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A Review of Malaria, Diphtheria, and Botulism Medication Distributions by CDC Port Health Stations From May 2006 to February 2024

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Abstract

Objectives: The Centers for Disease Control and Prevention (CDC) maintains a formulary of biologic agents and drugs not available commercially in the United States. For a subset of these (botulism and diphtheria antitoxins and, until 2022, intravenous artesunate for severe malaria), distribution is coordinated through CDC port health stations (PHS), located mainly at major US

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This activity, a secondary data analysis of data collected during routine operational work, was reviewed by CDC (STARS ID: 0900f3eb821d861c), deemed nonresearch, and therefore did not require submission to CDC institutional review board. The operational work was conducted consistent with applicable federal law and CDC policy, 45 C.F.R. part 46.102(l)(2), 21 C.F.R. part 56; 42 U.S.C. Sect. 241(d); 5 U.S.C. Sect. 552a; 44 U.S.C. Sect. 3501 et seq.

international airports. CDC aims for these drugs to reach their destinations within 8 hours of release authorization. We analyzed CDC records to identify areas for efficiency improvement.

Design: We queried records detailing drug distributions from PHS that occurred May 2006 to February 2024, including timing of release authorization and delivery, geographic origins and destinations, mode of transportation, and patient characteristics and outcomes. We conducted descriptive and multivariate analyses to identify variables that may have delayed delivery.

Setting: CDC port health stations.

Main Outcome Measures: Time from release authorization to drug delivery.

Results: CDC PHS distributed 2912 drug shipments between May 2006 and February 2024 via 17 distribution sites to 54 jurisdictions across the US and 3 countries. Of 850 shipments for which data were available (those occurring December 2019 or later), 83% ($n = 702/850$) occurred within 8 hours of authorization. Commercial air transport (compared to other types of transport) (aOR: 11.43, 95% confidence interval [CI]: 6.94-18.81, $P < .001$) and release authorization time (outside of vs within routine work hours) (aOR: 5.10, 95% CI: 3.31-7.86, $P < .001$) were significantly associated with delays.

Conclusions: CDC PHS facilitated emergency distributions of life-saving drugs for botulism, diphtheria, and severe malaria to locations throughout the US mostly within 8 hours of authorization. Staffing, distribution locations, and expanded options for ground transportation are important considerations that may minimize delays.

Keywords

artesunate; artesunic acid; botulism antitoxin heptavalent; diphtheria antitoxin; drug distribution

The Centers for Disease Control and Prevention (CDC) Drug Service and the Port Health Protection Branch (PHPB) work together to maintain, authorize release of, package, and facilitate the distribution of certain lifesaving drugs nation-wide. Specific drugs are managed and distributed by the CDC Drug Service because they are not commercially available, are in limited supply in the United States, and may pose stock expiration issues for medical facilities that do not use them frequently.¹ Historically, many of these drugs have been made available by CDC under the expanded access Investigational New Drug (EA-IND) protocols with approval by the US Food and Drug Administration (FDA).² The EA-IND is an FDA regulatory mechanism that gives an entity permission to procure and then release non-FDA-approved drugs only under certain circumstances. Since the establishment of the CDC Drug Service in 1965, the types of drugs maintained have changed based on public health needs, treatment guidelines, and drug availability.²

The CDC currently distributes two of these drugs, botulism antitoxin (BAT) and diphtheria antitoxin (DAT), through CDC port health stations (PHS, formerly known as quarantine stations) managed by the PHPB. Although the FDA approved BAT for the treatment of symptomatic botulism in 2013, it is only available through the CDC due to its limited use and relatively short shelf life.^{2,3} CDC continues to sponsor DAT through an EA-IND protocol.⁴ Historically, CDC also distributed intravenous artesunate for the treatment of severe malaria through the CDC PHS as well; however, CDC discontinued distribution in

September of 2022 because of the wider commercial availability of artesunate in the US following FDA approval.^{2,5}

