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A Sore Subject?: An Examination of National Case-Based Chancroid Surveillance

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Abstract

Background: Chancroid has been a nationally notifiable condition in the United States since 1944, with cases reported to Centers Disease Control and Prevention through the National Notifiable Diseases Surveillance System (NNDSS). Although frequently reported during the 1940s, <20 cases have been reported annually since 2011. We assessed the performance and utility of national case-based chancroid surveillance.

Methods: We reviewed the literature to contextualize chancroid surveillance through NNDSS. We then assessed 4 system attributes, including data quality, sensitivity, usefulness, and representativeness: we reviewed chancroid cases reported during 2011–2020, conducted interviews with a) STD programs reporting ≥1 case in 2019 or 2020 (n = 9) and b) CDC subject matter experts (n=10), and reviewed published communicable disease reporting laws.

Results: Chancroid diagnostic testing is limited, which affects the surveillance case definition. National case-based surveillance has poor data quality; of the 2019 and preliminary 2020 cases (n = 14), only 3 were verified by jurisdictions as chancroid cases. STD programs report the

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system has low sensitivity given limited clinician knowledge and resources; experts report the system is not useful in guiding national control efforts. Review of reporting laws revealed it is not representative, as chancroid is not a reportable condition nationwide.

Conclusions: Critical review of system attributes suggest that national case-based chancroid surveillance data have limited ability to help describe and monitor national trends, and chancroid's inclusion on the national notifiable list might need to be reconsidered. Alternative strategies might be needed to monitor national chancroid burden.

Short Summary

We assessed the utility of national case-based chancroid surveillance in the United States by examining the sensitivity, data quality, usefulness, and representativeness of the surveillance system.

Keywords

STI; STD; chancroid; surveillance; *Haemophilus ducreyi*

Introduction

Chancroid is a sexually transmitted disease (STD) caused by infection with *Haemophilus ducreyi*, a fastidious, gram-negative bacteria that results in genital ulcer disease; transmission occurs through sexual contact, and humans are the only host. While a low infectious dose is thought to be needed for infection, sustained transmission within communities has historically involved dense sexual networks, such as those among sex workers.[1] The clinical presentation of chancroid includes painful anogenital ulcers and buboes (very inflamed and swollen lymph nodes) in the groin region. Buboes can take weeks to months to resolve if not treated[2] and can occur in up to 50% of cases.[3] Symptoms typically do not lead to hospitalization or death but might result in long-term sequelae such as genital scarring and rectal or uro-genital fistulas. Additionally, the infection can facilitate the transmission and acquisition of HIV.[4,5] Fortunately, multiple effective antimicrobials for the treatment of chancroid are available, which can cure the infection, resolve clinical symptoms, and prevent transmission to others.[6]

In the United States, chancroid has been a nationally notifiable condition since 1944, with case notifications provided to the Centers for Disease Prevention and Control (CDC) through the National Notifiable Diseases Surveillance System (NNDSS). Cases of chancroid reported through NNDSS peaked in 1947 (N = 9,515 cases) and then rapidly declined through 1959 (N = 1,537 cases), possibly because of increasing use of antimicrobials like sulfonamides and penicillin that were introduced in the late 1930s and early 1940s (Fig. 1).[7,8] Significant social changes, including reduced migration and improved economic options for women, and earlier changes in sex work communities might have also contributed to the decline.[8] A number of localized outbreaks, most of which were linked to commercial sex work, were identified in the United States during 1981–1990.[9,10] Since 2011, national case counts have declined to <20 cases annually. Because only diagnosed and reported cases can be included in NNDSS, it is likely that national trends are heavily

influenced by changes in diagnostic capacity, programmatic response, and adherence to case definitions and reporting practices. Other than NNDSS, there are no national surveillance systems in place to monitor trends in chancroid; therefore, there are no US chancroid prevalence estimates and most recently published studies are limited to case reports.[11-13]

There has been no documented evaluation of national case-based chancroid reporting since the surveillance case definition was last updated in 1996. To examine the performance of ongoing national case-based chancroid surveillance and identify areas for improvement, we conducted an evaluation of chancroid surveillance through NNDSS by describing the surveillance system, followed by a critical review of the system's attributes based on available evidence and key informant interviews.

