

Protocol for Mass Prophylaxis



Indiana State Department of Health

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Protocol for Mass Prophylaxis

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Comments, questions and suggestions regarding this protocol are welcome.
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This protocol, developed by the ISDH Epidemiology Resource Center and Communicable Disease Program, outlines the decision-making process to provide mass prophylaxis, the procedure for conducting a mass prophylaxis clinic, and resolution of the crisis.

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Brown County
Clinton County
Dubois County
Johnson County
Vanderburgh County
Wayne County

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Obtaining Assistance

To report a suspected outbreak or unusual public health occurrence, please call the Indiana State Department of Health, Communicable Disease Program, at 317-233-7125 or Epidemiology Resource Center at 317-233-7416. To call toll free, call 800-382-9480 and press “70” followed by the county code. After 4:45 p.m., **E.S.T.**, weekends or holidays, please call 317-233-8115 and follow the prompts.

For assistance with routine investigations or to obtain additional reference materials, please contact the Communicable Disease Program Monday through Friday, 8:15 a.m. to 4:45 p.m. Information regarding various disease agents can also be accessed via the Indiana State Department of Health web _site at www.statehealth.IN.gov. (insert space)

Important Phone Numbers

Communicable Disease Program	317-233-7125
	317-233-7009
	317-233-7272
	FAX 317-233-7805
Epidemiology Resource Center	317-233-7416
	317-233-7807
	FAX 317-233-7378

NOTES:

INDIANA STATE DEPARTMENT OF HEALTH

PROTOCOL FOR MASS PROPHYLAXIS

Certain public health situations may necessitate prophylaxis of large numbers of people in a short time frame to prevent the transmission of illness. Examples of such events include, but are not limited to:

- case of hepatitis A in a food handler
- influenza pandemic
- case of bacterial meningitis within a crowded setting
- mass exposure to a rabid animal
- bioterrorism event

Mass prophylaxis requires collaboration and communication among several entities to provide rapid, effective intervention. Local health departments and community health care providers will often be the first to observe a public health crisis developing; therefore, immediate notification of the ISDH of a potential public health crisis is critical. The decision to provide mass prophylaxis does not rest upon one agency alone, and several factors will influence the decision to provide intervention.

The ISDH has developed this protocol in cooperation with various intra-agency programs and local health departments to provide a consistent response for mass immunization or prophylaxis. This protocol is organized into three phases: the decision process to provide mass intervention, the procedure for conducting a mass prophylaxis clinic, and resolution of the crisis. This protocol also lists key ISDH contacts for quick notification and the responsibilities of various agencies.

PHASE ONE: DECIDING TO PROVIDE MASS PROPHYLAXIS

The most important aspect of the mass prophylaxis process is deciding whether or not to provide it. Protecting the public health is paramount and the first priority in any situation. If an epidemiologic investigation reveals an exposure has occurred that may threaten public health, mass prophylaxis may be an effective disease control measure. However, resources expended during mass intervention are enormous in terms of monetary costs, time, supplies, and personnel. Logistical parameters and public perception also present significant challenges. Therefore, involved parties must carefully balance the need to protect the public health without misusing public resources and creating panic.

For these reasons, providing mass prophylaxis is a collaborative effort between the ISDH and local health departments. Both the burden and the responsibility are shouldered by all involved. Once the ISDH has been notified of a potential public health crisis, a response team is formed, consisting of representatives from epidemiology, communicable disease, public affairs, and other relevant program areas. The local health department is contacted via conference call. Key personnel at the local health department should be identified to participate in this call. Other state and local agencies may also be included if necessary. During this conference call, the following questions are discussed to determine whether or not mass intervention is necessary. These questions are based on the Indiana Communicable Disease Reporting Rule 410 IAC 1-2.3:

- Is the etiologic agent confirmed and does a prophylactic measure exist for the etiologic agent?
- Is there potential for further exposure?
- Are pharmaceuticals available and can they be administered in time to prevent illness and secondary exposure?

Determining the Etiologic Agent and Prophylactic Measures

Etiologic agents, or causes of illness, include bacteria, viruses, fungi, and toxins. The etiologic agent is often suspected via clinical signs and symptoms but is confirmed only through laboratory testing. ***As a rule, mass intervention is not considered until laboratory testing has confirmed the etiologic agent.*** State or federal public health laboratories may be needed to identify etiologic agents.