The CDC Drug Service distributes these two drugs from CDC headquarters in Atlanta, Georgia, to PHS at 12 major US airports and a regional distribution center overseen by the PHPB. This decentralized model of drug distribution was shown to be more efficient, saving an estimated 7 hours compared to a hypothetical centralized distribution model from CDC headquarters.⁶ The PHS that presently support drug distribution for BAT and DAT include those located in Atlanta, Chicago, Dallas, Honolulu, Houston, Los Angeles, Miami, Minneapolis, New York, San Francisco, and Seattle, and near Washington DC. Additionally, Denver, which does not have a PHS, serves as a regional point of distribution (POD) for BAT and DAT (and previously, artesunate). In 2019, CDC had to expand the availability of intravenous artesunate under EA-IND because the only FDA-approved drug for severe malaria (intravenous quinidine) was no longer available in the US.⁷ The Denver POD was therefore added in 2019 to improve regional delivery of these drugs. Additionally, artesunate was distributed by PHS in Newark, Detroit, San Diego, and Philadelphia during 2019-2022. These stations no longer participate in drug distribution following the discontinuation of artesunate distribution.

The current procedures for drug distribution from PHS are informed by decades of experience. When a clinician or public health official suspects a case of botulism, diphtheria, or (up until 2022) severe malaria, they may request a clinical consultation with a subject matter expert (SME) from the CDC or, in certain states, a state or local health department. If the SME agrees that appropriate criteria are met for BAT or DAT administration, they will authorize release of the drug from the nearest PHS or POD. The CDC Emergency Operations Center (EOC) then connects the SME to that PHS, where staff will package the drug and arrange for air or ground transportation to deliver the drug. The requesting health care facility is responsible for retrieving the package from the destination airport, or from the PHS or POD if delivery is local (within 100 miles), but both local and remote destinations typically involve coordination with couriers, law enforcement, or other partners as needed. A cold chain is required throughout the shipping process and unused drugs must be returned to CDC. Notably, CDC PHS differ with regard to staffing and operational hours; the majority are not staffed 24/7; however, on-call coverage is in place 24/7 for urgent activities, of which drug release is one.

Because of the potential for rapid illness progression and deterioration of patients with the diseases treated by these drugs, timely drug delivery is critical, and in 2019 CDC established a target delivery time for these drugs of within 8 hours of release authorization.^{6,8,9} We sought to evaluate the success of this goal and identify areas for efficiency improvement by analyzing records for drug distributions from PHS, including drug distribution characteristics, geographic distribution, patient characteristics, patient outcomes, and timeliness of drug delivery.

Methods

We queried the CDC's Port Health Activity Reporting System (PHARS) database for records of distribution of artesunate, BAT, and DAT between May 12, 2006, and March 5, 2024. PHARS is a secure web-based system that allows PHS staff to record station activities including drug distributions. These distribution records cover the entirety of the US except for Alaska, where BAT and DAT are distributed by the Alaska State Department of Health and Social Services. CDC discontinued distribution of artesunate on September 30, 2022[§]; thus, artesunate data were limited to May 2006 through September 2022. Variables included time of drug release authorization, time of delivery to hospital, mode of transportation, type of drug, distribution volume of releasing PHS, type of authorizing agent, patient age and sex, and patient outcomes.

We divided PHS drug distribution volume into two categories: 25 or fewer or more than 25 drug distributions during the analysis period (2019-2024). We defined the time of drug release authorization as "within working hours" if the authorization occurred between 06:00 and 18:00 local time, or as "outside of working hours" if the authorization occurred between 18:00 to 06:00, for any day of the week. Modes of transportation were grouped into two categories: "commercial air" (commercial airlines) and "other" (all modes other than commercial airlines, for example, courier, transportation by military, police, or helicopter). Because helicopter transport is conducted by local partnerships and not commercial airlines, it was grouped with ground transportation. Transportation definitions only reflected the mode of transportation facilitated by PHS personnel, as the receiving hospital may have arranged for additional transportation (eg, ground transportation following arrival of drug at local airport).

