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TECHNICAL
R E P O R T



Recommended Infrastructure Standards for Mass Antibiotic Dispensing

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SUMMARY

Since the terrorist attacks in 2001, Congress and the White House have invested over \$7 billion in efforts to upgrade the nation's ability to address the health effects of bioterrorism, natural disease outbreaks, and natural disasters. Despite encouraging anecdotal evidence, however, the absence of performance standards and metrics for preparedness make it difficult to say whether the investments have left the country better prepared.

The Pandemic and All-Hazards Preparedness Act (PAHPA) of 2006 (P.L. 109-417) requires the U.S. Department of Health and Human Services (HHS) to develop evidence-based performance standards and metrics for preparedness and, beginning in 2009, to link funding to state and local agencies to their performance on these standards. As part of its response to the PAHPA legislation, the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR)¹ asked RAND to develop recommended infrastructure standards for mass antibiotic dispensing — specifically for the “points of dispensing” (or PODs, locations where the members of the public would go to receive life-saving antibiotics or other medical countermeasures during a large-scale public health emergency).

HHS asked that the standards

- align with the Cities Readiness Initiative's (CRI's) goal of preparing metropolitan areas to dispense medications to their entire communities within 48 hours of the decision to do so
- focus on PODs — the locations where medications and other countermeasures are to be dispensed to the public — and, more specifically, on the following four areas of POD infrastructure: (1) number and location of PODs, (2) internal POD operations, (3) POD staffing, and (4) POD security.

STANDARDS DEVELOPMENT PROCESS

The rarity of large-scale public health emergencies, while fortunate, means that there is little experience on which to develop standards that are responsive to the PAHPA legislation's mandate that standards be “evidence based.” Thus, the standards must rely on other sources of evidence:

- **data collection and discussions with practitioners**, in order to establish the current baseline level of performance
- **review of existing literature and policy documents**, to help ensure alignment of the standards with other programs

¹ Formerly the Office of Public Health Emergency Preparedness (OPHEP).

- **mathematical modeling of POD operations and locations**, to estimate the relationship between key operational variables and expected performance
- **an expert panel** of key stakeholders and practitioner groups, to ensure that the results of the models are reasonable and to provide guidance on making trade-offs and drafting standards.

The analysis and feedback from expert panelists and stakeholders suggested that several different configurations of POD infrastructure might plausibly lead to the same level of operational output. Thus, one-size-fits-all standards might foreclose viable and innovative approaches.² The recommended standards seek to provide flexibility to state and local CRI planners in how they meet the 48-hour goal.

More details on the considerations that informed the development of the standards — including analysis, review of current practice, and consultation with an expert panel — are provided in the body of this report. It also includes (1) recommended documentation requirements that would help federal officials assess compliance with the proposed standards and (2) information on standards considered but not proposed.

Throughout, readers should bear in mind that the standards proposed in this report are *not* intended to cover all aspects of infrastructure that must be addressed in POD plans. Consequently, it is quite possible that a jurisdiction could be fully compliant with all of the proposed standards and still not be able to mount a fully successful response. Moreover, the standards are intended to provide *minimal* requirements and should not discourage CRI sites from exceeding them.

NUMBER AND LOCATION OF PODS

The first set of standards applies to the entire *network* of PODs in a community. Modeling, analysis of current practice, and members of the expert panel suggested that the optimal number of PODs depends strongly on other planning factors (e.g., throughput) and on community context (e.g., population density, transportation infrastructure, availability of sites). Thus, instead of providing strict numerical targets in terms of the number of PODs, the standards outline a clear and auditable process for determining the appropriate number of PODs in a specific community.

Standard 1.1: The jurisdiction shall estimate the number of people who will likely come to PODs to pick up medication, along with their geographic distribution.

To ensure that the number of PODs is sufficient to provide initial prophylaxis within 48 hours, it is first necessary to develop an accurate estimate of the size of the population to be served via PODs. Thus,

² Note that the difficulty in developing clear infrastructure standards is one of the reasons for our recommendation that HHS move next to develop standards around operational capabilities (see Chapter Seven). The idea would be to insist that jurisdictions be able to meet certain operational goals and timelines using whatever infrastructure configurations can achieve those goals effectively and reliably.

Standard 1.1 requires that CRI sites provide a systematic analysis of likely demand for PODs, including both the *total number* of likely POD visitors and their *geographic distribution*. The standard assumes that individual jurisdictions are in the best position to define the scope of the population for whom they will be responsible for administering prophylaxis.

Standard 1.2: The number of PODs shall be greater than or equal to the number of persons needing to receive prophylaxis at PODs divided by per-POD throughput multiplied by 24 hours (48 hours minus 12 hours for initial CDC delivery to warehouse and 12 hours to get materiel from warehouse to PODs).

