SPECIAL REPORT

Measures of Effectiveness in Large-scale Bioterrorism Events

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Abbreviations:
CDC = Centers for Disease Control and Prevention
CMR = crude mortality rate
HIS = Health Information System
MOE = measure of effectiveness
NGO = Non-Governmental Organizations
Ro = transmission rate
U5MR = under-age-5-year mortality rates
UN = United Nations
UNSECORD = UN Security Coordinator
WHO= World Health Organization

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Abstract

Measures of effectiveness (MOEs) are defined as operationally quantifiable management tools that provide a means for measuring effectiveness, outcome, and performance. No clear MOEs exist for determining success or failure of the management of a bioterrorism response. This is especially critical because management requires a multi-agency and multi-disciplinary decision-making and evaluation process. It is suggested that the minimum MOEs required to operationally measure outcome must contain a measuring response capacity for: (1) real-time public health surveillance system; (2) full coverage health information system; (3) capacity to measure variance across management timelines; (4) demonstrated decline in mortality and morbidity; (5) control of transmission rates of communicable agents; and (6) resource distribution across the entire population.

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Introduction

Large-scale bioterrorism events carry the potential for disastrous public health consequences. Unfortunately, both the developed and developing world lack critical public health resources to respond effectively, especially with a transmissible bioagent, such as smallpox, inhalation plague, or Ebola. Existing public health deficiencies that adversely impact the ability to deal with a potential terrorism event are the lack of: (1) an effective and efficient interagency horizontal/lateral decision-making process; (2) a modern surveillance system that detects, with accuracy, real-time infectious agents; (3) critical management and organizational pathways (timelines); and (4) measures of effectiveness (MOEs) that evaluate whether the management response is succeeding or failing.[1,2]

Measures of effectiveness (MOEs) are operationally quantifiable management tools that provide a means for measuring effectiveness, outcome, and performance of disaster management.[1,3,4] Measures of effectiveness (MOEs) first were used in industry to measure the reliability and performance of industrial products. During the Vietnam war, the concept was used to measure performance of civil-action programs. Subsequently, military forces followed multiple indicators to measure security performance of peace-keepers. In Somalia, researchers used these techniques to retrospectively measure multi-agency humanitarian performance.[1] Lack of MOEs were seen as a contributory reason for operational failure of UNPROFOR in Yugoslavia, and led to the adoption of this process by the United Nations in subsequent humanitarian missions.[1,3] Research and application of MOEs were directed primarily toward sector-specific indicators, such as security or economic recovery. Later, multiple indicators were followed to determine the influence of

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multi-agency and multi-sectoral indicators on overall performance. Now, MOEs combine 'essential indicators' to define critical pathways (the multi-sectoral/agency architectural response), assess performance both qualitatively and quantitatively, and define end-state or sustainability of operations.[5] To be useful, indicators must be defined precisely, easily understood, reliable, valid, simple, and informative. Examples are crude mortality rates, and under-age-5-year mortality rates used to measure performance of management in infectious disease outbreaks. Based on the indicators, MOEs must be appropriate to the critical pathway, consistently measurable, cost-effective, sensitive, timely, and mission-related.[1]

Most recently, research has combined political, social, economic, and technical indicators to develop interagency MOEs.[5] To be valuable to the interagency process, the existing political framework, and to professional sectors (e.g., health, water), MOEs must provide a 'common language' that is easily understood and usable by all. Commonality is dependent on identification of shared critical indicators. In doing so, MOEs allow participants in the management process to know what others are doing and why, serve to bring together organizations and agencies that need to support each other, serve as a tool for coordination and communication, and minimize needless confusion and risk. Indicators and the MOEs they support must be amenable to graphic display and trend analysis, be flexible, phase-specific, and unifying for decision-makers by telling a story of performance (critical pathway support) from beginning to end.[5] With increasing demand for performance measures from political and donor communities in humanitarian operations, there is a critical need to know why a program works or it fails. During a bioterrorism event, decision-making responsibilities are more complex than can be accomplished by one person or agency. Technical experts, emergency managers, political authorities, and justice experts are required to work together to operationalize decisions. Thus, MOEs serve as an integrative performance tool that allows for the crossing of sector and professional boundaries while influencing both policy decisions and the operationalizing of policy.[1,2,5]

