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Evaluation of emergency drug releases from the Centers for Disease Control and Prevention Quarantine Stations

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Abstract

The Centers for Disease Control and Prevention (CDC) Quarantine Stations distribute select lifesaving drug products that are not commercially available or are in limited supply in the United States for emergency treatment of certain health conditions. Following a retrospective analysis of shipment records, the authors estimated an average of 6.66 hours saved per shipment when drug products were distributed from quarantine stations compared to a hypothetical centralized site from CDC headquarters in Atlanta, GA. This evaluation supports the continued use of a decentralized model which leverages CDC's regional presence and maximizes efficiency in the distribution of lifesaving drugs.

Keywords

public health; botulism; diphtheria; malaria

INTRODUCTION

The Centers for Disease Control and Prevention (CDC) Drug Service program and Quarantine and Border Health Services Branch (QBHSB) collaborate to distribute lifesaving drugs for critically ill patients nationwide on a 24/7 basis. These drugs are not commercially available or are in limited supply in the United States. To allow the treatment of patients with an unlicensed drug product, the US Food and Drug Administration (FDA) may permit the use of a drug or biological product under an expanded access Investigational New Drug (IND) application. These products are intended as therapy for serious or immediately life-threatening conditions, when no effective therapy is available commercially in the United States. Most are manufactured by foreign drug companies and are commercially available in other countries. FDA IND status is maintained by CDC so that these products are available in the United States, if needed. CDC provides these products free of charge to hospitals on an emergency basis when requested by public health officials or treating clinicians. However, this excludes any costs associated with the use or administration of the drug.

The CDC Drug Service distributes the majority of its products from the CDC headquarters in Atlanta, GA, through common courier services. Select drugs are prepositioned at nine CDC Quarantine Stations operated by QBHSB, which are located at major US airports. CDC Quarantine Stations provide strategic regional access and ensure rapid shipping of these lifesaving drugs. Earlier treatment can potentially make a substantial difference in the clinical outcomes of patients requiring these drugs.¹ Evaluation is needed to confirm that the emergency release of lifesaving drug products from quarantine stations is an expedient method of delivery.

History

The CDC Drug Service was established in 1965 to serve as a vaccine bank to prevent rare diseases in high-risk persons. Distribution of drugs from quarantine stations on behalf of the CDC Drug Service began in the late 1960s. Over the last 50 years, the types of drugs released by quarantine stations have changed as public health systems, disease risk, and patient needs have changed.

Previously, quarantine stations distributed drug products that included rifabutin, ribavirin, quinine, pentamidine, vaccinia immune globulin, varicella zoster immune globulin, and ansamycin. The distribution of these drugs was discontinued due to introduction of alternative therapies, decreased need for emergency distribution, or commercial availability. Currently, CDC Quarantine Stations release heptavalent botulinum antitoxin (HBAT), diphtheria antitoxin, and intravenous artesunate (for severe malaria).^{2,3} In March 2013, the FDA approved HBAT, and it is no longer considered an investigational drug.⁴ However, CDC continues to maintain the IND status as well as stockpiles of HBAT for distribution due to limited commercial availability of this product and in case treatment is not covered under the approved license.

Over the years, the number and locations of CDC Quarantine Stations that conduct emergency drug releases have changed. Currently, this list includes nine CDC Quarantine Stations located at regional gateway airports in Atlanta, Chicago, Honolulu, Houston, Los Angeles, Miami, New York, San Francisco, and Seattle. Drug release stations were selected based on staffing numbers and flight patterns that maximize geographic coverage of the country.

Drug product handling and distribution

The products on the CDC Drug Service formulary are available to public health officials and clinicians licensed in the United States when certain requirements are met.

Based on several decades of experience, CDC and state health departments have developed procedures for consultation prior to release of drug products. The initial request to CDC must be made by a state health department. This is required to ensure that the health department can appropriately report cases of infectious disease that are nationally notifiable and can conduct surveillance for additional cases. Health departments may request drug products by contacting the CDC Emergency Operations Center or CDC subject matter experts (SMEs). In addition, consultation between CDC SMEs and treating clinicians is required.