In December 2019, fields were added to PHARS to allow the PHS staff to report the reasons for drug distribution delays. We defined "delayed" drug distributions as those for which the delivery time exceeded 8 hours. Delivery time was calculated by subtracting the time of drug release authorization (ie, time when the PHS staff were notified by the EOC of the authorization) from the time of drug arrival at the hospital as reported in PHARS.

We conducted descriptive analyses using SQL, Excel and R using data from May 12, 2006, and March 5, 2024. Using data from December 27, 2019, to March 5, 2024, we conducted a multivariate logistic regression using R to determine factors associated with drug delay, including the following variables: mode of transportation (other vs commercial air), distribution volume of releasing PHS (25 vs > 25), time of drug release authorization (during vs not during business hours), and type of authorizing agent (CDC SME vs state/local SME). This activity was reviewed by CDC, deemed not research, and was conducted consistent with applicable federal law and CDC policy.[§]

[§]See e.g., 45 C.F.R. part 46, 21 C.F.R. part 56; 42 U.S.C. §241(d); 5 U.S.C. §552a; 44 U.S.C. §3501 et seq.

Results

Drug distribution and patient characteristics

We identified 2 912 PHARS drug distribution reports from May 12, 2006, to March 5, 2024. Reports described drug distributions from 16 PHS and one POD. Drugs were distributed domestically ($n = 2\,901/2\,912$, 99.6%) across 54 US jurisdictions including 49 states, Washington DC, and 4 territories, as well as internationally ($n = 11/2\,912$, 0.4%) to Haiti, Mexico, and the Philippines. All but one international distribution were undertaken as part of existing international agreements (Strengthening National Disease Surveillance and Response—Haiti, 2010-2015—PMC, Border Health and Migration | Border Health and Migration | CDC). The exception was a single distribution to the Philippines completed upon emergency request. California received the most drug distributions ($n = 953/2\,912$), accounting for 33% of all drug distributions (Figure 1). PHS conducted a median 140.5 drug distributions per year (range 82-375).

Artesunate accounted for 35% ($n = 1052/2\,912$) of distributions, BAT for 62% ($n = 1800/2\,912$) of distributions, and DAT for 2% of ($n = 58/2\,912$) distributions. Two reports had no drug identified. Commercial air transportation accounted for 44% of distributions ($n = 1\,293/2\,912$) and ground transport comprised the remaining 56% of drug distributions ($n = 1\,619/2\,912$) (Table 1). Median patient age was 47 years (IQR 32-59). Among all drug distributions, 10% ($n = 303/2\,912$) were conducted for patients younger than 18 years old with an average age of 8 years and youngest patient aged 0 years (11 days). Thirty-six percent (36%) of patients were female ($n = 1\,041/2\,912$), 61% were male ($n = 1\,778/2\,912$), and sex was not reported for 3% of patients ($n = 93/2\,912$) (Table 2).

Drug distribution delays

There were 856 distributions reported in PHARS from December 27, 2019, to March 5, 2024, after the addition of the shipment delay reporting panel. Of those, 850 (99%) had documented time of SME release authorization and time of drug delivery to hospital. Most deliveries (83%, $n = 702/850$) occurred within 8 hours, and 17% ($n = 148/850$) deliveries took ≥ 8 hours to complete. Of delayed drug distributions, 78% ($n = 115/148$) were for BAT, 20% ($n = 29/148$) were for artesunate, 3.5% ($n = 4/115$) were for DAT. Among the 148 reports of delayed deliveries, 132 (89%) provided at least one delay reason, with a total of 237 reasons documented. Of the 132 reports with at least one delay reason, 65% ($n = 86/132$) indicated no timely flight was available, and 38% ($n = 50/132$) indicated cargo facility was closed at destination (27%, $n = 35$), origin (8%, $n = 10$), or both (4%, $n = 5$). Other reasons for delay included courier delays from the airport after flight (14%, $n = 19$), difficulty or delay in hiring a courier (12%, $n = 16$), cargo facility processing delays (10%, $n = 13$), local courier delays (10%, $n = 13$), flights cancelled or delayed (9%, $n = 12$), and several additional reasons (Figure 2). Eighty-eight of 294 (29.9%) distributions occurring outside business hours (after 06:00 PM and before 06:00 AM local time) were delayed compared to 60 of 562 (10.7%) distributions occurring within business hours (after 06:00 AM and before 06:00 PM). One hundred and twelve of 288 (38.9%) commercial air transport distributions were delayed compared to 35 of 318 (6.2%) ground distributions.