Materials and Methods

To better understand the context and issues that might affect chancroid surveillance, we first reviewed the literature on current chancroid diagnostic capacity, as well as changes in the surveillance case definition over time. We then assessed 4 system attributes of national case-based surveillance through NNDSS, including data quality, sensitivity, usefulness, and representativeness, using available evidence and key informant interviews. To assess data quality, we analyzed chancroid case notifications provided through NNDSS during 2011–2020 (2020 data preliminary as of September 16, 2021) and calculated the proportion of cases reported with a case status of "probable" or "confirmed" in the current case definition. For jurisdictions reporting ≥1 cases in 2019 or 2020 (n = 9), we conducted phone interviews with key informants (state and local STD program managers to verify if reported cases met the current chancroid case definition. To assess sensitivity, we also asked informants to describe local reporting practices and control efforts for suspected chancroid cases. Additionally, we conducted key informant interviews with 10 CDC subject matter experts involved in national chancroid surveillance, including STD program officers and surveillance leads, to understand national uses of case data and assess usefulness; key informants were purposefully selected based on their subject matter expertise in STD surveillance or experience working with state and local STD programs. Finally, to assess representativeness, we reviewed the health department websites for all 50 U.S. states and the District of Columbia (DC) and abstracted published communicable disease reporting laws and guidance to investigate whether chancroid is a reportable condition in all areas.

Results

Literature Review: Contextual Issues Affecting Chancroid Surveillance

Laboratory and Clinical Diagnosis—Several methods exist for the laboratory diagnosis of chancroid, including microscopy, in vitro culture, and DNA amplification techniques; however, each has its own challenges. Regarding microscopy, studies show that Gram stain of clinical material has low sensitivity and specificity and does not compare favorably with either culture-proven or clinically-diagnosed chancroid cases in most studies.[14,15] As such, microscopy is not currently recommended to diagnose chancroid.[1,15] In vitro culture for *H. ducreyi* is required for a definitive diagnosis of chancroid in the clinical setting.[14-16] Culture has a high specificity, but low sensitivity (<75% in comparison to

molecular methods described below).[3,14] Further, the culture media required to grow *H. ducreyi* are not commercially available in the US and, therefore, culture is not widely used. More sensitive DNA amplification techniques were introduced during the 1990s and have improved sensitivity over culture.[14] Currently, polymerase chain reaction (PCR) is the gold standard for chancroid diagnostic testing in the United States; however, because no molecular assays are FDA-approved for use in the United States, it is infrequently used (i.e., only clinical labs that have conducted Clinical Laboratory Improvement Amendments verification studies on genital specimens can use PCR for diagnosing chancroid).

Chancroid is clinically characterized by painful genital ulceration and inflammatory inguinal adenopathy. In low-resource settings, a clinical diagnosis of chancroid based on patient history and physical exam findings can be made if culture media for *H. ducreyi* are not available (i.e., syndromic management).[1] However, the clinical presentation of chancroid is similar to other genital ulcerative infections like herpes and syphilis, making a clinical diagnosis of chancroid challenging. Studies have shown that clinical diagnosis accuracy for chancroid ranges from 33% to 80%.[14] Laboratory exclusion of these other STDs should inform clinical diagnoses, but these diagnostic tests also have limitations or might not always be performed.[10]

Surveillance Case Definition and NNDSS Case Notification—Surveillance case definitions are developed and approved by the Council of State and Territorial Epidemiologists (CSTE) and are recommended for use by all states for local and national reporting. Case definitions can change and CSTE last updated the chancroid case definition in 1996. The current surveillance case definition aligns with the current clinical case definition. The surveillance case definition provides a definition for both confirmed and probable cases,[17] and is based the following clinical and laboratory criteria:

Confirmed: A clinically compatible case that is laboratory confirmed by isolation of *H. ducreyi* from a clinical specimen (i.e., culture positive).

Probable: A clinically compatible case with

- no evidence of *Treponema pallidum* infection by darkfield microscopic examination of ulcer exudate or by a serologic test for syphilis performed ≥7 days after onset of ulcers; and
- either a clinical presentation of the ulcer(s) not typical of disease caused by herpes simplex virus (HSV) or a culture negative for HSV.

NNDSS currently serves as the national surveillance system for nationally notifiable conditions in the United States and uses surveillance case definitions of nationally notifiable conditions to monitor trends. Extensive documentation is provided to states on the standards and requirements for sending case notifications for national surveillance.[18] When states identify a surveillance case of chancroid through local laboratory or provider reporting, they send the case notification electronically to CDC through NNDSS; states are encouraged to send data at least weekly. As NNDSS includes a variety of conditions, the case status options available in NNDSS (i.e., confirmed, probable, suspect, or unknown) are

broader than what is valid for chancroid (i.e., confirmed or probable). Per the CSTE case definition for chancroid, case notifications should be sent with available demographic information (e.g., age, sex, race/ethnicity) and case status (probable or confirmed). Additional information, including HIV status, history of exchanging sex for drugs or money, sex of sex partners, and substance use, can be included in the chancroid case notification but they are not required variables. All case reports received through NNDSS are accepted and counted, regardless of the case status or information provided.

