# Guidelines for EPI-AID Investigations



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This document was prepared by the

Division of Training Epidemiology Program Office

We thank everyone who reviewed the guide and provided us with constructive comments. We especially acknowledge the skillful assistance of Peter M. Jenkins who not only participated in the production of this document, but was vital to the production of our *Guide for Supervising EIS Officers* and *Guide for Incoming EIS Officers*.

# Guidelines for EPI-AID investigations

## **FOREWORD**

We have come a long way since the first EPI-AID was conducted in 1946. Reflecting the mission of the then Communicable Disease Center, the first EPI-AIDs were epidemiologic investigations of acute infectious disease outbreaks. Today, states and the Centers for Disease Control and Prevention (CDC) address an ever-expanding range of health problems, such as birth defects, cancer and other chronic diseases, maternal and child health, injuries, smoking, and environmental health threats, and today's EPI-AIDs reflect these priorities. Although the majority of EPI-AIDs are still to investigate acute infectious disease outbreaks, an increasing number involve non-infectious diseases and occupational or environmental health concerns.

Participation in an EPI-AID represents an exciting opportunity to obtain firsthand experience in solving many of today's new and complex public health problems. At the same time, it helps to fulfill one of CDC's most important functions—that of assisting states with the attainment of their health priorities. Thus, the EPI-AID is the most visible and dramatic mechanism by which CDC fulfills its mission as the Nation's prevention agency.

This Guidelines document is provided to all CDC personnel involved with EPI-AIDs so that the rationale, mechanics, and processing of EPI-AIDs can be better understood and handled. Our ultimate goal is to facilitate the most important part of the entire process—the actual epidemiologic field investigation.

> **Division of Training Epidemiology Program Office**

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# I. Introduction and Purpose

'he Centers for Disease Control and Prevention (CDC) has gained national and worldwide recognition for its rapid and effective investigations of health emergencies. Speedy assessment of adverse health events and rapid application of prevention and control measures are fundamental to the overall mission of CDC. This is one of the most important ways in which CDC serves to protect the health of the American people.

Because of the difficulty in dealing with the complex and immediate demands created by epidemics and disaster situations, states and foreign nations frequently look to CDC for short-term epidemiologic assistance. CDC has unique epidemiologic expertise in a variety of diseases and conditions, including the investigation of rare conditions and unknown agents. When assistance is requested, CDC makes every effort to respond by dispatching epidemiologic investigators, supported when necessary by specialists in other areas (sanitarians, ventilation engineers, etc.) to participate in epidemiologic field investigations. During these investigations, CDC staff act as consultants to a state (and sometimes local) health department or the health ministry of the host nation, investigating the patterns of disease or injury occurrence, the levels of risk behaviors, the identity of the etiologic agent, the transmission of the condition of concern, and the impact of preventive interventions. The goal is for prevention and control measures to be rapidly instituted.

Within CDC, a formal request for epidemiologic assistance from a state or international health agency is frequently referred to as a request for "EPI-AID" assistance. The term EPI-AID denotes that a specific administrative mechanism has been invoked to support the field response. Since this mechanism was first used in 1946, more than 3,300 EPI-AIDs have been performed.

In 1981, the Epidemiology Program Office (EPO) was established and given primary responsibility for administering and managing EPI-AIDs. In 1991, EPO formed the Division of Training (DT) to better coordinate training in applied epidemiology throughout CDC. Since EPI-AID investigations provide unique training opportunities in the science and practice of epidemiology, especially for Epidemic Intelligence Service (EIS) officers, the responsibility for administering and managing EPI-AIDs now rests with EPO's Division of Training.

The purpose of this document is to acquaint CDC personnel with current policies, guidelines, and procedures related to the EPI-AID process. It reflects changes and revisions since the last issuance in 1993. Specifically, this document covers the policies and guidelines governing the use of the EPI-AID mechanism and the administrative procedures to follow when responding to requests for epidemiologic assistance, notifying appropriate officials, and conducting and reporting the EPI-AID investigation.

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# II. Overview

The EPI-AID mechanism is a means by which EIS officers and other CDC staff can provide technical support to requesting organizations for epidemiologic field investigations. This mechanism allows CDC to (1) respond rapidly to public health problems in need of urgent attention, thereby providing an important service to state and other public health agencies; and (2) provide supervised training opportunities for EIS officers (and, sometimes, other CDC staff) to actively participate in epidemiologic investigations.

The EPI-AID mechanism may be defined operationally as an administrative method that is used to facilitate epidemiologic field investigations by EIS officers, Preventive Medicine Residents (PMRs), and other CDC staff when the conditions detailed below exist:

- Epidemiologic assistance has been requested by appropriate officials of a state, international health agency, or foreign government;
- The request involves a problem of public health importance;
- Timely response is required;
- Epidemiologic methods are primarily required;
- An investigation would contribute to the professional development of an EIS officer/PMR in practical epidemiology;
- Other sources of support are not available; and
- The response is not part of previously planned or ongoing activities being undertaken by the relevant CDC program.

In operational terms, all CDC responses to requests for epidemiologic assistance should be considered EPI-AIDS when the response involves (1) a field investigation of an urgent health problem and (2) one or more EIS officers. Important exceptions to the above are the National Institute for Occupational Safety and Health (NIOSH) Health Hazard Evaluations (HHEs) and the field epidemiologic investigations performed by state-based officers. These investigations and the subsequent reporting requirements\* serve the same training purposes for EIS officers assigned to NIOSH and state health departments as EPI-AIDs for EIS officers assigned elsewhere.

#### Definition

<sup>\*</sup> Guidance on documenting these investigations is contained in the Hazard Evaluations Procedures Manual [draft] and the Division of Field Epidemiology Field Officer Handbook, respectively.

# Use of EPI-AID Funds

The Division of Training, EPO, is responsible for managing funds related to supporting EPI-AID investigations. The funds available each fiscal year for EPI-AIDs are limited within the overall CDC budget. Therefore, EPI-AID resources are not a bottomless pit!

The general guideline for the use of EPI-AID funds is as follows:

EPI-AID funds are used to support travel and per diem of epidemiologic investigators for a period of up to three weeks. The primary purpose is to support travel costs of EIS officers, PMRs, and students participating in CDC's Epidemiology Elective Program, not CDC permanent epidemiologic staff.

As noted above, EPI-AID funds are generally intended to support only travel costs associated with an EPI-AID investigation. In exceptional circumstances, these funds can be used for other expenses (e.g., medical supplies and laboratory expenses), but support for costs other than travel must be approved in advance by the Division of Training, EPO. Unauthorized investigation-related expenses will be assumed by the program with lead responsibility for the investigation, and personal expenses will be the responsibility of the individual investigator.

Circumstances under which EPI-AID funds may be used to support additional travelers and expenses other than travel may vary from time to time. Particularly during times of budgetary constraints, travel restrictions, etc., interim guidelines may be issued that limit the number of investigators and the duration of the investigation.

An investigation fitting the EPI-AID definition should be considered an EPI-AID and consequently assigned an EPI-AID number (see Section IV—Before the EPI-AID Investigation), regardless of whether EPI-AID funds are used. Non-EPI-AID funds include those from a CDC program or an international source. In cases such as these (when an investigation is assigned an EPI-AID number but is not supported by EPI-AID funds), it is expected that all EPI-AID reporting requirements will be fulfilled (see Section IV—After the EPI-AID Investigation).

# Approvals and Clearances

Human Subjects Review EPI-AID investigations, like all other epidemiologic field investigations, are subject to certain policies, approvals, and clearances. Most relevant to the conduct of EPI-AID investigations are the following:

Human subjects review by an Institutional Review Board (IRB) may or may not be required, depending on whether the investigation is "research" involving human subjects. It is not always clear when IRB review is required according to various written rules and guidelines. Nonetheless, it is important that the intent and spirit of the regulations on protection of human subjects be followed. EPI-AID

investigations are generally considered to be a response to a public health emergency (rather than research), both to determine the cause and/or extent of a particular, acute, current health problem in a community and also to develop plans for its control. This situation is the public health equivalent of an individual doctor-patient encounter in which the community as "patient" presents with a health problem, and CDC and other health agencies as "physician" are expected to diagnose, via the investigation, and control ("treat") without delay.

Nevertheless, situations arise in which the analogy described above is less clear. When any doubt exists about the need for IRB review, the Human Subjects Review (HSR) contact within the EIS officer's Center/Institute/Office (CIO) should be consulted. In those instances where IRB review is determined to be necessary and yet time is critical (e.g., specimens must be collected within a few days or they would be of little use), the HSR contact person can provide guidance and take steps to expedite the review process. The guide "Decision Making about Human Subjects Review Requirements" (CDC Manual Guide, 1994) is also available and includes helpful information on the basic elements of informed consent.

A common misconception exists that data collection initiated as a result of an EPI-AID does not require clearance by OMB. On the contrary, like other investigations performed by the Federal government, data collection in an EPI-AID requires official clearance by OMB. However, because of the urgent nature of EPI-AID investigations and to expedite the EPI-AID process, CDC has obtained this clearance in advance, provided that the time required for data collection does not exceed 30 days. Under this approval, CDC is required to document its data collection activities for each EPI-AID after the field investigation has occurred. These reporting requirements are discussed in Section IV of this document.