We evaluated factors that may have impacted delay of drug distributions from December 27, 2019, to March 5, 2024, via multivariate logistic regression in a model that included mode of transportation, PHS drug distribution volume, time of release authorization, and type of authorizing agent. Our analysis identified commercial air transport (commercial air vs other) (aOR: 11.43, 95% confidence interval [CI]: 6.94-18.81, $P < .001$) and release authorization time (outside vs within routine work hours) (aOR: 5.10, 95% CI: 3.31-7.86, $P < .001$) as significant causes of drug distribution delays >8 hours (Table 2).

In order to visually display the differences between distributions completed via commercial airlines versus other modes of transportation, we created a graph showing average time per quarter of drug distributions in each category, for the duration of the analysis period (Figure 3).

Patient outcomes

Eleven (1.3%, 10 treated for malaria, 1 treated for botulism) of the 850 patients with outcomes documented in PHARS died and of those only 1 patient (treated for malaria) had ≥ 8 -hour delay in medication shipment.

Discussion and Conclusion

CDC PHS successfully facilitated almost 3 000 distributions of life-saving drugs that were not commercially available within the US from 2006 to 2024. The top five requesting states (California, New York, Texas, Washington, Florida) accounted for over half of all drug requests, and there is at least one releasing PHS located in each of these states. Four of these states (California, Texas, Florida, New York) are also the top four states in terms of population, so the correlation with drug release requests is not unexpected. Three PHS (Los Angeles, New York, and San Francisco) accounted for over half of all drug distributions. A little over half (56%) of drug distributions used ground transport. This indicates that roughly half of drug distribution requests occurred within 100 miles of a releasing PHS/POD while the other half occurred beyond 100 miles. Together with our previous analysis, these findings suggest that current PHS are well positioned to meet the demand for emergency drug distributions.⁶

CDC PHS successfully facilitated delivery of 83% of drug distributions within 8 hours between December 2019 and February 2024. We identified two factors associated with delivery delays during this period: commercial air transportation and release authorization time outside of work hours. It is logical that commercial air transportation would be associated with delays given distributions using commercial air transportation are likely to require travel of greater distances to reach their destinations than those sent via ground transportation. Furthermore, most delayed distributions had documented problems with commercial air transportation, such as a lack of timely flights, closure of cargo facilities at the destination, and flight cancellations or delays. Releases authorized outside of business hours (occurring before 06:00 or after 18:00) were delayed more often, which may have been in part due to reduced domestic flight availability during overnight hours or closure of cargo facilities at origin or destination. Nighttime drug distributions may also present more coordination challenges due to reduced flight and courier availability as well as PHS

staff availability onsite, and evening personnel changes of airlines, transport companies, and hospital pharmacies.

Drug release authorizations, packaging, and shipments occur 24/7. Flight schedules and cargo station operating hours are controlled by airlines. However, minimizing the need for commercial air transportation and expanding use of other types of transportation are possible strategies that could potentially be implemented by PHS to reduce drug delivery delays. Measuring additional timepoints prior drug release authorization may also allow for identification of other areas for potential improvement in the system. Currently, CDC protocol indicates that deliveries traveling over 100 miles are eligible for commercial air transport, although this may not be a strict limit in practice. By expanding the zone of ground transportation to 150 or 200 miles in appropriate instances, fewer deliveries would require commercial air transportation. This approach could place additional costs on requesting hospitals, who would need to arrange and pay for ground transportation to travel farther distances. PHS and health departments can also explore establishing relationships with courier services located near PHS to allow for faster, one-way deliveries. The additional costs of courier services or other ground transportation would benefit from exploration for feasibility.