The appropriate prophylaxis, such as immune globulin, vaccine, or antimicrobial drugs, depends upon the etiologic agent. Vaccines, immune globulin, and antimicrobial drugs are effective against different types of agents. No prophylaxis exists for some etiologic

agents, and it may be important to provide this education to concerned agencies and the public.

Potential for Further Exposure

This parameter depends on the circumstances of possible exposure, the likelihood of the agent being introduced into the surroundings, and to some degree whether or not the etiologic agent is communicable. Agents may be transmitted to a sizable population from a specific source, such as food, water, animals, or bioterrorist exposure. If the agent is communicable, potential for further person-to-person exposure exists. The infectivity of the agent and the survival of the agent outside of the body also influence the likelihood of continued exposure. Non-communicable agents may continue to spread through contaminated surfaces or air currents if the agent is hardy enough.

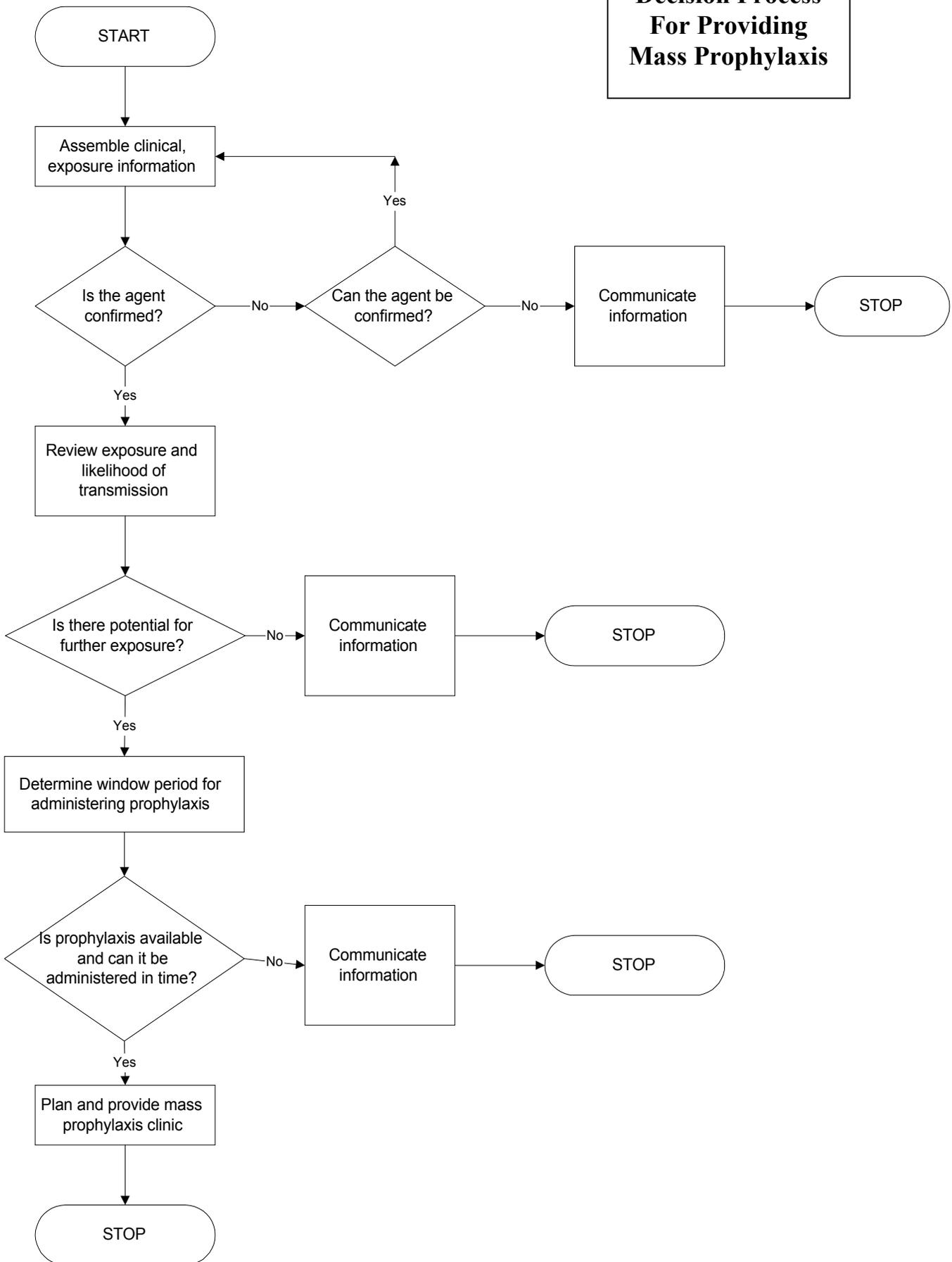
Those exposed will generally fall into three categories: those who have already developed symptoms, those who have not developed symptoms, and those who may risk secondary exposure. Prophylaxis is most beneficial to those exposed who have not developed symptoms or who may be at risk for secondary exposure. For those who have already developed symptoms, treatment (if available) rather than prophylaxis is indicated. If the potential exists for further exposure to large numbers of people, either from an infected person or an environmental source, mass prophylaxis is considered. If this potential does not exist, mass prophylaxis is not recommended, and prophylaxis is provided only for those directly exposed.