Process for Generating Operational MOEs

In any large-scale disaster, management resources must address certain goals and in the process, answer the following:

1. What is to be done?
2. When will it be done?
3. Where will it be done?
4. Why will it be done?
5. Who is responsible?
6. How much will it cost?
7. How will we know its effectiveness (success)?

Step one in the process of generating operational MOEs is to identify event-specific tasks necessary to the management of the event. This is performed first through a process that pulls together the existing knowledge-base of real or hypothetical terrorist events. Prior to the post-11 September 2001 anthrax attacks, the knowledge-base regarding bioterrorism for the most part was speculative in nature. Baseline knowledge came from a wide variety of scientific evidence and studies of how bioagents act depending on delivery mechanisms, environmental factors, and potential for mortality and morbidity. International terrorist events, such as those perpetrated by Iraq on the Kurds and Shiite populations, bioagent events planned by the Aum Shinrikyo, and exercise scenarios developed for education and training in bioterrorism, generated an extensive 'lessons learned' library. The author suggests that what emerges is a pattern of three major management categories: medical/health care, public health infrastructure, and public communication under which the most essential management tasks and their indicators reside. This is similar to complex humanitarian emergencies in which humanitarian assistance delivered to mitigate the consequences of the conflict on the population, is categorized under one of four areas: (1) security; (2) infrastructure; (3) medical/public health care; and (4) agriculture and economy of countries involved.[1] The critical indicators that generate the medical/public health care MOEs for complex emergencies are crude mortality rates (CMR), under-age-5-year mortality rates (U5MR), and nutritional measurements (Z-scores) that have proved to be the most sensitive indicators for assessing both the effect of conflict on vulnerable populations, as well as a measure of management effectiveness. In addition, within the categories of agriculture and economy, indicators measuring the market prices of food and animals, the amount of food remaining in households, and food purchasing power have been the most sensitive. Under the security category, the most sensitive outcome indicators are the number of checkpoints required to maintain security over a mission essential road, the number of violent acts against humanitarian workers, and monitoring the percentage of relief supplies reaching the distribution sites.[1]

Additional steps in MOEs development must identify which participants (agencies and organizations) will use which indicators. For example, in complex emergencies, public health and medical indicators are assessed routinely by non-governmental organizations (NGO), UN Agencies and the Centers for Disease Control and Prevention (CDC), whereas security-related indicators are the purview of the military and UN (UN security coordinator (UNSECORD)). In turn, each benefits from the cumulative MOEs that are monitored. In both a domestic as well as an international bioterrorism event, the World Health Organization (WHO), CDC, and other public health national laboratories worldwide are responsible for collating and evaluating the data monitored. Only those data that have a source and a consistent and standardized measurement (including frequency: daily, weekly, monthly reporting) critical to mission success are used.

Bioterrorism-Related MOEs

By using the traditional format of disease-outbreak control investigation methodology, bioterrorism-specific MOEs can be developed. Table 1 suggests a generic list of operational MOEs suitable for measuring the performance outcomes of a large-scale, bioterrorism event. It is important

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- Measuring response capacity of deployed biological sensor devices linked to a real-time public health surveillance system
- Measuring how rapidly a full coverage Health Information System (HIS) is mobilized with timely dissemination of accurate information
- Measuring variance compliance to a bioagent-specific management time-line
- Measuring decline in mortality and morbidity
- Measuring control of transmission rate (Ro)
- Measuring management resource distribution across entire cohort