Distribution locations and staffing are additional considerations. Denver was added as a regional POD in 2019 and since then has successfully facilitated 22 ground deliveries without any delays. The addition of more regional PODs at other travel hubs could both alleviate the cost of increased ground transportation and decrease the need for air transport. Continued evaluation to identify and address gaps in the distribution network impacting the 8-hour delivery target, and adjusted staffing schedules for broader coverage, may help further reduce delays. Prepositioning supplies in states has been suggested as an alternative model in the past⁶; however, given these distributions require logistics infrastructure, shipment, and tracking support systems, and rely on limited supply, CDC PHS positioned across the country allow for strategic localization of distribution points at travel hubs.

Finally additional partnerships with state or local agencies may be helpful. For example, currently, the Los Angeles PHS partners with the California Highway Patrol, and the Seattle PHS partners with the Seattle Fire Department to deliver CDC-maintained drugs. Anecdotally, these partnerships work efficiently. However, we were unable to conduct a formal analysis of these partnerships due to how these deliveries are tracked in PHARS.

There are at least three limitations to this evaluation. First, analysis was limited to variables tracked by PHARS. There may be additional factors associated with delay and reasons for delivery delays that were not captured in the reports (eg, our data do not capture time from initial call from the health provider to SME authorization, or when PHS staff needed to return to the office to conduct a shipment after regular operating hours). Second, given the relatively recent addition of delivery/shipment delay reporting to PHARS, factors associated with delay could only be analyzed in a fraction of the total reports. Third, analysis of patient outcomes was limited due to incomplete data in PHARS for most patients following drug distributions. Thus, we were not able to assess the impact of delays on patient outcomes.

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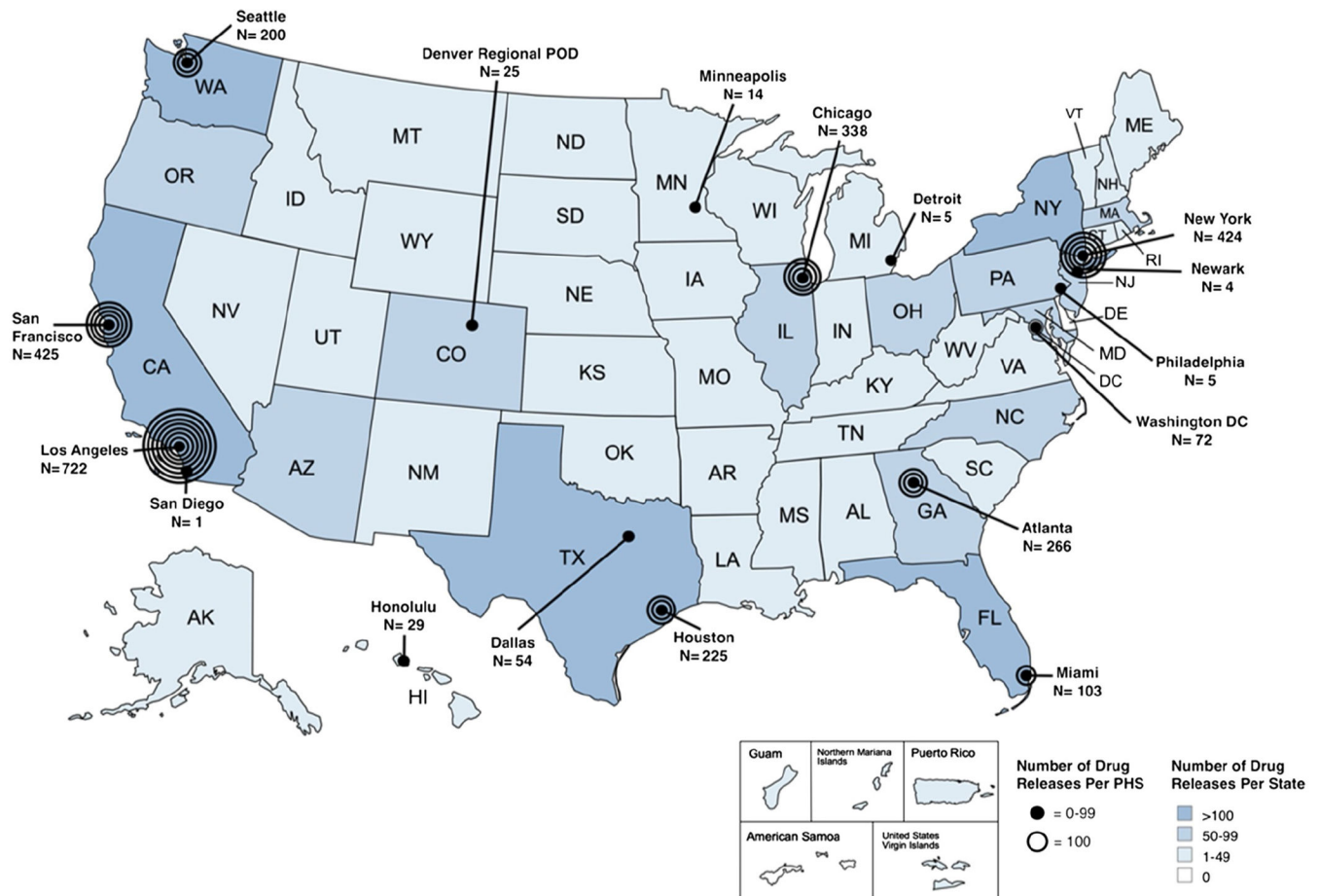
The findings and conclusions of this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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Implications for Policy & Practice