Availability and Distribution of Pharmaceuticals

Even if the etiologic agent is identified and potential for further exposure exists, mass intervention cannot be implemented if the necessary pharmaceuticals are not available in large quantities or cannot be administered within the time frame required to prevent infection. The ISDH contacts pharmaceutical distributors to determine supply availability and directs distribution. Shortages of vaccine, immune globulin or antimicrobials may necessitate prioritization of distribution to high-risk groups within the exposed or potentially exposed population.

Prophylaxis must be administered within a given time period, depending on the etiologic agent, to reduce the likelihood of infection. If pharmaceuticals can be administered within the given time period, (generally the incubation period of the agent), mass prophylaxis is considered. If pharmaceuticals cannot be administered within the given time period, mass prophylaxis is not useful. If the exposure period is unknown or ongoing, such as with an influenza pandemic, mass intervention may be considered with the understanding that infection may still occur. Education regarding availability and distribution of pharmaceuticals to concerned agencies, the media and the public is extremely important.

Decision Process For Providing Mass Prophylaxis



PHASE TWO: CONDUCTING A MASS PROPHYLAXIS CLINIC

Once mass prophylaxis is deemed necessary, coordinating and conducting a mass prophylaxis clinic requires the utmost cooperation and communication between the ISDH and the local health department (LHD). Each agency has specific responsibilities, and everyone needs to be aware of continued developments and what others are doing. In multi-county situations, clear delineation of procedure is even more important. In general, a conference call between all parties is useful to determine the exact course of action. Subsequent conference calls are helpful for maintaining communication. Since the state and local health departments have their unique responsibilities, many steps will occur simultaneously.

Planning the Clinic

1. **Obtain pharmaceuticals.** The ISDH will obtain pharmaceuticals and locate storage facilities. The ISDH will coordinate distribution of pharmaceuticals to the LHD. Law enforcement may be considered for secure transport of pharmaceuticals to clinic sites.
2. **Identify a site.** The ISDH and the LHD will discuss an appropriate site for administration of prophylaxis. If possible, estimate the number of people to receive prophylaxis. Consider factors such as size, layout for smooth traffic flow, accessibility (especially for those with disabilities), comfort, adequate restroom facilities, parking, refrigeration, and privacy (if necessary). The site should be cool enough for comfort to prevent fainting. Consider the availability of shelter during the winter if lines of people will form outside. Examples include a school gymnasium, armory, or expo center. The LHD will make reservations of the site and notify the ISDH of the times and dates when the site is reserved.
3. **Alert the public.** The ISDH Office of Public Affairs will issue news releases and handle print and electronic media inquiries if the crisis involves multiple counties. If the crisis occurs in one county, the LHD may elect to issue news releases and take media inquiries or may request that the ISDH cover that responsibility. **If the LHD elects to handle media issues itself, it should send copies of releases to the ISDH prior to sending them to the media.** The ISDH Office of Public Affairs is available at any time to assist the LHD with media issues. Prepare extra staff to handle the large number of phone calls that will result after the news release is issued. Evaluate alternative media avenues that might effectively reach potentially high risk populations, hearing impaired, vision impaired, and shut-ins. Effective strategies to reach culturally diverse populations include:
 - identifying respected healers or leaders within the population
 - identifying bilingual programs to craft and translate public health information
 - developing lists of locations where culturally diverse groups gather (e.g., churches, restaurants, markets)