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Table 1—Operational measures of effectiveness for a large-scale bioterrorism event

to recognize that whereas other categories and indicators exist, they may not be considered "essential" to the generation of a major MOE. Major MOEs include the measuring of critical (key) indicators for which other indicators either are dependent, fall under, or support. Critical indicators and MOEs, may stand alone in defining a performance outcome, but more often than not, the foundation of each MOE is made up of a variety of diverse indicators none of which can stand alone in defining the outcome performance. Also, major/essential MOEs can be seen as pivotal in nature: when they exist as an MOE, it is understood that other, less inclusive MOEs are functioning to support them.[1,2] For example, mortality rates are dependent on the effective use and distribution of resources as well as patient access to care. If any one of these is deficient, the accuracy of the mortality rate suffers. The key indicator, the appropriate fall in mortality rate, tells a confirmatory tale that the system is functioning well. When values of key indicators are not what they should be, an investigation of all of the dependent indictors is performed. In Somalia, two of eight sectors failed to register improved mortality rates from famine relief despite the fact that adequate tonnage of food has been delivered. In evaluation of the MOEs, it was found that whereas food had being delivered to the region warehouses, the warring factions were preventing the distribution to the vulnerable populations.[1,2]

Measuring response capacity of deployed biological sensor devices linked to a real-time public health surveillance system

Lack of reliable and early detection of bioagents remains the primary weakness in outcome performance. Current surveillance systems are dependent upon identification of early clinical manifestations of disease (syndromic surveillance). Certain syndromes would be characteristic of potential bioterrorism attacks, and awareness of these syndromes by practitioners may promote early discovery. Many symptoms from bioagents are non-specific and similar, requiring healthcare providers to maintain a high level of suspicion.[6–8] Quality of existing surveillance systems worldwide are lacking in consistency. Routine analysis of suspicious cases is problematic. Reliable detection devices that provide real-time diagnosis of pathogens are not yet available to the practitioner. With the potential for bioagents to be chemically or genetically altered and delivered to the victim in unique ways, there remains the need to develop more sensitive and timely biosensors. The proposed 'Z-chip' genetic sequencing analysis that rapidly and accurately would identify any pathogen from a variety of bodily fluids is years away in development.[9] That being said, the MOE most essential for the future remains a measurable, rapid, and sensitive sensor easily deployed and linked to a universal surveillance system managed by a central database and monitoring agency that provides instant feedback to any clinician. This, in turn, automatically would mobilize a consequence management system if a bioagent was discovered and confirmed. Until this is realized, the current surveillance system is subject to abuse and delay.

Only one study has looked at MOEs for the deployment of biological sensors. This study focuses on the cost-mix of sensors required to achieve selected levels of protection. Of the two types of MOEs studied, one is a reactive MOE in that the MOE adaptively reacts to changes in lethality as sensors are varied in the area in which sensors are deployed. The second MOE calculates the weighted area that is left undetected after the deployment of sensors as a fraction of a total lethal area. Both of these MOEs evaluate the percentages of casualty-weighted attacks that are being detected by the deployment of the biological sensors.[10] Whereas these studies have broad practical limitations for what healthcare providers routinely seek as information, they illustrate the complexity that deployed sensor technology brings to the overall monitoring process. Indeed, it is for these purposes that both patient-related sensor devices using bodily fluids of a suspected victim and environmental security-related sensors protecting critical civilian and military facilities are equally critical components of any future surveillance system. Cross-cutting MOEs will need to be developed for both.

Measuring how rapidly a full coverage Health Information System (HIS) is mobilized with timely dissemination of accurate information

Any surveillance system must be inextricably tied to a health information system (HIS) that alerts and informs the population over radio, television. Internet websites, and volunteer services for those handicapped or lacking in access to available public alert and education systems. In fact, experience has shown that the earlier the HIS is mobilized, the less chaos and panic will occur.[8,11]

During the anthrax event when no governmental information system was forthcoming, the media stepped in to become the default conduit for health information and governmental messages and guidelines. The initial working knowledge of clinical anthrax available to healthcare providers primarily was textbook and experience based. However, this information proved inconsistent with the findings and guidelines later gained from an analysis of the first 10 cases rapidly published by the CDC over the internet to alert clinicians of the new working case definition and requirements for testing and evaluation of suspected victims.[12]