Office of Management and Budget (OMB) Clearance for Data Collection

## Use of EH-AiD Funds

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# **III. EPI-AID Process**

he remainder of this document will cover in greater detail the EPI-AID process, from initiation to completion of an EPI-AID. It will describe WHAT steps need to be followed, WHEN they are to occur, and WHO is responsible, as depicted below:

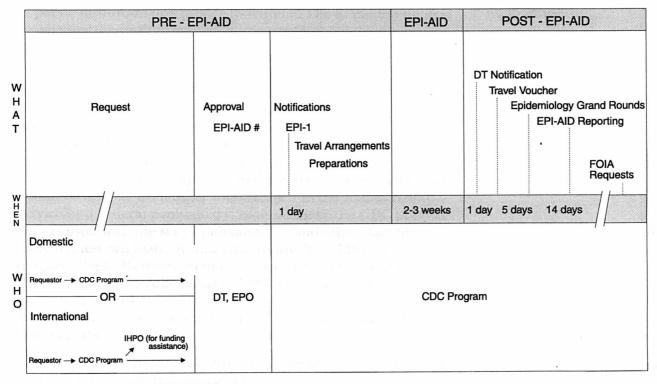


Figure 1. Schematic of the EPI-AID Process

# III. EPI-AID Process

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## IV. The EPI-AID Process

his section covers the specific procedures to follow for initiating an EPI-AID, obtaining necessary approvals, and preparing for the field investigation.

A request for epidemiologic assistance may be initiated by a private or public institution or a private individual. The next steps depend on whether the health problem originates from a domestic or international source.

If the request for assistance is from a **domestic** source, usually the state official (or his/her designee) with responsibility for the particular health problem (generally the state epidemiologist) is notified. After determining that epidemiologic assistance is needed, the state official may offer a formal invitation to CDC, generally to the program with primary responsibility for the health problem involved. On rare occasions CDC may receive requests for EPI-AID assistance directly from other sources, such as the Indian Health Service or a Federal penitentiary. In these cases, the CDC program must consult with the state epidemiologist and other state officials. If the request originates from a state to which an EIS officer is assigned, the CDC program must discuss the request with that officer and his/her Atlanta-based EPO supervisor to determine whether the state-based officer is able to provide the necessary assistance to the state, perhaps with guidance provided by other CDC experts.

If the request for assistance is from an international source, usually the CDC program with primary responsibility for the health problem involved is contacted. Whenever the possibility of an international EPI-AID arises, the CDC program should then inform both the Director, Division of Training, EPO, and international health area experts as appropriate (e.g., International Emergency and Refugee Health Unit, Childhood Survival, Newly Independent States, or Office of Global Health) as soon as possible. Possible sources of financial support should be explored and relevant expertise in other CIOs should be identified. Sources of funding that should be considered include the government of the host country, WHO or PAHO, USAID, other non-CDC federal funding sources, and other CDC sources of funds. If alternate funds are unavailable, the CDC program may then request assistance through the EPI-AID mechanism.

# Before the **EPI-AID** Investigation

Request for **Assistance** 

## **Approval**

Once a request is received and the CDC program (and appropriate international experts) determine that CDC assistance is needed, the EPI-AID Coordinator, through whom approval will be obtained, should be contacted at 404/639-3182. During nonbusiness hours, Division of Training staff should be contacted at home in the following order: (1) Director, (2) EIS Program Chief, (3) Deputy Director. If none of these individuals is available, the Office of the Director, EPO, staff should be contacted at home in the following order: (1) Assistant Director for Science, (2) Assistant Director, (3)Deputy Director, (4) Director, (5) Assistant Director for Program Operations. Without prior approval from one of these individuals, EPI-AID funds will not be available to support the investigation and any expenses incurred prior to approval will be the responsibility of the program.

Considerations for approval include determining whether an EPI-AID is the appropriate mechanism to provide assistance, the level of support that EPI-AID funds can provide, the individuals involved, supervision, duration of the investigation, etc. In general, the following guidelines apply:

- State-based EIS officers are CDC's first line of epidemiologic assistance in a given state. They and their Atlanta-based supervisors should be notified of impending investigations in their states. The decision about whether the state-based officer will assume primary responsibility or will assist in the investigation should evolve after discussions among the officer, the local supervisor, the Atlanta-based supervisor, and the program that is preparing to respond to the EPI-AID. This improves collegiality, facilitates conduct of the investigation, and allows for local follow-up of the investigation.
- The number of persons supported by an EPI-AID should be appropriate to the size and nature of the investigation. Except under unusual circumstances, no more than one EIS officer can be supported under this mechanism. However, when resources permit, an EIS officer going out on an EPI-AID for the first time can be accompanied by a second-year EIS officer for a short period of time (usually 2–3 days) to help initiate the investigation. If the investigation is in a state that has a second-year EIS officer assigned to it, the state-based officer can provide the mentoring function.
- One student participating in the Student Elective Program may be approved to join in an EPI-AID investigation if it will provide a good training experience and the student has not participated in a prior EPI-AID.
- Except in extremely unusual circumstances, EPI-AID funds are not available to support CDC (non-EIS, non-PMR) staff who accompany EIS officers on EPI-AIDs.

- The CDC program with expertise in the subject area has responsibility for supervising investigators involved in an EPI-AID, regardless of the CIO of assignment of the EIS officer who will lead the investigation. However, if a state-based officer is involved, the CDC program and the Atlanta-based supervisor should discuss and mutually agree on supervisory responsibility.
- The anticipated duration of support should be verbally agreed upon by the Division of Training, EPO, and the relevant CDC program when the EPI-AID investigation is initiated. In general, EPI-AID investigations are of no more than three weeks' duration.
- If needed, extensions of time spent in the field should be negotiated and approved in advance. Keeping in mind that OMB approval for data collection under the EPI-AID mechanism is limited to 30 days, the justification for an extension should be scientifically reasonable and related to immediate problems of public health importance, not long-term program research interests.
- In general, a single trip should be sufficient to complete an EPI-AID. Under extremely unusual circumstances, one follow-up trip can be supported by this mechanism, if the program and the Division of Training, EPO, consider it necessary for the completion of the response to the public health emergency.

International EPI-AIDs have additional requirements for approval. Once approved by the Division of Training, EPO, the CDC program with lead responsibility for the EPI-AID should inform appropriate international health program officials of who will be investigating the health problem, when the investigator plans to depart, etc. International health program officials will then be responsible for notifying and obtaining necessary approvals from appropriate Health and Human Services (HHS), State Department, Agency for International Development, and other international agency officials. For example, State Department clearance is needed whenever government employees travel outside the United States.

When an epidemiologic assistance request is approved as an EPI-AID and the travel is initiated, the automated travel system will assign a sequential number to each EPI-AID for purposes of reporting, accountability, and tracking.

State governments are responsible for public health in their own jurisdictions. At CDC's request, many states have delegated to the state epidemiologist and other state officials the authority to invite CDC staff to their state. Most requests for epidemiologic assistance are received by CDC from state health officials. In the rare instances when a state official did not request epidemiologic assistance but an EPI-AID was approved (e.g., a cruise ship investigation when state jurisdiction is less clear), the responsible

### **EPI-AID** Number

#### **Notifications**

# CDC program should notify the appropriate state epidemiologist and other state officials.

## The EPI-1 Report

The purpose of the EPI-1 report is to officially inform appropriate individuals (CDC Director, CDC professional staff, and state epidemiologists) of the suspected health problem. The program directing the EPI-AID investigation is responsible for writing the EPI-1 report (usually written by the investigating officer or supervisor), which should be completed and approved before the EPI-AID mission begins. At the time the EPI-1 is prepared, responsibility for writing the summary report of the investigation, called the EPI-AID Trip Report, should be assigned.

Detailed instructions for preparing the EPI-1 and an example of a completed report are contained in Appendix 1.

#### **Format and Content**

The EPI-1 report should be short (usually two to three pages), clear, factual, and logically organized. It should also follow a prescribed format. To facilitate completion, a WordPerfect merge document for the EPI-1 has been developed and may be obtained from the EPI-AID Coordinator.

The statement of the **nature of the problem** should be brief (one to three sentences). Both the seriousness and urgency of the problem should be evident from the language chosen. Mention of the history leading up to the request or of the request itself is discouraged.

The **sources of invitations** should always include the state official as one of the inviting officials regardless of the initial source of the request.

The nature and timing of the response should basically list who went out (and when) to assist in the investigation. To reflect the state's and/or country's lead public health responsibility, an EIS officer is never sent out to "conduct" or "perform" the investigation. Rather, he/she is sent to "assist" or "join in" the investigation.

The **objectives of the EPI-AID mission** should be presented in general terms, such as "to assess the extent of Disease X in the population, identify factors influencing risk, and develop recommendations for controlling the problem." A description of methods or methodology is not necessary and is generally undesirable. (In the real world, study plans often change depending on what is found in the field).

For EPI-AIDs with **co-investigating officers**, the names, titles, and organizational affiliations of all participating EIS officers should be included. Occasionally, EPI-AID requests involve participation of more than one officer and more than one CDC program.

Distribution should list, at a minimum, mailing keys WF-2 (EPO professional staff); WF-3 (CDC professional staff); and ZW (all state epidemiologists). The names, titles, and mailing addresses of all other individuals who are to receive copies of the EPI-1 should appear below the list of mailing keys.

Draft EPI-1 reports are reviewed and approved by the Division of Training, EPO. The responsible CDC program should send the draft EPI-1 report via E-Mail to the EPI-AID Coordinator (with a FAX number for return with changes and approval by DT). Because of the need to convey the information to public health officials, the draft EPI-1 report must be submitted to EPO within 24 hours of when the EPI-AID number is assigned.

After the EPI-1 is approved, the originating office is responsible for (1) preparing the EPI-1 in final form; (2) completing a Request for Printing Services form (CDC 0.103A); and (3) submitting this printing request as soon as possible to the Publications Management Section, Management Services Branch, Management Analysis and Services Office (MASO) (see Appendix 1). If additional individuals are listed under "Distribution" in the EPI-1, the number of additional copies to be returned to the program for mailing to these individuals should be noted in Item 27 of this form.

Because of the urgent need to inform appropriate CDC and State officials, the final EPI-1 and request for printing should be completed no later than three days following approval of the draft EPI-1.

MASO will print and mail the EPI-1 to the individuals included in mailing keys WF-2, -3, and ZW. The CDC program is responsibile for mailing copies to all persons not included on CDC mailing keys.