- linking with school nurses in schools that serve students who speak languages other than English.
4. ***Alert community medical personnel and those in outside regions.*** The LHD should notify all hospital emergency rooms, clinics, and infection control departments in the area. Fax these facilities copies of the press release and disease information sheets to medical providers so they will have adequate information to manage the care of their patients. Encourage providers to maintain active surveillance to identify additional cases and contacts at risk of secondary person-to-person exposure. In situations involving an infected food worker of a commercial establishment, notify the corporate headquarters. The ISDH will notify groups from other parts of the state or out-of-state.
 5. ***Locate staff and supplies.*** The LHD will provide personnel and supplies (see appendix A) for the clinic. Recruit volunteers from the community, such as hospitals, nursing homes, visiting nurse and home health agencies, American Red Cross, and paramedics. Student nurses, dentists, and veterinarians may also be considered. Check with hospitals and pharmacies for supplies if necessary. The LHD should develop a memorandum of understanding with local facilities to obtain additional resources quickly. The ISDH has limited personnel and supplies available to supply a clinic, but can assist with finding them. The ISDH has copies of sample consent forms and risk factor questionnaires. Disease fact sheets can be accessed at www.statehealth.IN.gov or by fax from the ISDH.
 6. ***Provide training for volunteer staff.*** The ISDH will help provide information on disease transmission, prophylaxis and control strategies to the LHD to train volunteer staff for the clinic. The LHD should ensure that all volunteer clinic staff be adequately trained to answer client questions, screen prospective clients for prophylaxis, and assist medical personnel in administering prophylaxis if necessary, such as loading syringes.
 7. ***Provide for crowd control.*** The LHD will arrange for security at clinic sites and provide signage directing people to appropriate entrances, waiting areas, intake, prophylaxis and exit. Local and state law enforcement can be used for security. Security is especially important in instances of pharmaceutical shortages or the prioritization of those who receive it.

Conducting the Clinic

1. ***Form clinic teams.*** The LHD will coordinate staff into clinic teams. Delineate staff duties clearly prior to conducting the clinic (see appendix B). The local health officer writes standing orders for prophylaxis administration, approves content of information materials, and serves as a consultant for nursing staff. At a minimum,

teams should include an educator, technical assistant, and nurse. Ideally, the following assignments should be made:

- A. Clinic director: assigns tasks, oversees clinic operations, troubleshoots the clinic
 - B. Educators: greet recipients, answer basic questions about the disease in question and location of restrooms, parking, and handicapped access, identify candidates for prophylaxis and distribute handouts
 - risk factor questionnaire to identify candidates for prophylaxis
 - disease fact sheet
 - prophylaxis fact sheet/consent form
 - C. Traffic controller: directs clients to the forms checker, nurse, or forms collection station
 - D. Forms checker: assures all information on forms is complete
 - E. Nurse: screens clients for contraindications to prophylaxis administration, instructs on administration, administers prophylaxis, initials forms
 - F. Forms aide: verifies form is correctly completed, notes prophylaxis administered, location and lot number
 - G. Technical assistant: loads vaccine syringes, notes correct lot number, stocks supplies at nursing station, performs tasks directed by nurse
 - H. Forms collector: collects all forms prior to clients' departure
2. ***Transport pharmaceuticals and supplies to clinic sites.*** The ISDH will order necessary pharmaceuticals, arrange delivery to points in the state, and assist the LHD with modes of transport to clinic sites or central storage area. Law enforcement may be needed to transport pharmaceuticals. The LHD transports and maintains supplies at the clinic site. Check that stocks at each site are secure and stored appropriately. Be sure to arrange authorization for dispensing pharmaceuticals, such as standing orders from the local health officer. Some pharmaceuticals may require dispensing by a pharmacist only, and therefore special authorization may be necessary.
 3. ***Distribute information sheets and forms to clinic sites.*** The LHD will transport copies of the risk factor questionnaire for prophylaxis, disease fact sheet and prophylaxis fact sheet/consent form to each clinic site. ISDH can fax samples to the LHD.
 4. ***Set up clinic layout.*** The LHD will clearly post signs describing the various stations of the clinic and the traffic flow (see appendix C). Consider having chairs or cots and beverages near the exit station for clients who may feel faint. A zigzag line formation into the clinic allows for smooth flow. Position educators where lines form. Upon arrival, give each client the following:
 - a number to be called when the client's turn is ready, e.g., using rolls of tickets
 - risk factor questionnaire to identify candidates for prophylaxis
 - disease fact sheet
 - prophylaxis fact sheet/consent form

Educators screen candidates waiting in line for prophylaxis by using the risk factor questionnaire. This prevents inappropriate use of prophylaxis and also eliminates unnecessary waiting. Distribute handouts describing disease control information, such as handwashing and hygiene practices, to those who are not candidates for prophylaxis.

