received and any adverse events to them
Assess contraindications	Identify relevant contraindications that could make an immunization unsafe or unwarranted (e.g., relevant severe allergies, pregnancy, immune suppression)
Administer vaccine	Administer the recommended dose by the proper route, observing safety and infection-control principles
Document	Record the vaccinee's name, age, type of vaccine, dose, name of vaccine provider, date administered, manufacturer, and lot number
Monitor for adverse events	Monitor patient for acute adverse reactions and treat appropriately. To improve knowledge about vaccine-associated adverse events, report adverse events to national authorities or program managers

5.1 Objectives and Standards

Before the details of a mass immunization campaign can be determined, the campaign's goals and purpose must be defined. Will the campaign deliver one vaccine or several? Who will be eligible or excluded? What facilities will be used, where, and when? Who will provide the services and with what quality standards? Will any nonimmunization services be provided [e.g., pregnancy testing, tuberculin skin testing, testing for human immunodeficiency virus (HIV), vitamin A supplementation, malaria prophylaxis, water purification measures]?

To facilitate logistical planning, planners must estimate the number of people to be educated, screened, immunized, and documented. They also must estimate the available labor supply, both professional and paraprofessional [2, 7], to perform these tasks. Budgets and job descriptions clarify constraints and roles. Complex programs may warrant exercises or mock scenarios to test contingency plans.

To properly deliver immunization services, each mass immunization site must adhere to high standards of excellence. These standards can be applied even in austere field environments, albeit with recognition of the circumstances.

5.2 Facility, Equipment, and Supplies

The logistical requirements for a mass immunization campaign can be daunting. Buildings, vehicles, tables, chairs, computers, syringes, needles, needle-disposal containers, bandages and more must be on-site, in sufficient quantity. Documents providing detailed logistical checklists appear in Table 4.

Room and furniture should be arranged to provide for a common education area. This allows one educator to orient and inform dozens or hundreds of people at the same time. After common educational sessions, the room arrangement or the time schedule should allow the speaker to answer personal questions not covered by the common briefing.

Evaluating the physical arrangement of the building or rooms available for the mass immunization program will allow a customized flow of people from reception through education, immunization, observation, and then exit. Recent documents developed by the Centers for Disease Control and Prevention (see Table 4) for mass smallpox vaccination clinics feature detailed depictions of room layout and patient flow.

Setting up multiple lanes allows the immunization process to relieve the rate-limiting steps (i.e., 'bottle necks') that slow throughput. After patients

Table 4 Core resources for mass immunization programs

Specific mass immunization resources
WHO. Control of epidemic meningococcal disease, WHO practical guidelines, 2nd edn. WHO/EMC/BAC/98.3. Geneva: WHO, 1998. www.who.int/emc-documents/meningitis/whoemcbac983c.html
WHO. Safety of mass immunization campaigns. Geneva: WHO, 2002. whqlibdoc.who.int/hq/2002/WHO_V&B_02.10.pdf
WHO. Immunization, vaccines, and biologicals document centre. www.who.int/vaccines-documents/DoxGen/H3DoxList.htm
CDC. CDC guidance for post-event smallpox planning. Atlanta: CDC, 29 Oct 2002. www.bt.cdc.gov/agent/smallpox/prep/post-event-guidance.asp
CDC. Smallpox Response Plan and Guidelines. Annex 2. General guidelines for smallpox vaccination clinics. Atlanta: CDC, 29 Oct 2002. www.bt.cdc.gov/agent/smallpox/response-plan/files/annex-2.pdf
CDC. Smallpox Response Plan and Guidelines. Annex 3. Guidelines for large scale smallpox vaccination clinics. Atlanta: CDC, 29 Oct 2002. www.bt.cdc.gov/agent/smallpox/response-plan/files/annex-3.pdf
General training resources
CDC National Immunization Program Resources: www.cdc.gov/nip
US Department of Defense (DoD) Vaccine Healthcare Centers Network: www.vhcinfo.org (includes 50 hours of internet-based training called "Project Immune Readiness")
DoD Clinical Guidelines for Managing Adverse Events After Vaccination. Washington, DC: DoD, September 2004. www.vaccines.mil/documents/564acg040909.pdf

have started flowing through the steps, administrators should assess the process to find where patients back up. At those points, additional processing stations can be added to alleviate the delay. For examples, if people are waiting to have the vaccine injected, more immunization stations should be added. If people are accumulating in front of the station where contraindications are screened, more screeners should be added. When pressure is relieved at any point in the process, some other point may become the rate-limiting step, so the assessment process should be repeated iteratively.