If the requested drug is one distributed by QBHSB, a CDC SME will authorize the nearest quarantine station to release the drug to the requesting healthcare facility. If air transport is required, quarantine station staff will package the drug for shipment on the next available flight. For ground transportation, coordination with couriers, law enforcement, or other agency personnel may be needed. The receiving healthcare facility is responsible for retrieving the drug package from either the quarantine station or the destination airport, or arranging ground transportation. CDC tracks the arrival of the package.

The drug products are temperature sensitive; therefore, cold chain management must be preserved during storage and throughout the shipping process. Drug products are packaged with an insert that includes full prescribing information approved by the FDA, along with any other instructions for the pharmacy and treating clinician. Treating clinicians must comply with the approved IND protocol and notify CDC of any adverse events that occur during or after drug administration. Unused drug products are returned to the CDC Drug Service.

PURPOSE

To evaluate the operational efficiency of the CDC Quarantine Stations' emergency drug release activity, we retrospectively analyzed drug release records for a 2-year period. In addition, we compared actual delivery time for a subset of the shipments with a hypothetical estimate of the time it would have taken to ship the drug from the CDC headquarters in Atlanta, GA.

METHODS

Drug release records were obtained from CDC's Quarantine Activity Reporting System (QARS) for October 1, 2010 through September 30, 2012. QARS is a secure web-based system which allows quarantine station personnel to record station activities, including drug release requests. Variables included the date and time of the request, drug requested and number of doses, requesting location, responding quarantine station, method of delivery, arrival time, patient age and sex, clinical outcome, and drug disposition. SAS version 9.2 software (SAS Institute Inc., Cary, NC) was used to conduct descriptive analyses.

To assess the effectiveness of the decentralized model of drug releases from quarantine stations, we compared the actual delivery times to estimated delivery times from a hypothetical situation where drug releases occurred from the CDC headquarters in Atlanta. Drug releases from January 1, 2012 to September 30, 2012 were used for this portion of the analysis. Drug releases from the Atlanta Quarantine Station were excluded from this portion of the analysis because delivery times were not likely to be appreciably different than those from the CDC headquarters.

For shipments from CDC headquarters, we estimated that it would take approximately 4 hours from the time of SME authorization to shipment departure on a commercial flight from Atlanta, GA. This estimate allowed time for station staff commuting from home to CDC headquarters, packaging the shipment, driving to the Atlanta airport, processing the package at the cargo facility, and meeting airline deadline requirements for package submission prior to flight departure. As historical flight data were not available, we used GoogleFlights (www.google.com/flights) to search for current flights departing from Atlanta at least 4 hours after the request time and arriving at the airport closest to the requesting location. Flights during the same month and day of the week as the actual drug release and with the earliest arrival time were selected.

Actual delivery time was calculated by subtracting the request time from the arrival time as recorded in QARS. Time for delivery from CDC headquarters was calculated by subtracting the request time recorded in QARS from the arrival time of the selected flight. A paired t-test was used to evaluate for a significant difference between actual delivery time and estimated delivery time from CDC headquarters. Actual delivery time was subtracted from estimated delivery time to determine if time was saved.

RESULTS

From October 1, 2010 to September 30, 2012, CDC Quarantine Stations received a total of 287 requests for emergency drug releases: 173 (60 percent) for HBAT, 105 (37 percent) for artesunate, and 9 (3 percent) for diphtheria antitoxin. Drug type requested varied considerably by responding quarantine station (Figure 1).

One hundred fifty-two (53 percent) of drug releases were delivered by airplane. The remaining 135 (47 percent) were delivered by helicopter or ground transportation, including retrieval by hospital personnel or delivery by law enforcement or courier services. Ground transportation was primarily used when the requesting location was within 100 miles of the responding quarantine station. One hundred fifty-four (54 percent) of drug requests were made outside regular quarantine station operating hours.

Most US states (78 percent) received at least one drug release during the evaluation period. California had the highest number of drug release requests, accounting for 28 percent of all releases during the evaluation period. Five states (California, New York, Texas, Florida, and Washington) accounted for more than half of all drug releases; each of these has at least one quarantine station that currently distributes drugs.