When EPI-AID funds are used to support the investigation, certain procedures should be followed to process the travel order. More detailed instructions are provided in Appendix 2.

When the EPI-AID request is approved during working hours:

- The EPI-AID Coordinator should be contacted at 404/639-3182 once the travel order has been entered into the travel system (See Appendix 2).
- Before departure, if an advance of funds is desired, travelers must use their government-issued credit card at the nearest automatic teller machine (ATM).

When the EPI-AID is approved during nonbusiness hours and travel must be initiated immediately, the following steps should be taken:

**Approval** 

Distribution

# Travel **Arrangements**

# ■ The airline or other ticket should be purchased with a government-issued credit card, cash, or Government Transportation Request (GTR). Every effort should be made to obtain the lowest unrestricted fare possible. Using the government-issued credit card will assure the government rate for airfare. The traveler must request a contract airline or risk not being reimbursed for the ticket.

- The government rate for expenses should be requested at all times. To obtain these rates, a government identification card must be shown and should be carried at all times. Always use the government-issued credit card to pay for lodgings, rental car, and other related expenses. Present a tax-exempt form to the hotel for possible exemption of all or part of the taxes.
- Paperwork for the travel order must be done on the following work day and a copy of the orders sent to the officer.

# Preparation for the EPI-AID Investigation

Many officers have found it useful to review past EPI-AID reports, *MMWR* articles, etc., to help prepare for the EPI-AID. The EPI-AID Coordinator maintains files on all past EPI-AID reports and can assist you in locating relevant documents. However, the program of expertise is usually the best source of background information.

Since EPI-AID funds do not generally support materials and supplies needed for the investigation, careful consideration should be given to such items when packing to avoid purchasing them in the field. Moreover, particularly with international EPI-AIDs, appropriate supplies and equipment may not be available in the field. Laboratory personnel are excellent resources to help you determine relevant supply and equipment needs.

The need for Human Subjects Review should also be evaluated, as described in Section II. One issue to consider is whether a diagnostic procedure is planned that may be regarded as invasive. IRB approval is not necessarily needed for tests that patients get as part of their usual care, such as those involving collecting blood or other body fluid.

While preparing for the EPI-AID investigation, data-collection instruments are usually being considered. Whenever questionnaires or other data-collection instruments are used in an EPI-AID, the following statement must be placed on the bottom of the first page of the data collection instrument:

Public reporting burden of this collection of information is estimated to average XX [please complete] hours/minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect

of this collection of information, including suggestions for reducing this burden, to DHHS Reports Clearance Officer, ATTN: Paperwork Reduction Project (0920-XXXX); Hubert H. Humphrey Building, Room 531-H; 200 Independence Ave., SW; Washington, DC 20201.

For an EPI-AID investigation aboard a cruise ship, the Crew Survey Questionnaire and Passenger Survey Questionnaire are highly recommended for use in the EPI-AID. These forms and additional information on how to proceed in a cruise ship investigation may be obtained from the Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, since this Division supervises most cruise ship investigations. Additional information may be obtained from the Special Programs Group, National Center for Environmental Health; this office is responsible for the Vessel Sanitation Program and should be notified about all such investigations. Staff from this program frequently join investigators on outbreak investigations aboard cruise ships.

Upon arrival at the investigation site, the investigating officer should contact state and/or local officials who requested CDC assistance. It is important both to establish rapport with state and local health officials and others involved in the outbreak, as well as to develop lines of communication and expectations concerning the extent and frequency of interaction among the parties involved. At the conclusion of the investigation, the officer should conduct an exit briefing with the appropriate state/local/ministry officials. This briefing should summarize the findings of the investigation and detail the recommendations for further action.

CDC supervision is established before the EPI-AID investigation begins. Except when logistically impossible, the investigating officer should call the supervisor daily to discuss progress and plans. In the course of the investigation, the supervisor and officer may determine that additional time in the field is needed to complete the investigation, or that additional costs, such as laboratory expenses, are necessary. Any changes from the agreements made at the time of original approval must be discussed with and approved by the Division of Training, EPO, in advance.

If the points of travel change or an extension of more than two days is approved, the travel order will need to be amended (see Appendix 2). EPI-AID travel orders contain a standard statement "Traveler is authorized variation of itinerary of not more than two days at temporary duty point in order to perform official business (REF JFTR U2135A)." This statement is included for administrative purposes only to avoid preparing a travel amendment when extended travel is approved. This statement does not replace the requirement to obtain prior approval for extensions of any duration, including one- or two-day extensions.

# During the EPI-AID Investigation

Occasionally, the investigating officer may remain in the field to conduct other program business or for personal preference. EPI-AID funds will be used only for expenses incurred while conducting investigations approved by the Division of Training, EPO.

# After the EPI-AID Investigation

Following completion of the investigation, several administrative procedures and reporting requirements must be completed.

# Division of Training Notification

At the conclusion of the EPI-AID investigation, the officer should contact the EPI-AID Coordinator immediately upon return. At this time, the officer will be scheduled to provide a two-minute oral update of the investigation at Epidemiology Grand Rounds. At a future date, the officer may be requested to present a more comprehensive report of the methods and results of the investigation as the main presentation at Epidemiology Grand Rounds.

#### **Travel Voucher**

Within five working days of return, the travel voucher should be prepared. The original of the voucher and receipts should be forwarded to the EPI-AID Coordinator. After review, the EPI-AID Coordinator will forward the voucher to the Assistant Director for Operations, Division of Training, EPO, for approval. More detailed instructions are provided in Appendix 2.

#### **EPI-AID Trip Report**

It is important that the inviting local official receive a timely report of the field investigation and that the Division of Training, EPO, receive adequate documentation of EPI-AID field activities. Therefore, within 14 days of the officer's return, the EPI-AID Trip Report should be completed and forwarded to the Division of Training, EPO. This report documents the early findings of the investigation and should describe (1) what was known about the problem at the beginning of the investigation; (2) what was done in the field, including recommendations; and (3) what is pending or planned for the future. It should emphasize the proceedings of the field investigation, should contain the results and recommendations presented in the exit briefing, and is **not** intended to be the final report of the study. A summary letter to the local health official may be substituted for the EPI-AID Trip Report if it contains the items required in the EPI-AID Trip Report. Examples are provided in Appendices 3 and 4.

#### **Format**

While the EPI-AID Trip Report has no required format, a suggested outline is as follows:

- Abstract or summary
- Background of the field investigation

- Methods used in the field
- Results obtained in the field
- Brief discussion of findings obtained in the field (interpretation of results obtained in the field within the context of information available at that time)
- Recommendations made and actions taken in the field
- Future plans (additional analyses, lab studies pending or planned, multivariable modeling, etc.)

Although the EPI-AID Trip Report is considered an internal document with limited distribution, it may be subject to disclosure under either the Freedom of Information Act (FOIA) or the Privacy Act. Therefore, it is important to keep the following considerations in mind when writing the EPI-AID Trip Report:

- Use of Personal Identifiers Based on advice from the CDC Office of General Counsel, personal identifiers of persons who are the subject of reports, such as an EPI-AID Trip Report, should not be brought back to Atlanta from the field unless this is necessary for public health purposes. Although data collected in the course of an EPI-AID are considered confidential and normally have limited distribution, they may not be exempt from disclosure under either the FOIA or the Privacy Act. Inadvertent releases of these reports are possible and could constitute an invasion of the subject's privacy. In no case should a subject's name (or means of identifying him/her) be included in a report of an EPI-AID investigation.
- Preliminary Information If a program wishes to emphasize the preliminary nature of the data and interpretations made, a paragraph may be placed on an EPI-AID Trip Report. An example of possible wording is as follows:

This Trip Report summarizes the field component of our EPI-AID investigation. Because of the preliminary nature of this investigation, it is possible that future correspondence, *MMWR* articles, or other published reports may present results, interpretations, and recommendations that are somewhat different from those contained in this document.

The EPI-AID Trip Report **does not** need formal Division or Center clearance. Rather, it is a memo addressed to the Director, Division of Training, EPO. The trip report should be signed by the EIS officer and routed through the immediate supervisor on the EPI-AID investigation. The EIS officer's primary supervisor (who may or may not be the immediate supervisor on the EPI-AID) should provide guidance in preparing the Trip Report. All CIO reviewing officials should give a high priority to timely review of these reports.

**Content Considerations** 

Clearance and Distribution

When a summary letter to the local health official is substituted for the EPI-AID Trip Report, a cover memo should be addressed to the Director, Division of Training, EPO, noting that the attached letter is being submitted as the EPI-AID Trip Report (Appendix 4).

The EIS officer should make certain that the state epidemiologist and any other health official who issued the EPI-AID invitation receives a copy of the EPI-AID Trip Report (or summary letter). Distribution of other copies will be the responsibility of the individual program. We urge that the groups included on the EPI-1 receive either this report or a subsequent report of your activities. However, EPO will not distribute any copies of the trip report.

#### OMB Data Collection Reporting Requirements

As referenced in the section on "Preparing for the EPI-AID Investigation," whenever data collection occurs in an EPI-AID (which is most of the time), CDC is required to document the data collection activities for each EPI-AID. Therefore, investigators are required to: (1) complete the "Emergency Epidemic Investigations" form (Appendix 5) if data were collected or *indicate on the form if data were not collected*; (2) attach a copy of the survey questionnaire used in the EPI-AID if appropriate; and (3) submit to the Division of Training, EPO, as attachments to the EPI-AID Trip Report.

# Publications Related to the EPI-AID

Frequently the results obtained from an EPI-AID investigation are later documented in a final report, an *MMWR* article, or journal article. The Division of Training is interested in the final disposition of all investigations related to EPI-AIDs. Therefore, the EIS officer or CDC program should send a copy of all publications related to the EPI-AID investigation to the Division of Training, EPO.