Standard 1.2 requires jurisdictions to combine the population analysis developed pursuant to Standard 1.1 with estimates of hourly POD throughput in order to ensure that the *supply* of PODs matches demand. Specifically, the following relationship among these four factors must hold:

$$\text{Number of PODs} \geq \frac{\text{Population visiting PODs in person}}{\text{Hourly per - POD throughput} \times 24 \text{ hours}} .$$

The estimate of 24 hours for POD operations (in the denominator) is based on the assumption by the Centers for Disease Control and Prevention (CDC) that it might take up to 12 hours for initial delivery of materiel from the Strategic National Stockpile (SNS) and the Target Capabilities List's (TCL's) assumption that it might take up to 12 hours to get materiel from warehouse to PODs.

Standard 1.3: All POD locations shall meet relevant SNS site guidelines and security criteria.

Standard 1.3 specifies that planned POD locations shall meet the basic site and infrastructure requirements in the SNS program guidance. The standard refers to the facility requirements written into the SNS program guidance (currently version 10.02) in order to avoid unnecessary duplication of effort.

INTERNAL POD OPERATIONS

In routine circumstances POD operations might prioritize accuracy over speed and include a broad range of functions (e.g., thorough client education, detailed screening for contraindications). The requirements of a large-scale emergency, especially the need to serve a large number of clients, may require reducing the amount of time spent with each client and reducing staff requirements for formal medical training. Thus, the next set of standards concerns the internal operations that must take place at PODs.

Standard 2.1: Jurisdictions shall have at least one viable and exercised rapid-dispensing³ protocol. For the purposes of this standard, a rapid-dispensing protocol is one in which the following functions are provided by means that minimize the need for medically licensed personnel at the POD sites:

- **directing clients through the POD**
- **deciding which medication to dispense**
- **disseminating information about the medication**
- **dispensing the medication.**

Such means might include, but are not limited to, information campaigns to educate the public before arrival at the POD, signage and automated messages at the POD, and standing protocols so that non–medically licensed personnel can perform POD functions.

A common theme in panel discussions was that POD protocols must be appropriate to the specific circumstances at hand. Accordingly, less elaborate dispensing protocols are not only appropriate but are required in situations necessitating full-community prophylaxis in a short time period. Thus, Standard 2.1 requires jurisdictions to develop and exercise at least one POD protocol in which many traditional POD functions are performed by non–medically licensed personnel or outside the POD entirely to reduce the number of staff required at the POD and increase POD throughput.

Standard 2.2: Jurisdictions shall ensure that legal and liability barriers to rapid dispensing are identified, assessed, prioritized, and communicated to those with the authority to address such issues. Such issues include standards of care, licensing, documentation of care, civil liability for volunteers, compensation for health department staff, rules governing the switch between dispensing protocols, and appropriation of property needed for dispensing medications.

The POD protocols governing the provision of medication to an entire metropolitan area within 48 hours (e.g., relaxed screening and recordkeeping requirements, use of non–medically trained personnel) might conflict with routine legal strictures. Thus, Standard 2.2 requires that jurisdictions work with relevant state and local authorities to ensure that they have the legal authority to operate rapid-dispensing PODs during a public health emergency. Note that the standard does not require CRI sites or other health departments to change laws — only to “identify, assess, prioritize, and communicate” such issues to those who do have the authority to change them.

Standard 2.3: Jurisdictions shall have viable and exercised procedures for selecting an appropriate dispensing protocol (e.g., medical model versus rapid dispensing).

While the need to provide prophylaxis to an entire metropolitan area within 48 hours argues for streamlined, rapid-dispensing protocols, changing circumstances might require more time, skill, and

³ *Rapid dispensing POD* is the term used in the CDC Division of the Strategic National Stockpile (DSNS) Technical Assistance Review (TAR) tool.

attention to be applied to each client. For instance, as jurisdictions move out of the initial 48-hour period, further epidemiological investigation might suggest follow-up prophylaxis of only a limited portion of the population. This and other changes in the situation might necessitate a different balance between dispensing speed and screening accuracy. Thus, Standard 2.3 requires that jurisdictions have clear procedures for moving to and from streamlined prophylaxis operations.

POD STAFFING

Perhaps the most difficult aspect of conducting a mass prophylaxis operation in the CRI scenario is having sufficient staff to operate the PODs. As with the other sets of standards, the standards development process revealed concern that uniform, one-size-fits-all staffing standards would fail to account for community differences, unnecessarily require jurisdictions to undo work already completed, and stifle innovation. Thus, instead of providing strict numerical staffing targets, the next set of standards requires jurisdictions to undertake a clear and auditable process to determine appropriate staffing configurations.

Standard 3.1: Jurisdictions shall estimate the number of individuals who are likely to visit each POD location and determine the required hourly throughput at each POD.

The first step in determining the staffing required for PODs is to determine the throughput that will be required at each POD. Thus, Standard 3.1 requires an estimate of the number of people who will likely come to *each* POD seeking prophylaxis. It should be noted that the standard does *not* require individuals to be assigned to particular PODs to pick up their medications; it only requires that jurisdictions' plans be based on *estimates* of the number of individuals *likely* to come to each POD.

Standard 3.2: Jurisdictions shall determine and verify the number of staff required to administer prophylaxis to their identified population (identified pursuant to Standard 1.1) by conducting drills with time studies.