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Accurate information in disasters is critical. In the aftermath of the nuclear spill 70 miles outside Tokyo, the local population dutifully stayed inside and listened to the television and radio for instructions from the government. Several hours later, the announcement called for the evacuation of all families within two miles of the nuclear plant. Although helpful in part, few knew the distance that their homes were from the plant, causing undue confusion and delay.[8] Measures of effectiveness (MOEs) monitor the speed that a HIS is mobilized, the coverage of vulnerable populations, and the accuracy of the information disseminated. An unprepared HIS inadvertently may cause a secondary disaster of the un- or misinformed that is more serious than the precipating event. Prior arrangements with the media and well-trained public health-oriented public relations experts with pre-scripted disease-related messages and prepared responses to a "frequently asked questions" library are critical to averting unnecessary use and abuse of healthcare facilities.

Measuring variance compliance to a bioagent-specific management timeline

The majority of natural disasters and the responses are fairly predictable, and as such, are amenable to the development of management timelines. Timelines are critical pathways that illustrate, on a day-by-day basis, what is expected for management of a particular event. Complex emergencies are more complicated and dissimilar in their presentation, and have resisted the development of compatible timelines. Timelines exist for chemical and other technological disasters. Management requirements for an infectious disease outbreak work under protocols (serve as timelines) that are geared to control the outbreak and prevent escalation to an epidemic. Until the recent threats of bioterrorism, there was little reason to place these infectious disease outbreaks into disaster categories where they would be seen as multi-agency and multi-sectoral disasters requiring management timelines. Timeline generation for specific disasters is beneficial not only for planning and monitoring purposes, but for many other reasons. Bioagents are dissimilar enough to warrant specific bioagent timelines that combine strict medical protocols with the required public health, political, judicial, and logistics demands peculiar to each bioagent. Individual practitioners of medicine, public health, and disaster management are unfamiliar enough with the nuances of each infectious disease that a timeline approach would be helpful for anticipatory management. The major benefit of using timelines comes with determining variances. Based on the assumption that most disasters and their management are predictable, variances are defined as deviations from the predicted timeline or critical pathway. Variances either are positive or negative. Negative variances cause an unexpected delay in the management timeline and require corrective action in a timely manner. A positive variance represents an improvement in the timeline that is beneficial operationally. It positively adds to the system of management and is collected in the after-action report for inclusion in future timelines. Variances from the expected timeline can be measured as the indictor-based MOE, with each negative variance forcing the evaluation of the variance on overall mortality and morbidity.[2]

Variance studies also determine where in the management system the variance exists, allowing for the immediate corrective analysis to occur. Any one of three focus points is vulnerable for variance. A *system variance* points to a deviation in the overall planning and policy levels of disaster management. Failures in planning for global coordination of transport of resources to a bioterorism event, shortfalls in authority to control disease outbreak coverage by the WHO, and non-essential supplies arriving to the disaster site ahead of essential resources are but a few that designate system-level failures. *Responder variances* place the responsibility in the lap of those directing logistics at the site of the event. Backup of supplies at an airport due to poor planning, failures to keep the cold chain 'cold', and equipment arriving at distribution points lacking trucks to get them to the needed areas represent responder variances. *Recipient-level* variances signify failures of management between the local responders and the recipients. Examples include: families refusing to comply with burial restrictions of Ebola victims, lack of security to ensure quarantine compliance, and non-compliance of healthcare providers with isolation procedures. Out of necessity, MOEs may be developed to monitor each focal variance point in the system.[2]

Measuring decline in mortality and morbidity

Mortality and morbidity rates remain the most sensitive of indicators of infectious disease outbreaks and epidemics. This is because they show the impact of the overall management scheme and sensitively serve as a 'unifying indicator' that is affected by any variation in the expected timeline, medical or not. The majority of non-health-related agencies use mortality rates to measure, to one degree or another, their non-health-related performance outcomes. For this reason mortality rates are considered universal and unifying MOEs.[1]