#### Information Requests Under Freedom of Information Act (FOIA)

Trip Reports and other written reports on the EPI-AID investigation can be released to persons outside CDC when requested under the FOIA. A requestor must make the request in writing to the CDC FOIA Officer for processing. The program conducting the investigation, and not EPO, is responsible for responding to requests for EPI-AID reports. All requests for such documents made to EPO will be referred to the responsible program. This will permit the programs, in consultation with the Office of the General Counsel, to determine what information should be released.

#### Appendix 1

#### Instructions for Preparing and Processing EPI-1 Reports

The preparation of an EPI-1 report begins immediately following approval of an EPI-AID and should be completed expeditiously. An example of a completed EPI-1 is presented on pages 24-25.

These instructions cover the entire process from preparation to distribution, as follows:

#### Preparing the Draft EPI-1 Report

Step-by-step instructions for preparing an EPI-1 are provided on pages 26-29. The format for an EPI-1 report is available in a WordPerfect merge document and may be obtained through E-mail from the EPI-AID Coordinator (404/639-3182).

#### **Obtaining EPO Approval**

Because of the need to convey the information quickly to public health officials, the draft EPI-1 report must be completed and submitted to EPO for approval within 24 hours of when the EPI-AID number is assigned. The draft EPI-1 should be sent the the EPI-AID Coordinator via E-Mail or FAX (404/639-2222).

#### **Preparing the Final EPI-1 Report**

Following approval by Division of Training, EPO, the EPI-AID Coordinator will return the draft EPI-1 to the initiator (or appropriate editorial staff person) by FAX for corrections, final formatting, and signatures from the appropriate division director(s). Be sure to include the FAX number on the draft for return of the approved EPI-1. The final report should be complete within 2 days of the date the EPI-AID number is issued.

#### Preparing and Submitting the Print Request

The Management Analysis and Services Office (MASO) will print the required number of copies of the EPI-1 report. A Request for Printing Services (CDC Form 0.103A) form should be completed; detailed instructions for completing this form are provided on pages 30-31.

The camera-ready copy of the EPI-1 report should be attached to the Request for Printing Services (CDC 0.103A) and sent to the Publications Management Section, Management Services Branch, MASO, Executive Park, Mailstop E71, or delivered to Bldg. 1, Room B122 (to be picked up by courier and delivered to Executive Park).

#### Distribution of the EPI-1 Report

MASO will distribute copies to all individuals included in the Mailing Keys. However, the initiating office is responsible for distributing copies of the EPI-1 report to any additional individuals listed in the Distribution portion of the report.

#### Appendix 1 (cont'd.) Example: EPI-1



#### **DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Centers for Disease Control and Prevention (CDC) Atlanta, GA 30333

EPI-AID:

EPI-96-30-1

DATE:

March 13, 1996

TO:

Director, Centers for Disease Control and Prevention

FROM:

Director, Division of Viral and Rickettsial Diseases (DVRD),

National Center for Infectious Diseases (NCID)

SUBJECT:

Outbreak of Gastroenteritis in a Long-Term Care Facility

LOCATION: King County, Washington

Nature of Problem: Between February 20 and March 13, 1996, 50 of 85 residents and 18 of 100 staff of a long-term care facility in King County, Washington, developed acute gastroenteritis. Illness has been characterized by acute onset of nausea, vomiting, and diarrhea. Three residents required hospitalization, and one additional resident died. Cultures of stool samples from ill persons were negative for bacterial pathogens; results of electron microscopy analyses were consistent with the presence of small round structured viruses.

Date Problem First Identified by the Requesting Agency: March 6, 1996

Date of Initial CDC Contact: March 7, 1996

<u>Initial CDC Contact</u>: Paul Kilgore, MD, EIS Officer, Viral Gastroenteritis Section (VGS), Respiratory and Enteric Viruses Branch (REVB), DVRD, NCID

<u>Caller/Correspondent</u>: Sherry Lipsky, PA-C, MPH, Epidemiologist, Seattle-King County Department of Public Health, Washington

Source of Invitation: Paul Stehr-Green, DrPH, State Epidemiologist, Washington Department of Health E. Russell Alexander, MD, Chief of Epidemiology, Seattle-King County Department of Public Health, Washington

#### **CDC Staff Contacted**

CIO/	Division/	Branch	Section

NCID, OD

Name/Title

Stephen M. Ostroff, MD

NCID, DVRD, OD

Associate Director for Epidemiologic Science

Brian W.J. Mahy, PhD, ScD, Director

Rima Khabbaz, MD

Associate Director for Medical Science

NCID, DVRD, REVB NCID, DVRD, REVB Larry Anderson, MD, Chief Joseph S. Bresee, MD

Medical Epidemiologist

Arthur Marx, MD EIS Officer

NCID, DVRD, REVB, VGS

EPO, DFE, SB

Stephen Monroe, PhD, Acting Chief John Horan, MD, MPH, Chief

John Ho

Mark Dworkin, MD, EIS Officer Pamela Chin, Acting Director

EPO, DT

Patsy Bellamy, Program Analyst

Example: EPI-1

Page 2—Director, Centers for Disease Control and Prevention

#### Other Persons Contacted

State/Local Health Officials: John Kobayashi, MD, MPH, Director of Communicable Diseases, Washington State Department of Health

Other (non-CDC) Federal Officials: None

Others: David Shay, MD, Preventive Medicine Resident, University of Washington

Nature and Timing of Response: On March 14, Dr. Marx traveled to Washington State to join state and local health officials in an investigation of the outbreak.

Anticipated Duration of Field Investigation: 10 days

Branch/Division/CIO Providing Primary Oversight of the Investigation: REVB, DVRD, NCID

CIO Sharing Oversight: None

<u>CDC Supervisor Responsible for Technical Supervision of Investigator and EPI-AID Trip Report</u>: Joseph S. Bresee, MD

<u>Objectives of the EPI-AID Mission</u>: To determine the extent of the outbreak, to determine the modes of transmission, and to develop appropriate control measures.

/S/ Brian W.J. Mahy, PhD, ScD Director, DVRD, NCID

DISTRIBUTION: Mailing Keys WF-2, -3, ZW

#### **Preparing the EPI-1 Report**



#### DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention (CDC) Atlanta, GA 30333

**EPI-AID** 

(1)

DATE

(2)

TO

(-)

:

(3) Director, Centers for Disease Control and Prevention

**FROM** 

(-

**SUBJECT** 

(5)

LOCATION

(6)

Nature of Problem:

(7)

Date Problem First Identified by the Requesting Agency:

(8)

Date of Initial CDC Contact:

Initial CDC Contact: (10)

Caller/Correspondent:

(11)

Source of Invitation: (12)

CDC Staff Contacted (13)

CIO/Division/Branch/Section

Name/Title

(14)

(15)

- 1. Type the EPI-AID number provided by the EPI-AID Coordinator, Division of Training, EPO. If you do not know the number when the draft is prepared, send to EPI-AID Coordinator without it, and it will be filled in by EPO.
- **2.** Type the date the EPI-AID number was issued.
- **3.** Type "Director, Centers for Disease Control and Prevention." Note: The EPI-1 report is always addressed to the Director, CDC.
- 4. Type Director, Appropriate Division, and CIO responsible for the EPI-AID investigation.
- **5.** The subject is a brief title of the health problem.
- **6.** Type the state or city and state where the urgent health problem exists.
- 7. Provide a short statement of the problem (1–3 sentences). Both the seriousness and urgency of the problem should be evident from the language chosen. Mention of the history leading up to the request or of the request itself is discouraged.
- 8. Type the date the requesting agency first identified the problem.
- 9. Type the date the requesting agency made the official request for CDC assistance.
- **10.** Type Name, Branch/Division/CIO of the person receiving the initial call for assistance.
- 11. Type the name of the person contacting CDC.
- 12. Type the name(s) and title(s) of the person(s) requesting epidemiologic assistance. This is usually a state health official. However, some EPI-AID requests may come from other sources (e.g., Indian Health Service, Federal penitentiary, hospital, cruise ship). In such situations, the CIO responding to the request is responsible for informing the state epidemiologist and seeking concurrence. Regardless of the initial source of the request, in all cases the state epidemiologist must be one of the inviting officials.
- 13. This section documents all CDC staff contacted about the investigation. Occasionally, EPI-AID requests involve participation of more than one EIS officer (EISO) and more than one CIO. When preparing the EPI-1 report, include names, titles, and organizational affiliations of all participating EISOs.
- **14.** Type in acronym form, e.g., NCID/DBMD/EDB/EDES.
- 15. Type full name, degrees, and title of all persons contacted.

# Appendix 1 (cont'd.) Preparing the EPI-1 Report

Page 2—Director, Centers for Disease Control and Prevention

Other Persons Contacted(16)

State/Local Health Officials: (17)

Other (non-CDC) Federal Officials: (18)

Others: (19)

Nature and Timing of Response: (20)

Anticipated Duration of Field Investigation: (21)

Branch/Division/CIO Providing Primary Oversight of the Investigation: (23)

CIO Sharing Oversight: (24)

CDC Supervisor Responsible for Technical Supervision of Investigator and EPI-AID Trip Report: (25)

Objectives of the EPI-AID Mission: (26)

a sidd by more age from the

(27)

Signature

Name and Degree(s)

Title

Division, CIO

DISTRIBUTION: (28)

- 16. This section documents all non-CDC persons contacted concerning the EPI-AID investigation.
- 17. Type names, titles, and locations of all individuals contacted in the state and local health departments.
- 18. Type names, titles, and locations of all individuals contacted in the (non-CDC) Federal government. If none, type "none."
- **19.** Type names, titles, and locations of all individuals contacted. If none, type "none."
- 20. Provide a brief statement including the name of the EISO assisting in the investigation and when the officer will depart. Remember: EISOs are "assisting" in, not "conducting," the investigation.
- 21. Type in the length of time verbally agreed upon by EPO and the CDC program when the EPI-AID investigation is initiated (usually not to exceed three weeks).
- 22. Type in acronym form the Branch/Division/CIO accepting primary responsibility for assisting in this investigation, e.g., EDB/DBMD/NCID.
- **23.** Type the acronym of the CIO(s) sharing oversight. If none, type "none."
- 24. Type the name, title, and location of the person who will supervise the EISO(s) involved in the EPI-AID and provide guidance for writing the EPI-AID Trip Report.
- 25. Provide a brief statement describing the objectives, e.g., "To identify the cause and risk factors . . . " or "To assess the extent of Disease X in the population . . . ".
- **26.** The only signature required is that of the division director of the program responsible for the EPI-AID investigation. The signature block should be typed as it appears in official correspondence. If more than one division is involved, all other division directors' signatures should be included.
- 27. Since many Officers have requested that they not be sent "hard copies" of EPI-1's because they hear about them through E-mail, please type the following mailing keys: WF-2,-3, ZW. These mailing keys include EPO and CDC professional staff and all state epidemiologists. Below the mailing keys, list the names, titles, and complete mailing addresses of all other persons who are to receive copies of the EPI-AID documents (i.e., those with whom the investigation has been discussed who are not included in the mailing keys).