Vaccine will typically be ordered from the regional health authority or directly from the manufacturer. Maintaining the cold chain at each step from manufacturer to clinic is essential to delivering potent immunizations. Other consumable supplies (e.g., syringes, needles, bandages, sharps containers) should also be ordered. Quantities should be neither so large that vaccine is wasted nor so small that people are turned away unimmunized.

Adhering to vaccine handling and storage recommendations is critical. Mishandling or inappropriate storage can render vaccines ineffective without anything appearing to be wrong. Vaccines either need to be refrigerated or frozen, in appliances where records of storage temperature are maintained. When vaccine supplies arrive, they need to be promptly moved to the appropriate storage conditions. Training all personnel who might receive a vaccine shipment is essential. Large stocks of vaccine inventories should be connected to recording thermometers and alarm systems that can call prompt attention to discrepancies 24 hours a day, 7 days a week.

Autodestruct or single-use syringes are preferred in most cases. Sterilizable syringes are neither practical nor economical for mass immunization settings and should not be used [36].

In the 1960s, needle-free multi-use-nozzle jet injectors (MUNJIs) capable of 600 or more injections per hour were used in the smallpox eradication campaign and other mass immunization settings [24]. Unfortunately, their use of the same unsterile nozzle and fluid pathway to inject consecutive patients could allow transmission of blood-borne pathogens (e.g., hepatitis B, HIV) [33]. In contrast, a new generation of needle-free disposable-cartridge jet injectors (DCJIs) avoid these safety concerns by using a disposable, sterile fluid pathway for each patient. Research is underway for automated prefilling and finger-free loading and ejecting of cartridges, to make future high-speed DCJIs suitable for mass immunization programs.

Computers can aid several elements of mass immunization campaigns. Electronic record-keeping is probably the most important one, as well as in educational presentations, supply reordering, and other forms of electronic communication [37]. In rural settings without reliable access to electricity, batteries and alternate energy supplies can be used to power computers.

5.3 Prepare Staff

As important as logistics is the quality of the education and preparation of the professional, paraprofessional, and clerical staff who will perform the steps in the immunization process. Vaccine providers must be appropriately trained in all aspects of their enterprise, including vaccine storage and handling, obtaining information from candidates before immunization, providing information before immunization, injection techniques, and the clinical ability to handle adverse reactions. The professional staff must be trained in the indications and the contraindications for vaccines given in the mass immunization campaign.

Training materials are available from a wide variety of national, international, professional, and other authorities. Several examples appear in Table 4.

For their own safety and the safety of vaccinees, all staff members need to be trained in appropriate infection-control procedures. This training should focus on blood-borne pathogens (e.g., hepatitis B, HIV) as well as hand washing and general hygiene. Avoiding needle sticks and other kinds of accidents should be emphasized [38]. Staff concerns about liability and worker compensation should be resolved before the campaign begins.

5.4
Invite Potential Vaccinees

When the timing and location of the mass immunization campaign sites is clear, it is appropriate to begin inviting people to come to be immunized. Culturally sensitive marketing and advertising materials should explain who is and is not eligible for immunization [2, 39]. People should be informed if they should bring anything (e.g., personal immunization records) to the campaign site or if specific types of clothing are encouraged (e.g., short sleeve length).

