



CDC's Division of Strategic National Stockpile Emergency MedKit Evaluation Study Summary

Background, Key Results, and Next Steps
(as of November 15, 2007)

Background

The overarching aim of the emergency MedKit evaluation study was to evaluate a strategy that addresses the timeliness of distributing antibiotics to the general public as an effective measure against a release of anthrax. Five modalities are proposed for bolstering the nation's capacity to respond to large-scale events by providing the necessary countermeasures to the population in a timely manner:

- 1. Classical Points of Dispensing (or PODs) for medicines or vaccines.** This is the primary means local governments currently use. The federal government delivers material to local authorities that, in turn, are delivered to affected people. This mechanism has been used by many communities over many years, albeit not on the scope or at the tempo that a major bioterrorism event would require.
- 2. Direct residential delivery of antibiotics by postal carriers.** With this approach, postal workers would deliver medicine directly to residences. Discussions are ongoing with the U.S. Postal Service to explore the advantages and limitations of this approach.
- 3. Pre-deployed community-based caches of pharmaceuticals for emergency use.** Locally stored caches of pharmaceuticals could be at the front lines of an emergency very quickly. They would be prepositioned in selected institutions with healthcare infrastructure, e.g., hospitals.
- 4. Pre-event dispensing of pharmaceuticals as equipment to first responders.** Providing first responders with potentially needed medicines in advance can better equip them to respond to biological or chemical emergencies.
- 5. Pre-event placement of pharmaceuticals in individual households for use only as directed by public health authorities.** Families in the United States would be supplied a medical kit with critical prescription pharmaceuticals needed during an emergency.

While one or more of these modalities could be used simultaneously, the combination of strategies should be tailored to fit a community's need. One strategy under consideration is the provision of medicines to individual households prior to any direct bioterrorism threat for use only as directed in a declared public health emergency. An evaluation study was designed to provide evidence about the feasibility of placing a cache of antibiotics in individual households.

In January 2006, the Missouri Department of Health and Senior Services agreed to partner with the Centers for Disease Control and Prevention (CDC) to conduct the evaluation. The specific aims of the emergency MedKits evaluation study were to:

- assess the ability of households to maintain MedKits in the home as directed and reserve for emergency use;
- explore attitudes, perceptions, and other social factors that may influence participant behavior regarding storage and proper use of the MedKit; and
- provide information about the acceptability of the household MedKit prototype.

In collaboration with the Food and Drug Administration (FDA), CDC designed an antibiotic MedKit prototype. The prototype consisted of a four-fold cardboard blister pack with a five-day supply of medicine. The blister pack was stored in a sealed bag that was transparent on one side and included instructions for use in an open pouch on the outside.

To meet all federal and state regulatory requirements, the MedKit prototype has been evaluated as an investigational new drug (IND). The study protocol was reviewed and approved by three Institutional Review Boards and the U.S. Office of Management and Budget. A local physician was contracted to serve as the medically qualified professional for clinical oversight. Each enrolled household received monetary incentives.

Design: The design was prospective over a period of eight months. A baseline interview was conducted in-person and each household member was medically screened. Informed consent was required for each member. At the time of enrollment, households were randomly assigned to a two-, four-, or eight-month time interval for a follow-up interview and to return their kit.

Setting: The St. Louis metro area, also a Cities Readiness Initiative (CRI) participant, was the pilot test site. Most of the enrolled households were in St. Louis City, St. Louis County, and St. Charles County.

Participants: The study population consisted of three cohorts: clients and some employees of a community health clinic; corporations (n =10) such as Sigma and ATT; and first responders, including the FBI.

Key Results

Each household was represented by one household member who was selected to be the custodian of the MedKit and survey responder. The unit of analysis is the household. There were 174 households lost to follow-up; data are complete for 4,076 households (12,040 persons).

Ability of households to maintain MedKits in the home as directed and reserve for emergency use:

- 97% (3,946 out of 4,076) of all study respondents returned the household MedKits upon completion of the study. There was no statistical significant difference between cohorts.
 - Clinic: 1,351 households (94%)
 - Corporate: 1,077 households (98%)
 - Responders: 1,535 households (99%)
- 130 (3%) households did not return their MedKits; 125 of these households (96%) could not locate their MedKit and five (4%) simply refused to return them.
- Four households (3%) reported having used their MedKits. All four were in the clinic cohort.
 - 1 household: elderly woman used during a declared emergency for storm
 - 2 households: member in household had “sore throat”
 - 1 household: refused to state why pills were taken
- Among the MedKits returned, all but 34 of the MedKit bags were intact (more than 99% with no pills missing).
- Curiosity about the contents was the most frequently mentioned reason (55%) given for opening the MedKit bag.
- Majority of the households (28 out of 34) that opened the bag were from the clinic cohort.

Attitudes, perceptions, and other social factors that may influence participant behavior regarding storage and proper use of the MedKit.

- At the time of the follow-up interview, more than 75% (n = 3,086) reported that having the emergency MedKit in their homes increased their awareness of the need to prepare for a public health emergency, including a terrorist attack.
- Overall, 75% (n = 3,059) of all respondents reported that they feel “not too prepared” or “not at all prepared” for such an attack.
- The majority of study participants (94% or more in each cohort) reported that based on their experience with the study, they would like to have a MedKit in their home.
- The majority of respondents in all three cohorts (83% to 86%) would pay for a MedKit.
- The average price that households would pay per person was \$23.

Next Steps

An overwhelming majority of study participants appropriately followed instructions regarding storage and reserving the emergency MedKit for use until directed by public officials. A similarly large proportion of study participants reported that they would like to have emergency MedKits in their homes and would be willing to purchase these MedKits, but the MedKit prototype has not yet received approval by the FDA.

The FDA requires additional testing on the MedKit prototype, which is currently under development in the Department of Health and Human Services’ Biomedical Advanced Research and Development Authority (BARDA). Along with the findings from the home MedKit evaluation, the FDA will use the information from the additional studies to facilitate a New Drug Application (NDA) for the MedKit prototype.

The additional studies will provide information about:

- the overall comprehension of the MedKit product labeling and instructions among various literacy levels in the general population;
- participants’ understanding of correct use of medications through laboratory simulation;
- palatability of Doxycycline and Ciprofloxacin when mixed with several food substances that are common to most households; and
- participants’ ability to understand and implement home preparation instructions for administering to children in the household.

Assuming industry interest and regulatory requirements are met, the overall optimistic timeframe for approval of the MedKit prototype is at least three years (2010).

For any further information, please contact Linda Neff, PhD, at LNeff@cdc.gov.