5. ***Maintain security.*** The LHD should activate and position security personnel at the entrance to the clinic where lines form. The ISDH can assist by activating state police personnel if necessary. Any disturbance, especially involving those who are turned away, is then kept outside of the clinic itself. Post announcements at the site indicating who should receive prophylaxis at that location. Distribute handouts diverting non-priority persons to alternate sites for prophylaxis if available.
6. ***Distribute clinic information to print and electronic media.*** The LHD will finalize details of dates, times and locations of sites. Relay information to ISDH for news release. If the LHD is handling its own media responsibilities, distribute news release and fact sheets to ISDH, then to print and electronic media outlets.
7. ***Maintain communication.*** The LHD should locate extra phone lines, walkie-talkies, cellular phones, or pagers to maintain communication during the clinic. Distribute phone numbers to clinic staff, staff at the LHD, and ISDH.
8. ***Monitor pharmaceutical supply.*** The LHD will keep track of how many doses of pharmaceuticals have been used. **Contact ISDH immediately if pharmaceutical supply begins to run low.** At the conclusion of the clinic, contact ISDH to arrange pick up of leftover pharmaceuticals.

Responsibility Checklist

ISDH:

- Have necessary pharmaceuticals been obtained and issued to the LHD?
- Has crisis information been relayed to print and electronic media?
- Have alternate media sources been considered for non-English speakers, hearing impaired, vision-impaired, and shut-ins?
- Have those in outside counties and states been alerted?
- Have fact sheets and forms been given to the LHD?
- Has pharmaceutical delivery to clinic site(s) been coordinated?
- Has clinic information been released to the media?
- Have leftover pharmaceuticals been transported and properly stored?

Local Health Department:

- Has the number of persons to receive prophylaxis been estimated?
- Have standing orders been prepared by the local health officer for nursing staff?
- Have appropriate clinic sites, i.e., convenient to risk groups, having adequate parking and proximity to public transportation, and comfortable facilities, been located and reserved?
- Have community medical providers been alerted?
- Have alternate media sources been considered for non-English speakers, hearing impaired, vision-impaired, and shut-ins?
- Has authorization been made for dispensing pharmaceuticals?
- Have clinic staff and supplies been identified and obtained?
- Has security staff been identified?
- Have extra personnel been recruited?
- Have clinic teams been selected and duties delineated?
- Have supplies and fact sheets/forms been transported to clinic site?
- Is a method of on-site communication available?
- Is there adequate proper storage for pharmaceuticals (refrigerator, freezer, etc.)?
- Has signage been posted to direct clients through the clinic?
- Has client line formation been arranged?
- Has clinic information been relayed to ISDH for media release?
- Has transportation been arranged for leftover pharmaceuticals?

PHASE THREE: RESOLVING THE CRISIS

Although the major hurdle has been cleared at the conclusion of the mass prophylaxis clinic, several factors still need to be addressed to completely resolve the public health crisis. First, some of those exposed may not have received available prophylaxis or did not meet the window criteria for receiving prophylaxis. Therefore, active surveillance must be maintained for at least one additional incubation period of the disease agent after the mass prophylaxis clinic is conducted. Second, financial issues need to be settled. If a corporate entity is involved, such as with a case of hepatitis A in a food worker, usually the corporation will provide some degree of monetary reimbursement for pharmaceuticals and supplies. Finally, information regarding the status of the public health event should be provided to the public after the clinic is held.