## **Preparing the Print Request**

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- 1. This is the date the Form CDC 0.103A is prepared.
- 2. This is the same date as 1. above. Type an "X" in the box indicating "MUST."
- Type the name of the responsible branch/section and CIO division. 3.
- Type the name, complete telephone number, FAX number, and mailstop code of the per-4. son to call if MASO has questions about the information on the request.
- 5. Type the name and title of the CIO administrative officer who will authorize the requisition.
- 6. Type the EPI-1 report number and subject, along with "Information for professional personnel."
- 7-8. No information required.
- 9. Check the box indicating New.
- 10. No information required.
- Type in the word "keys" plus the number of extra copies needed to distribute to persons 11. listed in the EPI-1 report who are not on the mailing keys. In the blank for "No. of copies to be distributed," type "keys." In the blank for "No. of copies to go to Publ. Dist. Facility Storage, type "none."
- 12. Check the boxes for "Printing" and "Distribution."
- **13–18.** No information required.
- Type "white" for Text-Paper Color. Type "offset" for Text-Weight. Type "black" for Text-Ink Color. (Leave "PMS No." blank.)
- 20. Check two boxes: Both Sides and Head-to-Head.
- Type "8-1/2" x "11". (No information required in blanks for "Folded Size." 21.
- Type "2" or "3". The EPI-1 should be no more than two to three pages in length. 22.
- No information required. 23.
- 24. Check the box marked "Other" and type in "Staple" if more than a single sheet will be required.
- **25–26.** No information required.
- 27. Check the box marked "MASO."
- 28. Type "WF-2,-3; ZW."
- **29–31.** No information required.
- Check the boxes marked "Pub Distribution Unit" and "Other." In the blank, type the 32. number of extra copies requested in Item 11 above, to be sent to the person designated to mail copies to those individuals listed in the Distribution section of the EPI-1 report, and the mailstop code (e.g., 10 copies to Jane Doe, Mailstop X01).
- **33–34.** No information required
- Under Effective Date, type in the same date as in Item 1. 35. Under CAN, type the CAN number for the responsible CIO.
- 36-37. No information required.

#### **Appendix 2**

#### Instructions for Preparing and Processing EPI-AID Travel

These instructions are provided to assist CDC staff in preparing EPI-AID travel documents when EPO funds are being used. The travel order, including all travel arrangements (airline tickets, hotel accommodations, etc.) and the travel voucher are prepared by the traveler's CIO. On the automated system, the preparer checks both Domestic Temporary Duty and Epi-Aid travel.

#### Preparing the Travel Order

EPI-AID travel is prepared on the automated travel system. However, it is a two-step process. The initial screen will be marked twice (Domestic Temporary Duty and EPI-AID Investigation). The travel is then input in the normal way. To ensure that EPO has control over the funds used for EPI-AID travel, the originator must first put in their own CAN numbers on both the screen for purchase of the ticket and financial information. Once the travel is forwarded to EPO for approval, the EPI-AID Coordinator will change the CAN number to the appropriate one for that CIO using EPO funds. At the time the travel is forwarded for approval, the preparer will go to the original screen where EPI-AID has been marked and place an "X" by Submit. The travel will then come to the EPI-AID Coordinator to review, change the CAN number, and assign an EPI-AID number. Once that has been done, the order will be returned to the sender to resubmit for authorization. It will then come back to the EPI-AID Coordinator, who will authorize the travel. At that point, the order can be cut and tickets picked up.

#### **Preparing the Travel Amendment**

An amendment to the original travel order must be prepared when the points of travel change or an extension of more than two days is approved. If the traveler needs to stay longer than specified in the original travel order, the EPI-AID Coordinator must be contacted by the supervisor, and a determination will be made if EPO funds will be used for the extension of time.

#### **Preparing the Travel Voucher**

The voucher should be completed within 5 working days of the officer's return. The signed voucher and original receipts must be forwarded to the EPI-AID Coordinator at Mailstop C08. Until these are received, the voucher cannot be reviewed. Please have all receipts taped on sheets of paper in the order that they are referred to on the voucher screen. This will facilitate the review of the voucher. Once it is reviewed by the EPI-AID Coordinator, it will be forwarded to the Assistant Director for Operations, EPO, for approval and submission to the Financial Management Office for payment. As a general rule, all vouchers over \$1,000 are audited by Financial Management. To speed up the approval process, at the time the signed voucher and original receipts are submitted to EPO, also send a copy to Mailstop E-12 (Financial Management). Make sure that all receipts on the copy are legible.

# Appendix 3 Example: EPI-AID Trip Report



#### **DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service Centers for Disease Control and Prevention (CDC)

#### Memorandum

Date

October 15, 1995

From

EIS Officer, Investigation and Prevention Branch (IPB), Hospital Infections Program (HIP), National Center for

Infectious Diseases (NCID).

Subject

Epi-Aid Trip Report: Serratia marcescens outbreak in a neonatal intensive care unit, Massachusetts (Epi-95-94)

To

Director, Division of Training, EPO (CO8)

Through:

Acting Director, HIP, NCID

Chief, IPB, HIP, NCID \_\_\_

#### INTRODUCTION

Serratia marcescens is a Gram-negative rod belonging to the family Enterobacteriaceae. It is a ubiquitous environmental organism which flourishes in moisture, soil, and sewage [1]. In recent years, it has become important as a cause of severe nosocomial infections [2]. S. marcescens' tendency to contaminate solutions and devices is well-documented [3-11]. Because of its propensity for water, hand-to-hand transmission can easily cause widespread dissemination in an intensive care unit [2].

#### BACKGROUND

Between August 1994 and October 1995, cultures of various sites of 32 infants in the neonatal intensive care unit (NICU) of a Massachusetts hospital (Hospital A) grew S. marcescens. No previous episodes of infection with this organism were ever documented in this NICU. In August 21, 1995, point prevalence rectal cultures were begun and infants and nursing staff were cohorted. In addition, environmental cleaning and healthcare workers (HCW) handwashing were enhanced. When, despite these measures, surveillance cultures demonstrated persistence of S. marcescens in the NICU, the Hospital Infections Program, Centers for Disease Control and Prevention (CDC) was asked to assist in an investigation. The objectives of our investigation were to seek the source of the organism, identify factors facilitating persistence of the organism in the NICU, assess risk factors for S. marcescens infection, and to implement control measures to terminate the outbreak.

#### **METHODS**

#### Case Definition and Ascertainment

A case was defined as any infant in the Hospital A NICU with ≥ 1 positive culture for S. marcescens between August 1994 and October 1995 (i.e., the study period). Case-patients were identified by review of Hospital A clinical microbiology laboratory and infant medical records. Case-control study

To identify which infants were at risk for infection/colonization with S. marcescens, we compared case-infants to randomly selected infants who were in the NICU for ≥2 days (the minimum length of stay of a case-infant from admission to the first positive culture) during the study period and who did not develop S. marcescens infection or colonization. Factors assessed included infant demographics, signs and symptoms of infection, duration of stay in the NICU, gestational age, APGAR scores, underlying diseases, types and duration of venous and arterial access, types and duration of intravenous antimicrobials, infusates, ventilation, receipt of total parenteral nutrition (TPN) or steroids, and severity of illness as measured by the score for neonatal acute physiology (SNAP)[12] 24 hours before the first positive culture or day 1 in control-infants, and outcome.

#### Personnel Study

Exposure to nurses were determined from the time of birth to the first positive culture for case-infants and the entire length of NICU stay for all control-infants. Exposure data were obtained from the daily nursing assignment ledger and infant medical records. To assess whether the nurse:infant ratio in the NICU during the study period was a risk factor in acquiring *S. marcescens* infection, time-sheets were examined and the monthly nursing hours:patient ratio was determined for the NICU.

#### Procedure Review and Microbiological Studies

We reviewed infection control policies and conducted observational studies to assess infection control procedures, housekeeping, and NICU HCW handwashing, and pharmacy medication admixture practices. The NICU Director and administrative staff were interviewed about policies and practices. Hospital A started saving isolates of *S. marcescens* only after July 29, 1995. These were sent to the CDC for confirmation and DNA typing using pulsed-field gel electrophoresis.

#### **Environmental Studies**

Hand cultures were obtained from all staff working in the NICU, using the handiwipe method [13]. The Hospital A NICU is divided into 5 pods which connect with each other. There is an adjacent pharmacy. For each pod and the pharmacy, cultures were obtained from the work surfaces surrounding the baby warmers and incubators, the warmers themselves, hot and cold water, the respective sink areas, weighing scales, door knobs, liquid soap, hand lotion, and moisture from the ventilator reservoirs. All samples were sent to the CDC for culture, identification, and DNA typing using standard methods [14].