Public information about the mass immunization campaign should motivate those who would benefit from immunization to come to the clinic. It should also dissuade those for whom immunization is not recommended. Planners should be ready if concerns about disease outbreaks cause large numbers of people to seek immunization despite public-health recommendations to the contrary. For example, meningococcal outbreaks in several Canadian provinces in 1991–1992 and in Rhode Island in 1998 led to greater public demand for meningococcal immunization than public-health authorities recommended [39–42]. When mass immunization programs are assembled hurriedly to deal with an outbreak, the need for consistent communication with the public is essential [43].

5.5
Educate Vaccinees

As people arrive at the immunization site and complete any registration process, they should be educated about benefits and adverse effects of the immunizations to be delivered. To help with screening for contraindications, they should be told early of any health conditions that are exemptions from immunization. Written information summaries are useful for people to read while waiting. Audiovisual presentations can be used when planning allows. Whether or not literacy is a concern in a given community, vaccine candidates should be educated verbally, so that they are personally advised. The educational content should strike a balance between being thorough and succinct. The most important information for the most people should be featured in a way to make the primacy of the key information apparent. Then allow ample time for questions and answers. Vaccine providers need to be ready to accurately answer questions and concerns posed by the vaccinee, and point the way to more detailed information if needed.

For people with special circumstances or who have a long list of questions, individualized counseling should be provided. This allows the flow of people through the immunization site to continue without undue disruption. Appropriate counseling on deferring pregnancy after immunization should be discussed.

Few health problems are caused uniquely by immunization [44]. One of the few examples is paralytic poliomyelitis that rarely follows use of the live attenuated poliovirus vaccine. Instead, immunizations can be risk factors that increase the relative risk of an adverse event occurring. For example, Guillain–Barré syndrome has been more likely to occur among recipients of some annual formulations of influenza vaccine, but not others [45]. On the other hand, health conditions that occur in unimmunized people are fully expected to occur in immunized people, at the same background rates of incidence. Discerning when an adverse event that occurs after immunization is an adverse reaction causally attributable to immunization can be a clinical challenge. People should be given factual answers about vaccine safety, in the proper perspective for interpretation of those facts.

5.6
Customize Procedures

Although similar general principles apply to most mass immunization campaigns, each one is different. The people to be immunized differ, as well as their knowledge base, the outbreak or cultural situation, and other parameters. These differences will affect the style of educational programs and the information products to be used.

When possible, preexisting immunity of individuals appearing for immunization should be taken into account. For example, it may be appropriate in some settings to use serologic tests or documentation of prior immunizations to reduce the immunization workload on site and to reduce the administration of redundant immunizations to people who are already immune. When a substantial proportion of vaccine candidates is already immune, the cost of high-quality serologic testing will tend to be overshadowed by the product cost of the vaccine [46, 47].

Serologic screening adds additional delays and risks to mass immunization campaigns that need to be weighed against the potential for cost-savings. Due to the high specificity of modern serologic tests, missed immunizations due to false positive tests do not result in clinically significant numbers of nonimmunes. Missed immunizations caused by a proportion of the screened population failing to return once test results are available may reduce immunization coverage. Rapid point-of-care testing for pre-existing immunity, although not currently available, would eliminate this concern.

5.7 Screen for Contraindications

Vaccine providers should read the records of earlier immunizations received and should succinctly interview each candidate for immunization. The goals are to avoid duplicate or redundant immunization and to identify contraindications to immunization. At a minimum, the following information should be obtained from the vaccinee: vaccines previously received, pre-existing health conditions, allergies, and adverse events that occurred after previous immunizations. For women, ask about the possibility of pregnancy in a private, respectful way to elicit candid information. Consulting the vaccinee's medical record is the most reliable method of determining immunization status. Before applying tuberculosis skin tests, history of BCG immunization and positive tuberculosis tests should be assessed.

Even when hundreds of people appear for immunization within a short period of time, their immunization needs or contraindications can be assessed individually. Decades of experience show that customized immunization delivery with high throughput can be performed by breaking the tasks down to several stations, performing education in groups, setting up multiple lanes to overcome rate-limiting steps, and listening to individuals.