Patient sex was known for 278 (97 percent) of patients; of those 65 percent were male. Age was known for 268 (93 percent) of patients; the median age was 44 years (range, 9 months to 85 years). Outcome data were known for 183 (64 percent) of the releases; of those 174 (95 percent) improved or recovered and 9 (5 percent) died (Figure 2). Type of botulism infection was known for 101 (58 percent) of the HBAT drug releases; 63 (62 percent) were wound botulism and 38 (38 percent) foodborne.

Ninety-four drug releases occurred from January 1, 2012 to September 30, 2012. This subset of releases was further studied for differences between the actual delivery time and an estimated hypothetical delivery time from CDC headquarters. Ten records were omitted from the analysis, five that were incomplete and five that were releases from the Atlanta Quarantine Station. For the remaining 84 records, the overall mean difference in delivery time for shipments from quarantine stations compared with CDC headquarters was 6.66 hours faster from quarantine stations (median of 6.00 hours, $p < 0.0001$). Delivery from quarantine stations was significantly faster for 74 (88 percent), with a mean time difference of 8.26 hours (median of 6.87 hours, $p < 0.0001$). For 10 releases (12 percent), delivery from CDC headquarters was faster, with a mean time difference of 5.19 hours (median of 2.78 hours).

DISCUSSION

The prepositioning of lifesaving drug products at quarantine stations results in the rapid distribution of medical treatment for critically ill patients. Our analysis indicated that prepositioning drugs at CDC Quarantine Stations reduced distribution time by an average of about 7 hours when compared to an estimated hypothetical centralized distribution site from the CDC headquarters in Atlanta, GA. This suggests that the decentralized model facilitated

more timely availability of treatment for critically ill patients with foodborne or wound botulism, diphtheria, or malaria.

Our analysis also found that CDC's emergency drug release caches are appropriately positioned geographically. The top five states requesting emergency drug releases accounted for more than half of all drug requests; at least one drug-releasing quarantine station is located within each of these states. The finding that close to half of all shipments were delivered via ground transportation further suggests that stations are well positioned. Two states that do not have quarantine stations, Utah and Arizona, received a high volume of releases during the evaluation period; however, these requests were related to outbreaks of botulism in incarcerated populations and did not reflect frequent or repeated emergency drug release requests.⁵

This evaluation identified several areas for program improvement. Certain QARS data elements including drug request and arrival times could be further refined and standardized. Patient outcome data were unavailable for more than a third of the drug releases. Enhanced collaboration with SMEs, hospital providers, and public health partners may help increase the quality of outcome data. This could enhance future analyses to determine if time saved by the decentralized model of drug distribution contributes to a reduction in morbidity and mortality.

Due to limited supplies and regulatory and logistical requirements, CDC is unable to preposition drug products in every community. CDC Quarantine Stations provide strategic regional access and ensure that the drug product supply is properly maintained, shipped, and tracked. The selected quarantine station locations provide maximum geographic coverage nationwide.

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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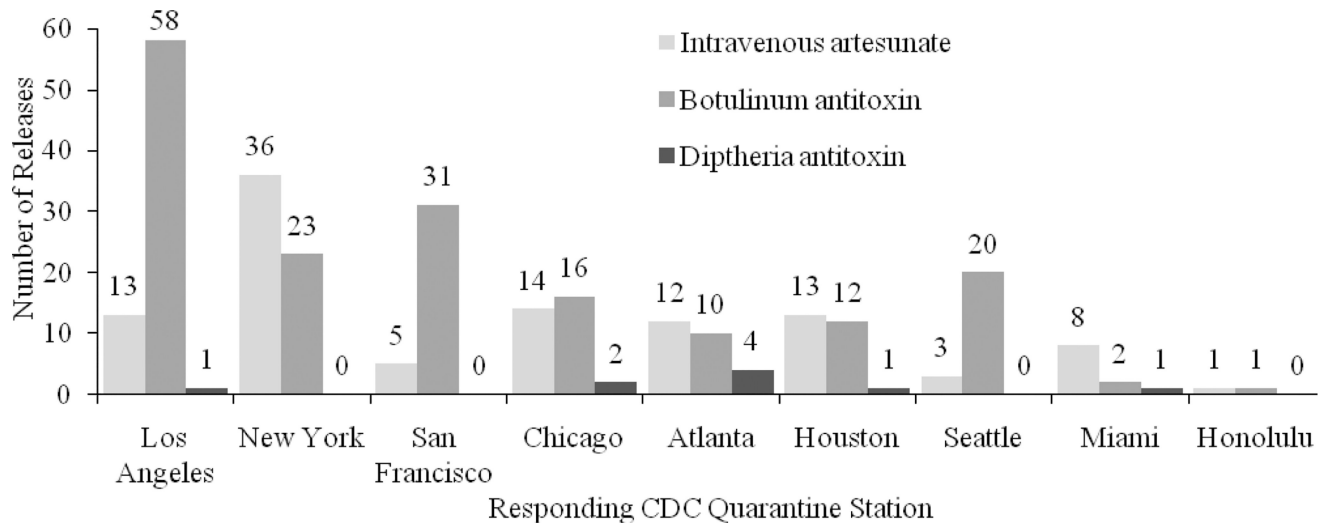