#### Statistical Analysis

All data were collected onto standardized forms, entered into a computer, and analyzed using Epi Info version 6.02 software [15]. Categorical variables were compared using the likelihood ratio test or, where appropriate, the Fisher's exact test. Medians of continuous variables were compared using the Wilcoxon two-sample test. Odds ratios (OR) and 95% confidence intervals (CI) were calculated. To control for confounding, we performed multivariate analysis using logistic regression.

#### RESULTS

#### Case Ascertainment and Characteristics

Thirty-two infants met the case definition (Figure 1). Case-infants were distributed among the five pods: pod1 (6, 19%), pod 2 (12, 37.5%), pod 3 (3, 9%), pod 4 (6, 19%), pod 5 (5, 15.5%). The median length of time from admission to the NICU to the first positive culture was 14 days. Sites of infection included the bloodstream 8(25%), conjunctiva 7(22%), or tracheal secretions 5(16%) (Table 1). Four infants died.

#### Case-Control Study

Case and control infants were similar in sex, premature rupture of membranes, type of delivery, APGAR scores at 1 and 5 minutes, SNAP scores on admission, and duration of NICU stay. Case-infants were more likely than control-infants to have: mothers suspected to have an infection before delivery, patent ductus arteriosus, respiratory distress syndrome, bronchopulmonary dysplasia, apnea-bradycardia, receive TPN, been ventilated, an umbilical venous catheter or nasogastric tube (NGT), receive vancomycin, or steroids, or exposure to three nurses: nurse 14 (pod 2) (12/32 vs 7/52, p=0.01, OR=3.9, CI=1.2, 13.1), nurse 15 (pod 4) (13/32 vs 9/52, p=0.01, OR=3.3, CI=1.1, 10.2), or nurse 53 (pod 2) (11/32 vs 8/52, p=0.04, OR=2.9, CI=0.9, 9.5) (Table 2). When stratified by birthweight, very low birthweight (VLBW) (≤1500 grams) case-infants were more likely than VLBW control-infants to have a lower median gestational age (28 vs 32 weeks) or birthweight (1175 vs 1350 grams), and longer median duration of stay in the NICU (43 vs 6 days). When we controlled for confounding variables by performing multivariate analysis using logistic regression, a case-infant was more likely to have a mother with clinical suspicion of infection before delivery, a patent ductus arteriosus, exposure to nurse 14, and VLBW.

#### Personnel Study

The monthly nursing hours:infant ratio did not vary significantly during the study period.

#### Procedure Review

Between August 1994 and August 1995, several handwashing agents were used by HCWs. In November 1994, a new brand of liquid soap was introduced in the wall dispensers in the NICU (**Table 3**). Many nurses subsequently developed severe hand dermatitis and in December 1994 they were given permission to bring in their own plastic bottles of commercial liquid soap which they carried in their pockets. In March 1995, personal bottles were refilled from a liter container of Acute-Kare® soap (active ingredient: 1% chlorxylenol) kept in the NICU. This was replaced soon after by pre-packaged 4 ounce bottles of Acute-Kare® soap. From interviews with HCW in the NICU, it became apparent that many of these soap bottles were left standing inverted near the sink areas in the NICU which invariably contained pools of stagnant water. By the time of our investigation on September 28, 1995, environmental cleaning in the NICU had been ongoing for almost one month, and infected infants and NICU nurses had already been cohorted. Moreover, the policy of the individual carrying his/her own bottle of soap had been stopped and wall soap dispensers which were in use before December 1994 were reintroduced. The work and sink areas in the pharmacy contained quantities of damp tissue paper and cardboard cups.

#### Microbiological Studies

Of cultures of 52 bottles of Acute-Kare® soap, S. marcescens was recovered from 16 (31%) bottles carried by staff or located in all five pods or the NICU pharmacy. Cultures of soap from 12 unopened bottles of Acute-Kare® soap were negative. Isolates from case-infants and the soap bottles and dispensers were confirmed as S. marcescens, and pulsed-field gel electrophoresis revealed that all but two of the

S. marcescens isolates from infants had identical DNA banding patterns.

#### Environmental studies

Environmental cultures obtained during our on-site visit yielded *S. marcescens* from the sink area in pod 4, and various Enterobacteriaceae and Gram-negative non-fermenters from the sink, tap water, and work areas in all 5 pods. Hand cultures from 2 (4%) of 49 NICU HCW yielded non-fermentative Gram-negative rods only; no *S. marcescens* was recovered.

#### DISCUSSION

Outbreaks of *S. marcescens* have been attributed to contaminated benzalkonium chloride [4,5], hexachlorophene [10], antiseptic soap containing triclosan [7,8], and hand lotions [9]. The source of the contaminating organism in many of these outbreaks included water, stock bottles, and rubber tubing used to prepare the antiseptic solution.

In our investigation, infants were brought directly to the NICU from the delivery room following a vaginal delivery or from the operating room following a caesarean section. Our analysis suggested that neither of these two forms of delivery were risk factors, nor were exposure to any of the midwives at delivery. Thus, case-infants must have acquired their infection at or following admission to the NICU. Despite documentation in the medical literature that *S. marcescens* can grow in triclosan [7,8], the organism was not isolated from any of the triclosan dispensers in the Hospital A NICU. It was isolated only from opened Acute-Kare® soap bottles and dispensers; there was no evidence of intrinsic contamination of unopened Acute-Kare® soap bottles. Notwithstanding, we believe that the Acute-Kare® soap itself was an unlikely initial source of the outbreak or else the incidence of *S. marcescens* infections would have been higher in 1994.

The source of *S. marcescens* in our investigation was probably the NICU environment (sink and work areas within the pods of the NICU and the pharmacy). The first isolate could have been introduced by an infant source with subsequent patient to patient to environment transmission via hands. Prevailing cleaning measures were evidently inadequate as suggested by the persistence of *S. marcescens* infection in infants in the NICU, and the growth of several Gram-negative organisms from cultures of various sites in the NICU. There are several factors that point to an environmental source: first, infants from all five pods were affected. Second, infants with *S. marcescens* infections were present in the NICU since January 1994. This persistence is more compatible with an environmental rather than a point source. Unfortunately, *S. marcescens* isolates from infants in the NICU before July 1995 were not saved. Whether those isolates were identical to the outbreak strain cannot be determined. Third, *S. marcescens* grew only from cultures of sink areas and soap obtained from opened bottles; culture of unopened bottles were negative. Fourth, there have been no new episodes of *S. marcescens* infection with the outbreak strain since removal of personal soap bottles, and thorough environmental "bucket" cleaning [16].

The question arises as to why the incidence of *S. marcescens* infections increased in the NICU after May 1995. We hypothesize that HCW handwashing technique and infection control procedures throughout 1994 and early 1995 were just adequate to prevent the emergence of a large outbreak. After individuals began carrying their own soap bottles, it is plausible that the soap in these bottles became contaminated with *S. marcescens* when the bottles were left inverted in the sink and work areas. With the bottles of soap and the respective staff inadvertently acting as amplifiers, the *S. marcescens* organism emerged and became more widely disseminated in the NICU. Although the handwashing technique of nurses in certain pods might have contributed to the dissemination of the organism, we commenced the investigation at a point where strict handwashing procedures had been in place for almost one month. During the study period, we observed good handwashing technique and frequency among NICU nurses; it was less satisfactory among other types of NICU HCWs. That pod 2 had the highest number of case-infants could be related to the fact that pod 2 nurses who had had significant contact with case-infants practiced unsatisfactory handwashing technique and transmitted the organism via hands. Or it could have been a reflection of more widespread *S. marcescens* dissemination within the pod 2 environment.

Our investigation had several limitations: isolates of *S. marcescens* from infants were not saved before July 1995. Therefore, we cannot be certain that all case-infant infections were caused by the same strain, although 17(89.5%) of 19 case-infant isolates tested at CDC had identical genomes. When we initiated the investigation, the *S. marcescens*-contaminated soap bottles had been removed from general use, and environmental cleaning and improved infection control practices in the NICU had been underway for over one month. These measures would have decreased environmental *S. marcescens* making cultures of the environment and HCW hands less likely to yield the epidemic strain.

#### RECOMMENDATIONS

- 1. All HCW, particularly physicians and nurses, should perform scrupulous handwashing before and between all infant contacts [17].
- Enhanced environmental cleaning with an Environmental Protection Agency (EPA)-approved disinfectant [16] should include
  walls, warmers/isolates, sink and work areas (both in the NICU and pharmacy areas), weighing scales, and inanimate objects and
  devices that remain in the warmer/isolate location after the infant is discharged.
- Sink areas in the NICU and pharmacy should be kept dry and free of clutter. Damp paper towels should not be left lying around the taps.
- 4. Soap for handwashing should be obtained through wall dispensers only. If feasible, all dispensers in the NICU should be operated via foot-operated pumps. Staff members in the NICU should not carry their own plastic bottles of soap nor should they leave bottles of soap lying inverted in the sink areas.
- 5. The initial handwashing procedure when a staff member comes on duty in the NICU should be at least 2 minutes in duration [17].
- 6. S. marcescens isolates from infants in the NICU should be saved for at least one year for potential further laboratory analysis.
- 7. An active surveillance system for nosocomial infections in the NICU should be implemented [18].

This trip report summarizes the field component of our investigation. Because of the preliminary nature of this report, it is possible that future correspondence or reports may present results, interpretations, and recommendations that differ from those contained in this document. If further analysis substantially alters any of these findings or recommendations, you will be notified promptly.

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EIS Officer
Investigation and Prevention Branch
Hospital Infections Program
National Center for Infectious Diseases

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Table 1.

Characteristics of case-infants, Hospital A, August 1994 to October 1995.