If a contraindication to immunization exists, this information should be provided to the clinic supervisor and the vaccine candidate, as well as documented in the medical record. Temporary and permanent contraindications should be annotated in (electronic) medical records, to avoid recalling someone for an immunization that should not be given or should be deferred. Vaccine providers should be aware of and avoid the most common misconceptions concerning contraindications [48]. Initial and update training for vaccine providers at all levels (e.g., medics, nurses, physicians) is important for quality immunization delivery.

5.8 Double-Check Safeguards

Before administering immunizations, assure that adequate preparations have been taken to cushion anyone who faints or to respond to anyone who develops an acute allergic reaction (e.g., anaphylaxis). For example, installing rubber mats on the floor and positioning furniture away from spaces where vaccinees are processed can help minimize injuries. Where syncope occurs without these measures, vaccinees can sustain injuries, ranging from simple contusions to dental trauma and facial or skull fractures. To further minimize these risks, those at greatest risk for syncope can be immunized while sitting in a chair.

5.9 Immunize

After all the preparatory steps described above, it is time to administer the immunizations. Vaccinees can assist with the procedure by swabbing their own arms with alcohol. For oral or nasal vaccines, it may be possible to observe them giving themselves the immunization. This is the point where it is essential to implement appropriate infection-control procedures. Discard used needles in rigid safety containers [38].

Specific information regarding the recommended route of administration and appropriate dose is included with each vaccine and summarized in various reference books. Most vaccines are administered intramuscularly or subcutaneously. The dose indicated should be the dose administered. Administering partial doses to potentially reduce the risk for adverse reaction is not an effective method and could result in inadequate protection against disease.

5.10 Observe

After immunization, observe vaccinees for a suitable period of time (e.g., 10–20 min), so that any acute allergic events can be properly treated. The risk of anaphylaxis is greatest within the first 10–20 min after immunization, but can occur as much as 1 h later. The interval of time to recommend should strike a balance between the safety benefits of observation and the more acute or practical uses of that time interval. The observation interval can serve a useful purpose if the time is spent in other educational or public-health activities. Making the interval an enjoyable experience will increase compliance.

Vaccine providers must be trained to recognize and treat adverse reactions. The supplies and equipment needed to do so must be readily available on site. Although severe systemic reactions are rare, they can be life threatening. Vaccine providers should be trained to use medications (e.g., epinephrine) and conduct procedures necessary to maintain the airway and manage cardiovascular collapse (e.g., cardiopulmonary resuscitation, use of a self-reinflating ventilating bag to provide positive-pressure ventilation during resuscitation).

Vaccine providers should be in close proximity to a telephone or radio, so that emergency medical personnel can be summoned immediately, if necessary.

To improve knowledge about vaccine-associated adverse events, all serious adverse events should be reported to national authorities or program managers. Reporting adverse events after immunization that involve hospitalization, a life-threatening event (e.g., anaphylaxis), or an event related to suspected contamination of a vaccine vial are especially important.

When vaccines are administered to groups, the physical responses of the recipients may be similar. The mechanism is the same as that for mass reactions in other circumstances. These phenomena have been categorized as mass psychogenic illness (MPI) [49]. MPI is the collective occurrence of symptoms (e.g., headache, dizziness, weakness, loss of consciousness) suggesting organic illness in a group with shared beliefs about the cause of the symptoms. Outbreaks have been reported in various cultural and environmental settings, including developing and industrialized countries, in the work place, in public settings, in schools, and in military cohorts. The perceived threats have involved food, fire, toxic gases, and vaccines. Immunization managers should be aware that mass immunization events can generate MPI reactions.

5.11 Document

All immunizations should be documented in the designated paper or electronic immunization tracking system promptly after immunization. Electronic records offer advantages in terms of data searching and sharing [37].

Planners should set minimum expectations for data elements to record, such as the vaccinee's name, age, type of vaccine, dose, site and route of administration, name of the vaccine provider, date vaccine was administered, manufacturer and lot number. For multi-dose vaccines, the date the next dose is due should be communicated to the vaccinee. Electronic immunization tracking systems can calculate these dates automatically. Transferring electronic immunization records to central repositories reduces the needless duplication of immunizations related to lost paper records.