Standard 3.2 requires jurisdictions to estimate staffing requirements for each POD, given estimated throughput requirements (see Standard 3.1). Jurisdictions are instructed to conduct POD drills, measuring the throughput of the POD *and* timing the operations of each of the different stations in the POD.

Standard 3.3, Alternative 1: Jurisdictions shall recruit sufficient staff to operate all the planned PODs in the jurisdiction at the levels of throughput required to meet the CRI timeline.

Standard 3.3, Alternative 2: Jurisdictions shall recruit sufficient core staff and provide plans for recruiting and training spontaneous, unaffiliated volunteers in sufficient numbers to operate all the planned PODs in the jurisdiction at the levels of throughput required to meet the CRI timeline.

Standard 3.3 requires jurisdictions to identify and recruit the staff necessary to implement their mass prophylaxis plan and enter them into a call-down roster. The standards development process revealed concerns about the burden – especially for large jurisdictions – of recruiting and maintaining call-down lists for what might be a very large number of staff (over 6,000 in some metropolitan statistical areas [MSAs]).

Given that there was neither a clear analytical basis nor consensus on how to address this concern, we present two alternatives for consideration.

Standard 3.4, Alternative 1: Jurisdictions shall assess the availability of all staff on their call-down rosters on a quarterly basis via a no-notice call-down drill.

Standard 3.4, Alternative 2: Jurisdictions shall assess the availability of the core staff on their call-down rosters on a quarterly basis via a no-notice call-down drill.

Standard 3.4 requires that jurisdictions demonstrate via quarterly no-notice call-down drills that they can promptly contact and assemble the required number of people to staff PODs within the first few hours of the decision to conduct mass prophylaxis operations. As with Standard 3.3, the standards development process revealed concerns about the burdens (especially in large MSAs) of testing extremely large call-down lists (over 6,000 for some MSAs). Again, given that there was neither a clear analytical basis nor consensus on how to address this concern, we present two alternative standards.

POD SECURITY

Adequate security planning is essential to the safety of POD staff and clients, the sustainability of operations, and the safeguarding of countermeasures being dispensed. The main challenge in developing appropriate standards for POD security is to ensure that a comprehensive set of security measures is in place while recognizing that state and local law enforcement agencies often have policies, procedures, and doctrine for performing many of these tasks. Thus, the proposed POD security standards favor flexible approaches over strict numerical thresholds.

Standard 4.1: Site security assessments shall be conducted at every POD location in coordination with the agency or agencies responsible for security functions at the PODs.

Discussions with the expert panel and security experts suggested that security assessments be conducted on every potential POD facility and that effective security requires collaboration between the public health and public safety communities. Thus, Standard 4.1 requires site assessments for each facility, coordinated with the agency or agencies responsible for security functions at the PODs (which, in most cases, will be the local law enforcement agency).

Standard 4.2, Alternative 1: The agency or agencies responsible for security functions at PODs shall be consulted on *and approve* the security aspects of the overall mass prophylaxis plan.

Standard 4.2, Alternative 2: The agency or agencies responsible for security functions at PODs shall be consulted on the security aspects of the overall mass prophylaxis plan.

Discussions with expert panel members and security experts emphasized that effective security planning requires consultation with the parties responsible for security at PODs (whether law enforcement or otherwise) regarding the development of the POD plan. There was some discussion among expert panel members as to whether the standard should also require simple consultation with or formal approval by the

agency or agencies responsible for security functions. Lacking either consensus among panel members or any evidence base to sway the decision, we present two alternatives for consideration by decisionmakers.

Standard 4.3, Alternative 1: Law enforcement in the form of sworn, uniformed officers shall maintain a physical presence at each POD location.

Standard 4.3, Alternative 2: Law enforcement in the form of sworn, uniformed officers shall maintain a physical presence at each POD location. This requirement may be waived with a written attestation from the parties responsible for POD security. The attestation shall include evidence that compliance with the standard as written is infeasible and that alternate measures designed to ensure adequate security are in place at each POD site.

A survey of current security practices adopted by CRI sites indicates that many of the security tasks required at a POD facility can be provided by trained volunteers, private security, or other personnel besides sworn law enforcement officers. However, the expert panel emphasized the need for some level of sworn law enforcement presence at each facility because some tasks (e.g., making arrests, integration with the law enforcement command structure) cannot be delegated. Thus, Standard 4.3 requires the physical presence of law enforcement at each POD. However, there was serious concern among some panelists and stakeholders that this requirement would be infeasible in some jurisdictions. Thus, an alternate version of the standard includes a provision for waiving the requirement for *physical* presence.

NEXT STEPS

The standards presented in this report are intended as proposals. A number of steps will be required to finalize and adopt them. Policymakers should

- review the recommended standards and consider enactment
- weigh the policy issues underlying the cases for which we have presented alternate versions of standards
- determine whether standards apply beyond CRI awardees
- initiate and complete the process for developing standards for *operational capabilities*⁴ within the next year
- ensure alignment with other standards, guidelines, and technical assistance
- clarify the consequences attached to standards
- develop a process for routinely reviewing and updating standards.

⁴ Operational capabilities involve the ability to translate capacities (e.g., plans, people, equipment, other resources or infrastructure) into real operational outputs.