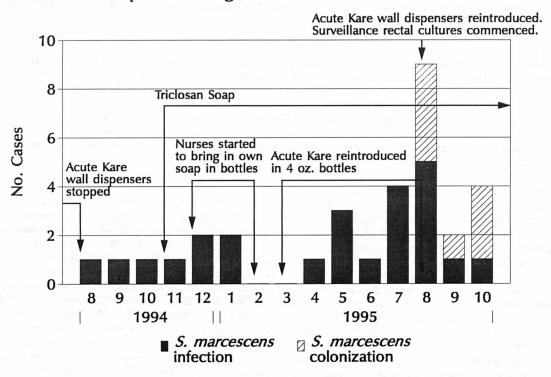
Characteristics	Case-infants (n=32)
Median gestational age (range)	29(23-41) weeks
Gender	
Male	17 (53%)
female	15 (47%)
The state of the s	
Race	20 (65%)
White	20 (65%)
Black	5 (16%)
Hispanic	5 (16%)
Other	2 ( 3%)
Site of infection	
Eye	7 (22%)
Tracheal secretions	5 (16%)
Blood	8 (25%)
Urine	2 (6%)
Wound	2 (6%)
Rectum	8 (25%)
Pod location at onset of infection:	
Pod 1	6 (19%)
Pod2	12 (37.5%)
Pod3	3 (9%)
Pod4	6 (19%)
Pod5	5 (15.5%)
Median birthweight (range)	1208 (480-3993)gms
Median interval from admission to first positive culture (range)	11 (5-135) days
Median APGAR at 1 minute (range)	6 (1-8)
Median APGAR at 5 minutes (range)	8 (1-9)
Median SNAP score on admission (range)	6 (3-10)
Median SNAP score 24hrs before first positive culture (range)	4.8 (0-18)

1	Variable	Number of o	case-	Number of control- infants (%)	Odds Ratio (95% CI)	P
	Suspected maternal infection before delivery	15/31 (48)		4/52 (8)	11.3(2.9,48.2)	0.00002
	Patent ductus arteriosus	7/32 (22)		1/54 (1.8)	14.9 (1.6, 344)	0.002
	Respiratory distress syndrome	26/32 (81)		33/54 (61)	2.8 (0.9, 9.1)	0.05
	Brochopulmonary dysplasia	8/32 (25)		0/54 (0)	Indeterminable	0.0001
	Apnea-bradycardia	13/32 (41)		9/54 (17)	3.4 (1.1, 10.6)	0.013
	Total parenteral nutrition (TPN)	28/32 (88)		36/54 (67)	3.5 (1.1, 13)	0.03
	Ventilation	24/32 (75)		22/54 (41)	4.4 (1.5, 13.1)	0.002
	Umbilical venous catheter	12/32 (37)		5/47(11)	5.1 (1.4, 19.5)	0.004
	Nasogastric tube	27/32 (84)		36/54 (67)	2.7 (0.9, 8.9)	0.07
	Received vancomycin	17/32 (53)		11/54 (20)	4.4 (1.5, 12.9)	0.002
	Received steroids	6/32 (19)		1/54 (1.9)	12.2 (1.3, 288)	0.006

Table 3

Description	15.2	Changes 6000
Acute Kare soap was available from wall dispensers		
2 week trial of Ballard CHG soap		Stopped after 2weeks
		19/15/
3 week trial of Triclosan soap		Stopped after 3 weeks
Recommenced Acute Kare wall dispensers		Stopped November 1994
Commenced Triclosan soap in wall dispensers. 47 cases of dermatitis reported.		Continued Triclosan but staff allower to bring in their own soap.
Staff brought in their own soap. Various brands of liqui soap used.	d 5 4 (0 %	
Decision made to go back to Acute Kare soap.  Dispensed from a jug kept on the NICU to personal cle  Staff refilled these bottles as deemed necessary.	aning bottles.	
4 oz. bottles of Acute Kare introduced.		
Acute Kare wall dispensers reintroduced		Use of all personal soap bottles including 4 oz. bottles stopped. Not Triclosan remained in use from its
	2 week trial of Ballard CHG soap  3 week trial of Triclosan soap  Recommenced Acute Kare wall dispensers  Commenced Triclosan soap in wall dispensers.  47 cases of dermatitis reported.  Staff brought in their own soap. Various brands of liqui soap used.  Decision made to go back to Acute Kare soap.  Dispensed from a jug kept on the NICU to personal cle Staff refilled these bottles as deemed necessary.  4 oz. bottles of Acute Kare introduced.	2 week trial of Ballard CHG soap  3 week trial of Triclosan soap  Recommenced Acute Kare wall dispensers  Commenced Triclosan soap in wall dispensers.  47 cases of dermatitis reported.  Staff brought in their own soap. Various brands of liquid soap used.  Decision made to go back to Acute Kare soap.  Dispensed from a jug kept on the NICU to personal cleaning bottles.  Staff refilled these bottles as deemed necessary.  4 oz. bottles of Acute Kare introduced.

Figure 1.
Distribution of Case-patients, Neonatal Intensive Care Unit, Hospital A, August 1994 - October 1995



### Appendix 4

### **Example: Summary Letter as EPI-AID Trip Report**



#### **DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Centers for Disease Control and Prevention (CDC) Atlanta, GA 30333

Dr. Alfred DeMaria State Epidemiologist Massachusetts Department of Health Boston, MA

Dear Dr. DeMaria:

The following is a preliminary report of the investigation of a pneumonia outbreak at a long-term care facility in Chicopee, Massachusetts. You will be contacted immediately if findings of additional investigations differ from those in this report.

#### Background

On October 12, 1995, Dr. Susan Lett of the Massachusetts Department of Health contacted the Respiratory Diseases Epidemiology Section (RDES), Childhood and Respiratory Diseases Branch, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, to report a cluster of seven residents of a 70 bed long term-care facility (Nursing Home A) diagnosed with pneumonia over an eight day period.

On October 14, Anthony Fiore, M.D., EIS Officer, and Christopher Iverson, epidemiology elective medical student, traveled to Chicopee, Massachusetts at the invitation of the Massachusetts Department of Health to assist state and local officials in an investigation of the outbreak. The objectives of the investigation were to define the scope of the outbreak, determine the etiology and the mode of transmission, and assist in interrupting transmission.

#### Establishment of surveillance and case definition

All persons residing in the nursing home, as well as all employees of the nursing home, were screened for symptoms suggestive of respiratory infection by medical record review, interviews with patient care staff, or self-reported illness on a questionnaire distributed to nursing home staff. A case definition of confirmed outbreak-associated pneumonia was established as acute respiratory illness with new chest x-ray infiltrate occurring after September 1, 1995 in a resident or employee of Nursing Home A. Hospital charts, nursing home charts, and chest radiographs of patients with confirmed pneumonia were reviewed by investigators. Blood, nasopharyngeal (NP) and throat swabs, and urine specimens were collected from all residents of the facility. Ten patients meeting the case definition of confirmed pneumonia were identified, all of whom were nursing home residents (Figure 1). All had lobar, or in one case multilobar, consolidation on chest radiographs. Eight of these case-patients resided on the North wing, and six of eight were at the end of the North wing hall (Figure 2). The geographic clustering of cases in the end of one hall was suggestive of person-to-person spread, or possibly a point-source outbreak. The average age of the 10 case-patients was 90.8 years (median 89.5, range=80-104 years). Two patients died. No confirmed cases have occurred in Nursing Home A after October 14, 1995. The investigation included extensive reviews of medical records, chest radiographs and microbiologic data on case-patients, collection of nasopharyngeal swabs from all 70 residents and 41 staff members, interviews with family members who visited residents, and collection of sera from all residents, several family members, and nursing home staff who reported being ill in October.

#### **Epidemiologic investigation**

We conducted a case-control study of residents of Nursing Home A with confirmed pneumonia who had onset of symptoms between October 1, 1995, and October 25, 1995. Controls were patients without signs or symptoms of pneumonia (new cough, shortness of breath, arterial blood oxygen saturation less than 90% as measured by pulse oximetry or airway congestion) who had been admitted to Nursing Home A prior to September 1, 1995. Two controls were matched to each case-patient, according to the following method: A patient list for each wing of residence (North or West) was obtained, and the lists subdivided into those with and without a physician's diagnosis of dementia. Two residents were then matched to each case-patient based on the presence or absence of dementia and closest age. A total of 10 case-patients and 20 controls were enrolled, and a standardized data abstraction form was developed to obtain information from the medical record about underlying diseases, previous respiratory illness, presence at and participation in scheduled social activities, and activities of daily living such as eating and washing. No statistically significant association with any activity or underlying disease was identified. However, case-patients (60%) were more likely than controls (25%) to have had an upper respiratory illness in September with

cough and nasal congestion (odds ratio 4.5, 95% CI 0.66-42.72, p=0.17). Other non-statistically significant associations between activities and illness with p value <0.2 are shown in Table 1.

Families and frequent visitors of case-patients were contacted by an Atlanta-based member of the investigative team (Ramon Guevara, an American Teachers of Preventive Medicine MPH Fellow assigned to RDES). Two families of case-patients reported having respiratory illnesses in September and October. One of these families reported a visit on September 11, 1995, at which six family members, two of whom had a respiratory illness at the time, attended a birthday party for a resident, who on October 5 became the first patient with pneumonia. This case-patient had also contracted an undefined respiratory illness 6 days after the family event. Serum specimens from two members of this family and one member of another family who had been ill during a visit to another case-patient were obtained, and testing of these specimens is under way. No family member had a pneumonia confirmed by chest radiograph. No other families reported respiratory illness in September or October.

An NP swab culture survey for pneumococcal carriage among Nursing Home A residents and staff was undertaken on October 15 and 16. Of NP swabs from 67 patients and 41 staff, only one, from a resident, grew *Streptococcus pneumoniae*; this resident had not been recently ill. Unfortunately, the isolate was lost prior to serotyping.