5.12 Check Quality

All immunization programs should adopt principles of continuous quality improvement. Planners should evaluate implementation early after mass immunization begins, and periodically thereafter. Evaluation parameters should include proper implementation of education and screening efforts, safe administration of immunizations, and the degree of the population that achieves immunity [2, 12, 20, 39, 50, 51]. For example, knowing that mass immunization against diphtheria in the Ukraine reached 92% of the rural population and 58% of the urban population, and why, allowed improvements to educational messages [13].

Conduct quality-improvement programs, to identify and respond to medication errors [52, 53], accidents [38], or other untoward incidents. Some of the most common errors involve selecting the wrong product or the wrong diluent. Logistical problems related to vaccine resupply and maintenance of the cold chain should be routinely reviewed [2].

6 Conclusion

Successful mass immunization programs require early planning that builds on existing competencies. These programs are best implemented with a deliberate timeline by experienced immunization staff supplemented by locally trained support personnel. Complex programs can benefit from exercises and mock scenarios. Mass immunization programs underway should be evaluated early and repeatedly to identify opportunities for improving the process. Good mass immunization programs share information with the public and the news media, fostering open lines of communication with all who have a stake in the program's success or failure [14].

In the twenty-first century, the quality of immunization delivery has taken on increased importance. People have more knowledge and inquisitiveness about the safety of vaccines than in years passed. Healthcare workers need to be able to answer questions about vaccinology and offer support services essential to the continued success of immunization for a population.

As the number of available vaccines increases, prioritizing which vaccines to administer during mass campaigns requires consideration of effectiveness, safety, and a cost–benefit equation from both the individual and the community perspectives. Extensive efforts have been made to evaluate and re-evaluate specific vaccine safety questions, including comprehensive analyses by the US National Academy of Sciences, the WHO, and other expert bodies.

Mass immunization campaigns aim to maximize immunization to maintain the health of a population, but the campaigns need to be customized based on individual contraindications to immunization. Mass immunization programs need to be conducted ethically, with considerations of benefit versus risk and the need for detailed education of healthcare workers and vaccinees.

References

1. Fenner F, Henderson DA, Arita I, Jezek Z, Ladnyi ID (1988) Smallpox and Its Eradication. World Health Organization, Geneva
2. Foege WH, Eddins DL (1973). Mass vaccination programs in developing countries. Prog Med Virol 15:205–243
3. Benenson AS (1984) Immunization and military medicine. Rev Infect Dis 6:1–12
4. Parish HJ (1965) A History of Immunizations. E & S Livingstone Ltd., London
5. Plotkin SL, Plotkin SA (2003) A short history of vaccination. In: Plotkin SA, Orenstein WB (eds). Vaccines, 4th edn. Elsevier, Philadelphia, pp 1–12
6. Woodward TE (1981) The public's debt to military medicine. Mil Med 146:168–173
7. Jajoo UN, Chhabra S, Gupta OP, Jain AP (1985) Annual cluster (pulse) immunization experience in villages near Sevagram, India. J Trop Med Hyp 88:277–280
8. Hinman AR (1960) Mass vaccination against polio. JAMA 173:1521–1526
9. McLean AR, Anderson RM (1988) Measles in developing countries. Part II. The predicted impact of mass vaccination. Epidemiol Infect 100:419–442
10. Bushra HE, Mawlawi MY, Fontaine RE, Afif H (1995) Meningococcal meningitis group A: A successful control of an outbreak by mass vaccination. East Afr Med J 72:715–718
11. Robbins JB, Schneerson R, Gotschlich EC, Mohammed I, Nasidi A, Chippaux JP, Bernardino L, Maige MA (2003) Meningococcal meningitis in sub-Saharan Africa: The case for mass and routine vaccination with available polysaccharide vaccines. Bull WHO 81:745–750
12. Richardson G, Linkins RW, Eames MA, Wood DJ, Campbell PJ, Ankers E, Deniel M, Kabbaj A, Magrath DI, Minor PD, et al. (1995) Immunogenicity of oral poliovirus vaccine administered in mass campaigns versus routine immunization programmes. Bull WHO 73:769–777
13. Lewis LS, Hardy I, Strebel P, Tyshchenko DK, Sevalnyev A, Kozlova I (2000) Assessment of vaccination coverage among adults 30–49 years of age following a mass diphtheria vaccination campaign: Ukraine, April 1995. J Infect Dis 181 (Suppl. 1):S232–S236
14. Plaitano S, Sagliocca L, Mele A, Bove C, Protano D, Adamo B, Palumbo F, Cauletti M, Franco E, Pasquini P (1993) Hepatitis B mass immunization of adolescents: A pilot study in a community. Eur J Epidemiol 9:307–310
15. Monath TP, Craven RB, Adjukiewicz A, Germain M, Francy DB, Ferrara L, Samba EM, N'Jie H, Cham K, Fitzgerald SA, Crippen PH, Simpson DI, Bowen ET, Fabiyi A, Salaun JJ (1980) Yellow fever in the Gambia, 1978–1979: Epidemiologic aspects with observations on the occurrence of orungo virus infections. Am J Trop Med Hyg 29:912–928
16. Legros D, Paquet C, Perea W, Marty I, Mugisha NK, Royer H, Neira M, Ivanoff R (1999) Mass vaccination with a two-dose oral cholera vaccine in a refugee camp. Bull WHO 77:837–842
17. Tarr PE, Kuppens L, Jones TC, Ivanoff B, Aparin PG, Heymann DL (1999) Considerations regarding mass vaccination against typhoid fever as an adjunct to sanitation and public health measures: Potential use in an epidemic in Tajikistan. Am J Trop Med Hyg 61:163–170