After the Clinic

1. **Compile total expenditures.** The LHD will calculate the total cost of the clinic, including doses of prophylaxis given, supply costs, staffing costs (such as overtime or reimbursement of a private employee), and any other expenses associated with the clinic. This figure may be reimbursed at least in part if a corporate entity is involved. These figures can also be included in a final report of the incident. Report these figures to ISDH. ISDH will notify the appropriate parties for reimbursement.
2. **Maintain active surveillance.** Some of those exposed may not have received available prophylaxis or did not meet the window criteria for receiving prophylaxis. In addition, prophylaxis may not be failsafe. Active surveillance should be maintained by the ISDH and the LHD after the last known case for at least one additional incubation period of the disease agent. This is particularly important for agents that can be transmitted person-to-person. Contact local health care providers, hospitals, urgent care clinics, and laboratories to determine if any suspected cases of illness have been identified and reiterate that they should be immediately reported. The LHD should report suspect cases to ISDH immediately and investigate them for exposure history and contact tracing. ISDH will determine the source of illness and any connection with other cases.
3. **Keep media informed.** Even after the crisis, local print and electronic media will usually want updates of any further cases of illness and doses of prophylaxis administered. The ISDH will generally handle these calls. If the LHD elects to take these calls, the LHD should inform the ISDH of the information released.
4. **Assess successes and challenges of the clinic.** One of the best ways to plan for future events is to learn from the past. Assemble the people involved and review the process for planning and conducting the clinic. What went smoothly? Were there

problems and if so, what were they? How can they be corrected? Be sure to recognize those who contributed to the clinic.

5. ***Document the event.*** The LHD should compile a report describing the clinic. The ISDH will generally issue a final report and forward copies to all involved parties. This report becomes public record.

Appendix A: Suggested Supplies for Mass Vaccine Clinic

ISDH

1. Pharmaceuticals (e.g. immune globulin, antibiotics, vaccine)
2. Prophylaxis screening questionnaires
3. Disease information sheets

Local Health Department

4. Emergency kit with instructions for anaphylaxis
5. Syringes and hypodermic needles
6. Alcohol swabs or prep pads
7. One large sharps container for each vaccine table
8. One cafeteria-style tray with white towel for each vaccine table
9. Latex or nitrile gloves in various sizes
10. Small adhesive bandages
11. Red infectious/biohazardous waste plastic bags
12. Tables and chairs determined by number of clients and staff
13. One or more plastic-lined wastebasket for each vaccine table and exit table
14. Screens to surround each vaccination site (if vaccine given in buttocks)
15. Cots or mats
16. Rulers for registration tables
17. Staplers for registration tables
18. Pens for registration tables
19. File boxes for forms
20. Tickets with numbers
21. Signs
22. Line ropes or cordons
23. Light refreshments (juice, crackers) and ice bag for those who feel faint
24. Scale for weighing recipients (if vaccine dose given by weight)
25. Cooler or portable refrigerator
26. Room fans

If mass prophylaxis does not involve vaccination, many of the supplies listed above will not be necessary. Supply requirements may be modified to address the situation. Some of the supplies, such as rulers, staplers and pens, may be available at the clinic site itself.

Appendix B: Suggested Assignment Sheet for Mass Vaccination Clinic

The following list of workers will be needed to immunize roughly 1,200 individuals in about three hours (approximately nine clients per minute). The number of clinic workers should be adjusted when the number of clients is expected to be less or more than 1,200 or to meet local needs. If the clinic involves administering antimicrobials instead of vaccine, administration will require more time than vaccine, since dosage explanation will be necessary. However, supply requirements will not include syringes and needles, alcohol pads, sharps containers, gloves, bandages, biohazardous waste disposal, screens and cots. Technical assistants may explain dosage requirements rather than load syringes.

In recruiting personnel to operate a large clinic, enter the name of the individual who will be assigned a specific responsibility into the appropriate space below. This helps firm up a commitment from the individual. The local health officer or clinic director will instruct all workers in their tasks. All workers should report to the clinic site a minimum of ____ hour(s) before the clinic is scheduled to begin.

Clinic Director _____

Media Coordinator _____

Educators

Traffic Controllers

Forms Checkers/Registrars

Nurses

Forms Aides

Technical Assistants

(1 or 2 each table)