#### **Etiologic investigation**

Only four of the patients had cultures of blood and/or sputum obtained prior to the administration of antimicrobial drugs. Streptococcus pneumoniae (serotype 14, susceptible to penicillin) was isolated from the blood of one patient. A sputum Gram stain was suggestive of S. pneumoniae infection in a second patient (Gram-positive diplococci in the presence of acute inflammatory cells). Sputum cultures were obtained in three cases and all grew only normal flora (including the sputum obtained from the patient with the suggestive Gram stain). Lung tissue obtained at autopsy from a third patient appeared to contain pneumococcal DNA (autolysin gene) by polymerase chain reaction (PCR). Serologic testing for Mycoplasma pneumoniae and Chlamydia pneumoniae was negative with convalescent-phase sera obtained at approximately 2 weeks. PCR testing of NP swabs obtained from pneumonia patients was negative for Mycoplasma, Chlamydia and Legionella species. Legionella pneumophila serogroup-1 urinary antigen testing was negative for all patients. Viral cultures of throat swabs from two case patients, as well as two ill employees with respiratory symptoms have not grown influenza, parainfluenza, Herpes simplex or adenoviruses at the Massachusetts state laboratory.

#### Interventions

On October 11, 1995, Nursing Home A, after consultation with the Massachusetts Department of Health, instituted a no-visitation policy for residents. No admissions were accepted, and group activities were canceled. The staff was assigned to separate wings, and mixing of staff or patients of one wing with the other wing was restricted. This policy was lifted on October 21, 1995, when it appeared no new cases had been identified for over one week, and evidence against *Mycoplasma* infection as the cause of the outbreak had been obtained. New admissions resumed on October 27. All but two (who refused) residents who had not been previously immunized received pneumococcal vaccine on October 12, and residents and staff received influenza vaccine on October 12 and 13. No new cases of chest X-ray confirmed pneumonia have been diagnosed since October 14.

#### VI. Conclusions

An outbreak of pneumonia among elderly residents of a long term chronic care facility in Massachusetts occurred in October 1995. The outbreak was characterized by the sudden appearance of a cluster of chest radiograph confirmed pneumonias over a 10-day span, with no new cases during the subsequent two weeks. While the etiology of most cases has not yet been established, the most likely cause of the outbreak is *Streptococcus pneumoniae*, based on the presence in all confirmed cases of a lobar infiltrate, the suggestion from the epidemic curve of person-to-person spread, and the laboratory evidence. It is not clear why the outbreak occurred. A non-statistically significant association with preceding upper respiratory illnesses suggests that an antecedent infection may have increased susceptibility to pneumococcal disease among residents of the nursing home. Additional serologic studies will attempt to determine whether case-patients have evidence of infection with a specific respiratory virus, as well seroconversion to *S. pneumoniae* serotype 14.

The reason(s) for the low NP carriage rates for S. pneumoniae seen in this study are unclear. All patients had received antibiotics prior to NP specimen collection. Carriage rates among the institutionalized elderly are undefined in the literature. Carriage rates in the healthy adult population are thought to be in the range of 5-10%. Potential problems with NP sampling of residents in this study included the difficulty of obtaining specimens from patients with dementia, delays in CO<sub>2</sub> incubation of blood agar plates (which were swabbed and streaked at bedside, then placed into the incubator within 6 hours of swabbing), and inability to detect colonies of S. pneumoniae without the use of a colony microscope. Alternatively, perhaps carriage of the organism is transient, and either disease occurs shortly after colonization, or colonization is terminated. NP swabs were obtained 11 days after the first case was reported.

#### **Pending Studies:**

- 1. Continued analysis of the matched case control study data.
- 2. Testing of acute (where available) and convalescent-phase serum samples for evidence of infection with M. pneumoniae, C. pneumoniae, and Legionella species.
- 3. Serologic testing of residents for serotype-specific pneumococcal antibodies.
- 4. Additional laboratory testing of autopsy specimens for evidence of pneumococcal disease.
- 5. Culture and serologic testing for other respiratory viruses.

#### Recommendations

- Workup of respiratory infections should be standardized to include culture of sputum and blood prior to the administration of antibiotics, as well as throat swabs for viral culture.
- The incidence of pneumonia and other respiratory infections among residents and staff at Nursing Home A should be monitored for the next 6 months.
- 3. All residents should receive a single dose of pneumococcal vaccine (unless they have received vaccine in the previous 5 years) with adequate chart documentation.

Please feel free to contact me by electronic mail (ABF4@CIDDBD1.EM.CDC.GOV) or by telephone (404-639-4729) if needed.

Sincerely,

Anthony Fiore, MD (EIS Officer)

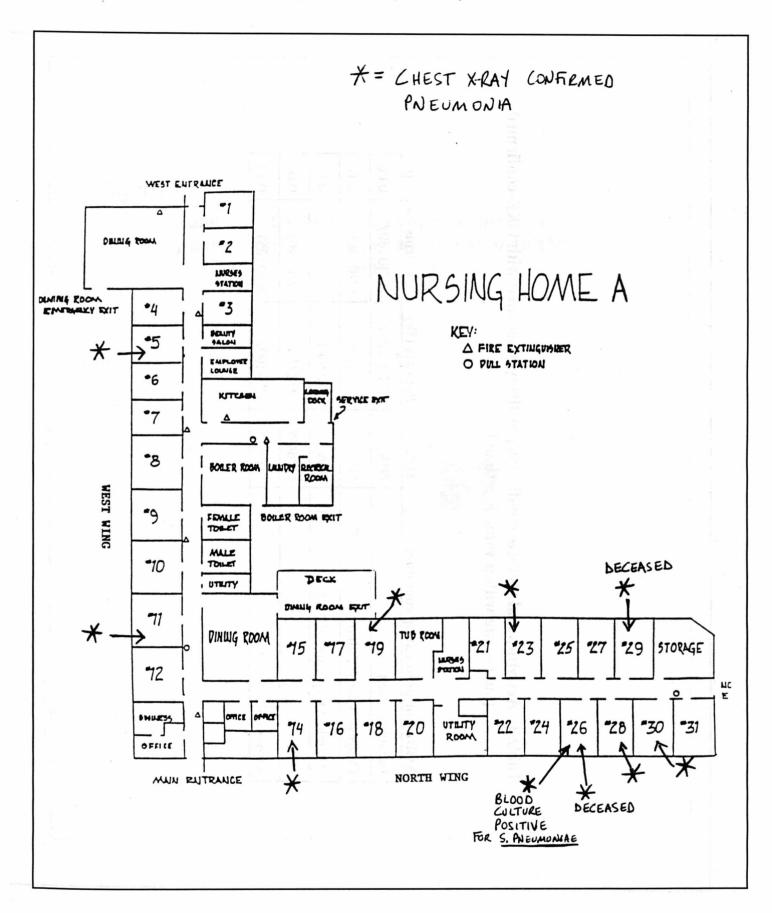
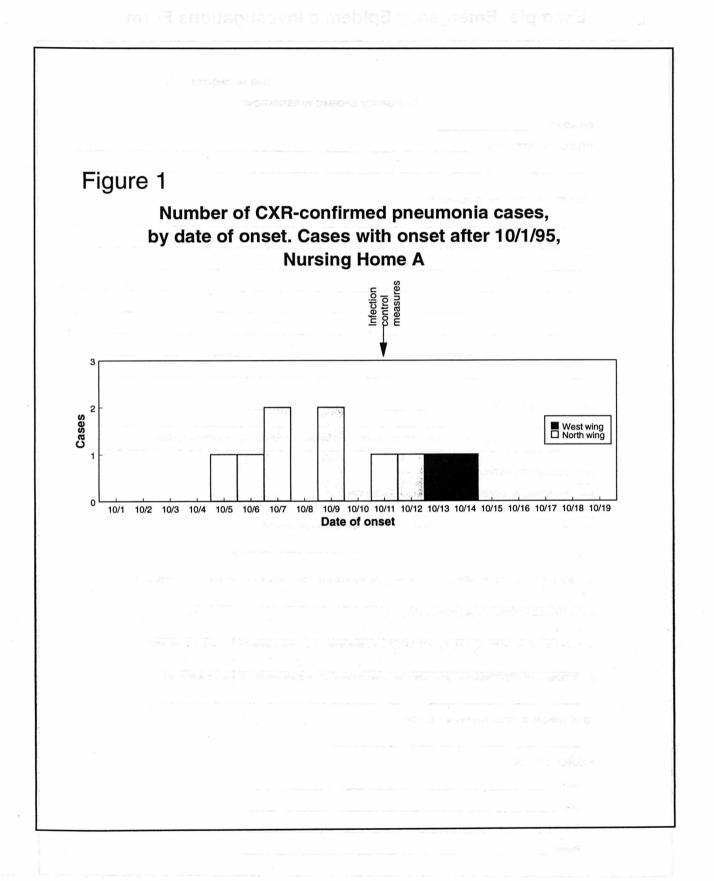


Table 1. Activities and medical conditions positively associated with CXR-confirmed pneumonia with p value less than 0.2

Activity or pre-existing condition	Date	Patients (%)	Controls (%)	) р
Feeding oneself	N/A	10/10 (100)	12/20 (60)	0.06
Congestive heart failure	N/A	7/10 (70)	8/20 (40)	0.16
Preceding respiratory illness (Sept 1995)	N/A	6/10 (60)	5/20 (25)	0.17
Exercise	9/26/95	5/10 (50)	2/20 (10)	0.04
Crossword	9/27/95	6/10 (60)	5/20 (25)	0.14



# **Example: Emergency Epidemic Investigations Form**

	EMERGENCY EPIDEMIC INVESTIGATIONS
501 AID AID	CHENCENCY ENDERIC INVESTIGATIONS
EPI-AID NO.:	
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USED FOR THE	FOLLOWING PURPOSE:
,325	FO ( <b>Bits teason</b> ) is not be factor to eight you
	i A seriel delegate
-	
	TIGATION: BEGINNING: ENDING:
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er No. 1 G	Complete this section for each instrument used during the investigation
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PERSONA  MAIL  A. DESCRIPTIO  B. ESTIMATED	OTHER (please specify):  OTHER (please specify):  N OF RESPONDENTS (i.e., individuals, households, physicians, state and local government, etc.)
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