18. Grabenstein JD, Smith LJ, Watson RR, Summers RJ (1990) Immunization outreach using individual need assessments of adults at an army hospital. Public Health Rep. 105:311–316
19. Veeken H, Ritmeijer K, Hausman B (1998) Priority during a meningitis epidemic: Vaccination or treatment? Bull WHO 76:135–141
20. Seghaier C, Cliquet F, Hammami S, Aouina T, Tlatli A, Aubert M (1999) Rabies mass vaccination campaigns in Tunisia: Are vaccinated dogs correctly immunized? Am J Trop Med Hyg 61:879–884
21. Barlow R (1976) Applications of a health planning model in Morocco. Int J Health Serv 6:103–122
22. Grenfell BT, Anderson RM (1989) Pertussis in England and Wales: An investigation of transmission dynamics and control by mass vaccination. Proc R Soc Lond B Biol Sci 236:213–252
23. Scherer A, McLean A (2002) Mathematical models of vaccination. Br Med Bull 62:187–199
24. Centers for Disease Control & Prevention (1986) Hepatitis B associated with jet gun injection—California. MMWR 35:272–276
25. World Health Organization (2004) Economics of immunization: Guide to the literature and other resources. WHO/V&B/04.02. Geneva: WHO www.who.int/vaccines-documents/DocsPDF04/www769.pdf
26. Loevinsohn BP, Loevinsohn ME (1987) Well child clinics and mass vaccination campaigns: An evaluation of strategies for improving the coverage of primary health care in a developing country. Am J Public Health 77:1407–1411
27. Silverman RD, May T (2003) Terror and triage: Prioritizing access to mass smallpox vaccination. Creighton Law Rev 36:359–374
28. National Vaccine Advisory Committee (2000) Adult immunization programs in nontraditional settings: Quality standards and guidance for program evaluation. MMWR 49(RR-1):1–13
29. Armed Forces Epidemiological Board. Recommendation 2004–04 (2004) Multiple concurrent immunizations and safety concerns. Falls Church, VA: 16 April 2004 www.vaccines.mil/documents/477AFEB2004.pdf
30. Fenn EA (2001) Pox Americana: The Great Smallpox Epidemic of 1775–82. Hill & Wang, New York
31. Kolata G (1999) Flu: The Story of the Great Influenza Pandemic of 1918 and the search for the virus that caused it. Farrar Straus Giroux, New York
32. Chase A (1982) Magic Shots. William Morrow, New York
33. Brundage JF, Ryan MA, Feighner BH, Erdtmann FJ (2002) Meningococcal disease among United States military service members in relation to routine uses of vaccines with different serogroup-specific components, 1964–1998. Clin Infect Dis 35:1376–1381
34. Advisory Committee on Immunization Practices (2000) Prevention & control of meningococcal disease; Meningococcal disease and college students. MMWR 49(RR-7):1–20
35. Grabenstein JD, Winkenwerder W Jr (2003) US military smallpox vaccination program experience. JAMA 289:3278–3282