- On average, CDC PHS facilitated over 150 lifesaving distributions of medication annually for the treatment of diphtheria, botulism, and (until recently) severe malaria, and 99% of patients with reported outcomes survived during our almost 18-year analysis period.
- Drug distributions are an important function of the CDC PHS and the decentralized system allowed CDC PHS to successfully deliver drugs within 8 hours of authorization for 83% of distributions with available data.
- Drug distributions requiring commercial air transportation or authorization outside of regular business hours were more likely to be delayed.
- Implementing practices that decrease the need for commercial air transportation may reduce drug distribution delays.

**FIGURE 1.**

Map of drug distributions in the United States from Centers for Disease Control and Prevention port health stations (PHS), Depicting Releasing PHS and Destination States, 2006-2024 (N = 2901*)

*Eleven additional drug distributions occurred with release by PHS to international destinations: Haiti (n = 7), Mexico (n = 3), and the Philippines (n = 1). POD = Point of distribution. The POD is a non-PHS satellite location that maintains drug inventory and distributes drugs in the local area on behalf of the POD's supervising PHS.

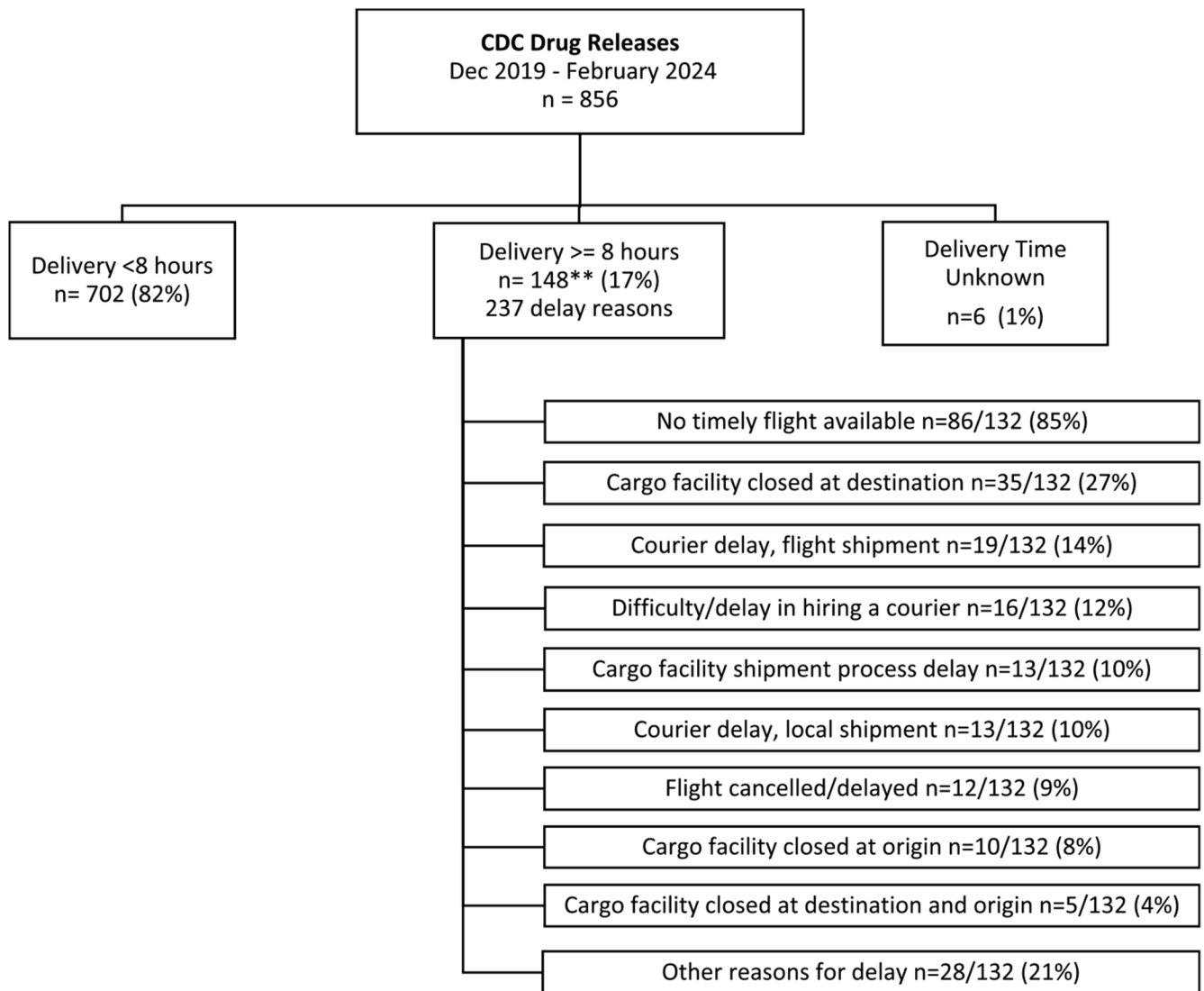
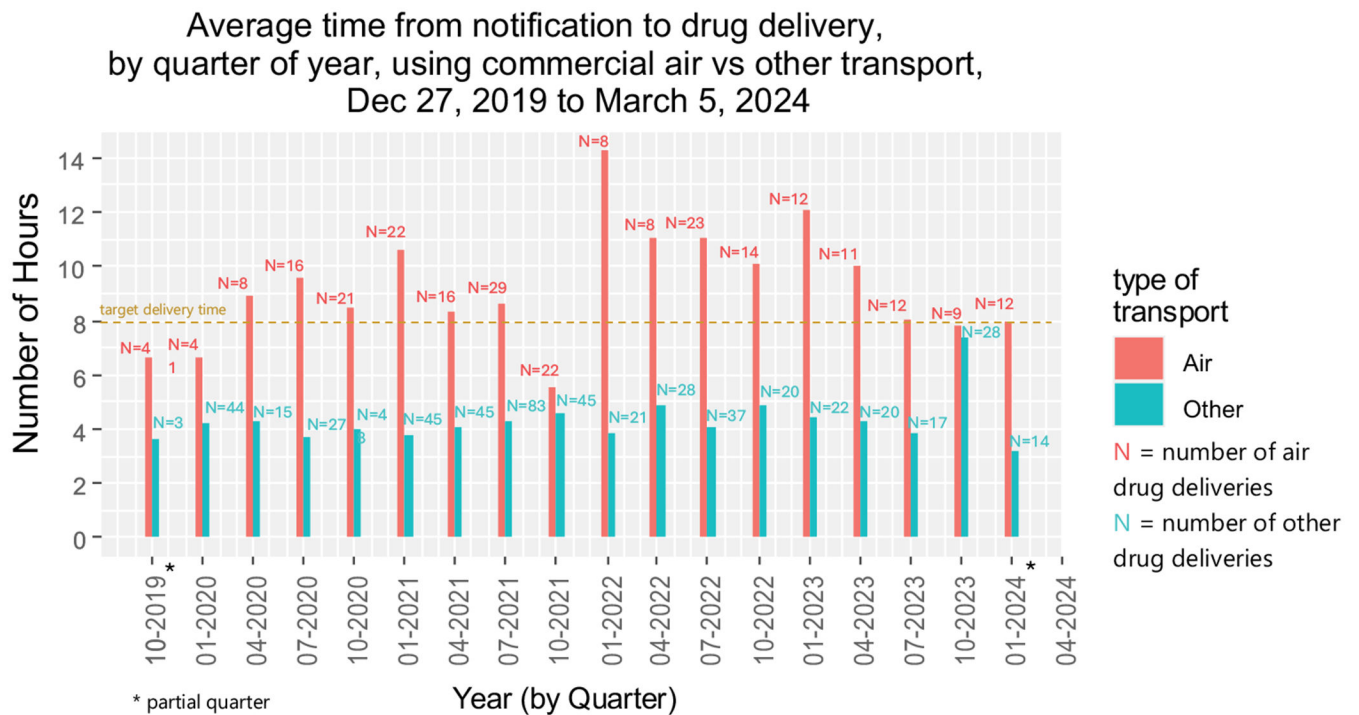