Measuring control of transmission rate (Ro)

For those bioagents that transmit infection easily, the goal of management is to prevent secondary infections. With the release of a transmissible bioagent, such as smallpox, inhalational plague, and Ebola, the transmission rate (Ro) becomes the most sensitive indicator of an essential MOE. The best method to prevent secondary infections is to reduce the basic transmission rate (Ro) of the pathogen by lowering the effective contact rate between individuals. This can be accomplished by treating infections (e.g., prophylactic antibiotics, vaccinations), changing behaviors (preventing religious rites and viewing of the infectious dead), sanitation (proper barrier precautions and handling of corpses, especially with Ebola), and quarantine (e.g., reverse quarantine, forced isolation). If this process is performed using epidemiological principles, the epidemic will die out.[13]

The Ro applied estimates in smallpox have varied widely (Ro from 1.5 to >20).This limits its usefulness and disregards the influence of population density, socio-economic factors, and herd immunity. However, Gani and Leach suggest through modeling that a more consistent derivation of the Ro exists. In isolated pre-20th century populations with negligible herd immunity, the numbers of cases rose exponentially, producing a Ro between 3.5

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and 6.0. Before outbreak controls could be applied, a sharp rise in secondary cases occurred, with the doubling of hospital-based cases due to early transmission. Similar estimates of transmission potential may occur today given the fact that little residual herd immunity exists now that vaccination levels are so low.[14]

By combining MOEs, such as mortality and morbidity rates, and the transmission rate (Ro), one can best facilitate the understanding of the unique interplay of variables affecting patterns of infections within a community, the roles of primary and secondary infections, the effectiveness of control measures such as quarantine, reverse isolation, evacuation and control zones, and casualty estimates.

Measuring management resources distribution across entire cohort

A timeline for management of resources is a necessity to provide order to decisions, especially logistics, before they unfold. This includes availability of consumable supplies and maintenance of an organizational structure that provide functional capability and capacity over time. Resources include hospital and outpatient professional and administrative personnel, detection devices, barrier devices, laboratory resources, pharmaceuticals, ventilators, emergency department and hospital beds, intensive care unit beds, morgue storage capacity, augmentation facilities and personnel, and volunteers. A MOE essential to a bioterrorism event would be monitoring and measuring the capability and capacity of the management response system to appropriately distribute resources across the entire cohort of the vulnerable population.

Resource distribution is complex and crosses agency and sectoral lines. Indeed, one key agency's resources (e.g., CDC) can stand alone and be used as a key indicator for a MOE. Unfortunately, during the anthrax event, the CDC stockpiling and distribution plan of medications, vaccines, and equipment proved limiting. The CDC has had oversight responsibility for maintaining and moving the stockpiles when needed. During the anthrax event, it was revealed that CDC's transport responsibility ended at the nearest local airport, leaving further transport and warehousing to unprepared and uninformed local jurisdictions. This alone would delay the timeline of performance expectations, and serve as a negative variance that requires immediate correction.

Distribution of management resources must be equitable, fair, and measurable. Any deviation (variance) for clinical and epidemic control purposes must be transparent to the population and appropriately reflected in the health information system (HIS).

Conclusions

Monitoring all of the possible indicators and complexities of a multi-agency and multi-sectoral response to any disaster is impossible. Measures of effectiveness function to identify the most (major) critical indicators and functions that serve to simplify and unify the management process and outcome performance. If major MOEs show good outcome performance, then a large number of hidden indicators also are performing well. It is suggested that six major generic MOEs will exist in a bioterrorism event, mostly public health-related, that must be followed closely to ensure good outcome effectiveness. Currently, the major impediment to accurately identifying and monitoring a large-scale bioterrorism event is the lack of a real-time detection and surveillance system.

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