36. World Health Organization (2000) Sustainable outreach services (SOS): A strategy for reaching the unreached with immunization and other services. V&B/00.37. Geneva: WHO www.who.int/vaccines-documents/DocsPDF00/www555.pdf
37. Billittier AJ 4th, Lupiani P, Masterson G, Masterson T, Zak C (2003) Electronic patient registration and tracking at mass vaccination clinics: A clinical study. J Public Health Manag Pract 9:401–410
38. Abraham E, Middleton D (1997) Needlestick injuries during a mass vaccination campaign. Can J Public Health 88:38–39
39. Nolan P (2004) The Rhode Island meningitis vaccine experience—Mass vaccination campaigns, politics and health policy. Med Health R I 87:65–67
40. Gold R. Meningococcal disease in Canada: 1991–92 (1992) Can J Public Health 83:5–6
41. Gray C (1992) Meningococcal disease: Was Ottawa's mass-vaccination program necessary? CMAJ 146:1033,1036–1037.
42. Hume SE (1992) Mass voluntary immunization campaigns for meningococcal disease in Canada: Media hysteria. JAMA 267:1833–34, 1837–1838
43. Ward JD, McCall BD, Cherian SG (2001) An exercise in communication: Analysis of calls to a meningococcal disease hotline. Commun Dis Intell 25:281–282
44. Advisory Committee on Immunization Practices (1996) Update: Vaccine side effects, adverse reactions, contraindications, and precautions. MMWR 45(RR-12):1–35, errata 227
45. Lasky T, Terracciano GJ, Magder L, Koski CL, Ballesteros M, Nash D, Clark S, Haber P, Stolley PD, Schonberger LB, Chen RT (1998) The Guillain-Barre syndrome and the 1992–1993 and 1993–1994 influenza vaccines. N Engl J Med 339:1797–1802
46. Howell MR, Lee T, Gaydos CA, Nang RN (2000) The cost-effectiveness of varicella screening and vaccination in US Army recruits. Mil Med 165:309–315
47. Jacobs RJ, Saab S, Meyerhoff AS, Koff RS (2003) An economic assessment of pre-vaccination screening for hepatitis A and B. Public Health Rep 118:550–558
48. Grabenstein JD (1998) Vaccine misconceptions and inappropriate contraindications lead to preventable illness and death. Hosp Pharm 33:1557–1558, 1561–1564, 1567
49. Clements CJ (2003). Mass psychogenic illness after vaccination. Drug Safety 26:599–604
50. Centers for Disease Control & Prevention (1994) Assessment of undervaccinated children following a mass vaccination campaign—Kansas, 1993. MMWR 43:572–573
51. Paneth N, Kort EJ, Jurczak D, Havlichek DA Jr., Braunlich K, Moorer G, Vanderjagt D, Sienko D, Lieby P, Gibbons C (2000) Predictors of vaccination rates during a mass meningococcal vaccination program on a college campus. J Am Coll Health 49:7–11
52. Grabenstein JD, Proulx SM, Cohen MR (1996) Recognizing and preventing errors with immunologic drugs. Hosp Pharm 31:791–794, 799, 803–804
53. World Health Organization (2000) Supplementary information on vaccine safety. Part 2: Background rate of adverse events following immunization. V&B/00.36. Geneva, WHO. www.who.int/vaccines-documents/DocsPDF00/www562.pdf