Forms Collectors

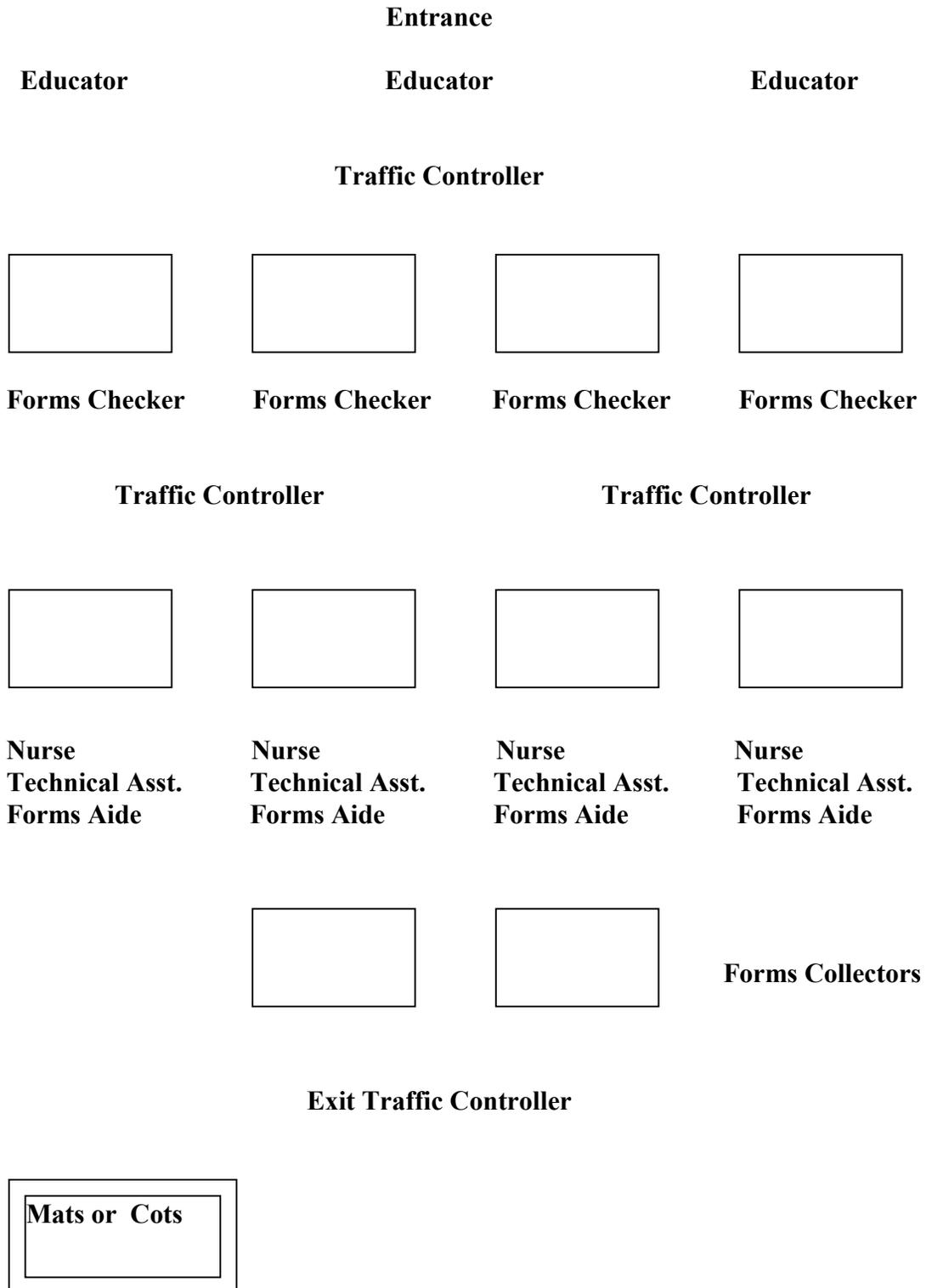
Alternates/replacements for clinic

Phone

NOTES:

Appendix C: Suggested Clinic Layout

Public transportation, parking, zigzag lines, security personnel



Appendix D: Sample Community Alert

The _____ Health Department and the Indiana State Department of Health are issuing a public health alert for the citizens of _____. People may have been exposed to _____ if they _____ at _____ on _____. _____ is a disease caused by a _____ that infects the _____. Symptoms include _____ about _____ hours after exposure. Those who may have been exposed can receive _____ at no charge at clinics provided by the _____ Health Department. Clinics will be held on the following dates and locations _____. For more information, please contact _____.

ISDH has information for each county regarding languages spoken other than English and the levels of English proficiency for those individuals whose primary language is not English. To obtain information regarding non-English language materials and distribution, please call the ISDH Communicable Disease Program.

References

Guide to the Management of Hepatitis A. D. Bixler, MD, MPH and A. Oglesby, MPH. Indiana State Department of Health, 1998.

Interim Guide for Influenza Pandemic Preparedness and Planning, Bioterrorism Working Group, Indiana State Department of Health, 2000.

Measles Outbreak Control Manual. Immunization Program, Indiana State Department of Health, 1993.