Figure 1. Centers for Disease Control and Prevention (CDC) drug releases by drug type and responding quarantine station, October 1, 2010 to September 30, 2012 (N = 287).

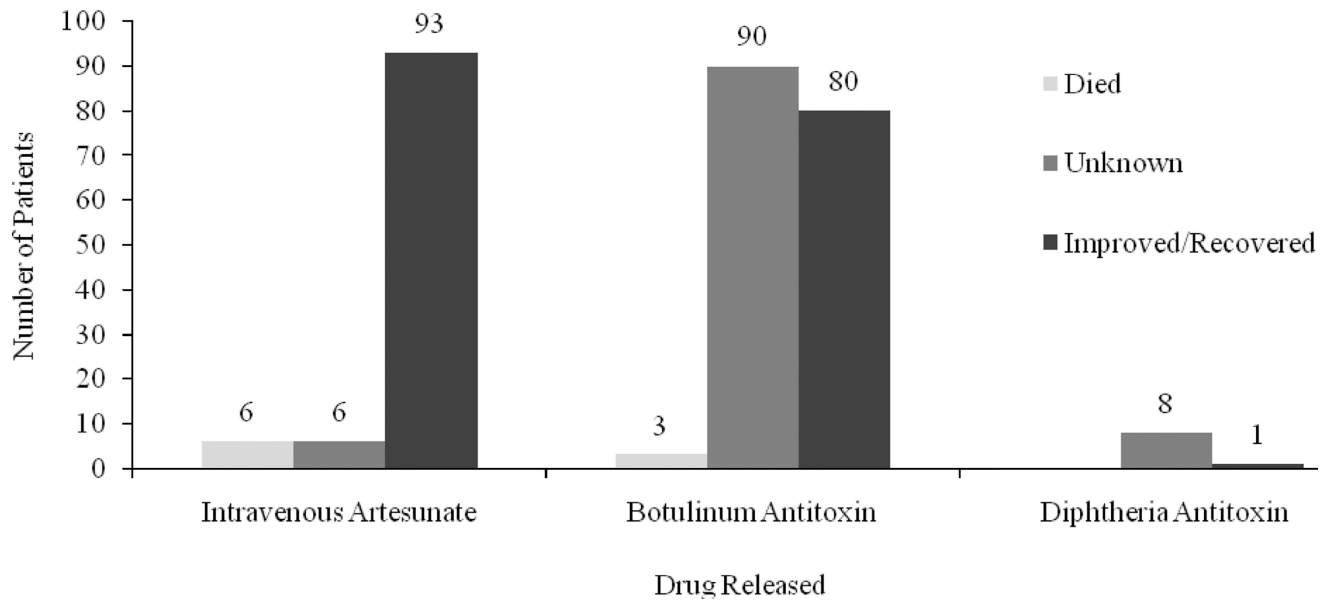


Figure 2. CDC Quarantine Station drug releases by drug released and reported patient outcome, October 1, 2010 to September 30, 2012 (N = 287).