FIGURE 2.

Flowchart of drug distributions from Centers for Disease Control and Prevention port health stations and reasons for delay, 2019*-2024

*Tracking of time and delay data began in 2019 when the shipment delay reporting panel was added.

**16 of the 148 reports did not provide reason for the delay.

**FIGURE 3.**

Average drug distribution time per quarter for distributions completed via commercial airlines versus those completed via other transportation modes* for Drug Distribution from Centers for Disease Control and Prevention (CDC) port health stations (PHS), 2019-2024

*Other types of transport included all modes other than commercial airlines, for example, courier, transportation by military police, or helicopter.

Table 1

Characteristics of 2 912 Drug Distributions from Centers for Disease Control and Prevention Port Health Stations between May 12, 2006 and March 5, 2024

Characteristic	N (%)
Drug Type ^a	
Artesunate	1052 (35)
Botulism antitoxin	1800 (62)
Diphtheria antitoxin	58 (2)
Transportation Mode	
Other	1619 (56)
Commercial air	1293 (44)
Patient age, median (IQR)	47, (32-59)
Patient Sex	
Female	1041 (36)
Male	1778 (61)
Unknown	93 (3)

^aTwo reports did not identify type of drug distributed.

Table 2

Multivariate Logistic Regression of Factors Associated with Delay of Drug Distribution from Centers for Disease Control and Prevention (CDC) Port Health Stations (PHS), 2019-2024 (N = 856 Distributions)

	Multivariate Logistic Regression		
	aOR	CI	P Value
Transport: Commercial air vs other ^a	11.43	6.94-18.81	<.001
PHS distribution volume: 0-25 vs > 25 ^b	1.86	0.71-4.88	.21
Agent: CDC vs state SME ^c	1.14	0.60-2.16	.69
Time: Outside vs within business hours ^d	5.10	3.31-7.86	<.001

^aTransportation mode is classified as “commercial air” (commercial airline) or “other” (all modes of transportation other than commercial airline, including transportation by military, police, or helicopter).

^bPHS distribution volume was divided into two categories: 25 or fewer drug distributions during the multivariate analysis period (2019-2024), and more than 25 drug distributions.

^cType of authorizing agent is classified as either a CDC subject matter expert (SME) or state/local SME.

^dTime of drug distribution authorization is classified as “within working hours” if the authorization occurred between 06:00 and 18:00 local time, or as “outside of working hours” if the authorization occurred between 18:00 to 06:00, any day of the week.