NNDSS Chancroid Case Notifications (2011–2020): Analysis of 'Probable' and 'Confirmed' Cases

Eighty-one chancroid cases were reported through NNDSS during 2011–2020, with an average of 8 cases per year (Table 1). Of the 81 cases, 17 (21%) had an invalid case status (i.e., "suspect" or "unknown"). Information on sex and age was available for most cases, but race/ethnicity was missing for one quarter of cases. Likely a result of lack of case investigations, the majority of cases were missing information on HIV status, sexual behaviors, and substance use.

Fourteen cases were reported for 2019 (n = 8) and 2020 (n = 6). Based on a review of cases with key informants during this evaluation, 3 cases were verified by the jurisdiction, 6 were found to be data entry errors by the jurisdiction (i.e., should have been reported as another STD), 2 were determined by the jurisdiction not to meet the chancroid case definition, and 3 were not able to be reviewed. None of 6 cases reported during 2020 were verified to meet the chancroid case definition by the reporting jurisdiction and all were removed prior to finalization of 2020 NNDSS data in December 2021.

STD Program Manager Interviews: Local Reporting Practices and Control Efforts

In our key informant interviews, local STD program staff felt that clinician knowledge of chancroid was limited. Some felt that clinicians were either not aware of chancroid or did not report it. More specifically, program staff felt that providers could misdiagnose a chancroid case as some other infection, treat it empirically with an antimicrobial that resolves symptoms, and therefore, never report the case. These practices further limit the sensitivity of a case-based surveillance system.

Beyond diagnosis, national case-based surveillance also relies on STD programs to investigate and follow up on suspected cases to determine if the case meets the surveillance case definition. Based on key informant interviews, many STD programs prioritize other STDs for case follow-up, particularly syphilis, so suspected chancroid cases are not always investigated. This means that, unlike other STDs, cases misreported by clinical providers are often not corrected through disease investigation.

Subject Matter Expert Interviews: National Uses of Case Data

During key informant interviews, CDC subject matter experts noted that the national chancroid case data had limited utility. Chancroid case notifications are included in annual surveillance reports; however, unlike other nationally notifiable STDs collected through NNDSS (chlamydia, gonorrhea, and syphilis), there are currently no chancroid

prevention and control initiatives at the national level. Further, the recent and ongoing 2018 Strengthening STD Prevention and Control for Health Departments Notice of Funding Opportunity, which supports health departments to conduct STD surveillance and respond to STD-related outbreaks across 5 years, does not mention chancroid. Finally, none of the current measures for monitoring national efforts to reduce the burden and impact of STDs in the United States (e.g., Healthy People 2030 objectives, Sexually Transmitted Infections National Strategic Plan indicators) use chancroid case data.[19,20]

Communicable Disease Reporting Laws and Guidance: Chancroid as a Reportable Condition

All published communicable disease reporting laws and guidance were abstracted from health department websites for all 50 U.S. states and DC (websites accessed October 7, 2021). Although the 3 other nationally notifiable STDs that are reported through NNDSS (chlamydia, gonorrhea, and syphilis) were identified as reportable conditions in all U.S. states and DC, chancroid was missing from the published list of reportable conditions in 7 jurisdictions. Therefore, even if case-based reporting was complete in the jurisdictions where chancroid was reportable, representativeness at the national level would be lacking because data would not include all states.

Discussion

Critical review of the system's attributes based on available evidence and key informant interviews suggest that national case-based chancroid surveillance data have limited ability to monitor national trends. Although the overall decline in reported chancroid cases in the US likely reflects a decline in disease incidence (as observed in previous endemic countries),[21,22] these data should be interpreted with caution because *H. ducreyi* is difficult to definitively diagnose: clinical diagnoses may be unreliable due to limitations in diagnostic testing or because tests are not performed[10] and the current surveillance case definition likely misses most *H. ducreyi* infections because the laboratory methodology required to confirm cases (culture) is not readily available.

Our review of recent case notifications found almost a quarter of reported cases in the past decade did not have a valid case status, suggesting erroneous reporting that could influence national case rates. Scrutiny of the recently reported cases confirmed only a fraction of reported cases were correctly reported, further undermining data quality. Additionally, likely because of the lack of resources for case investigation, few cases were reported with the clinical and behavioral data needed to fully describe populations being diagnosed with chancroid. Local STD program manager interviews determined that surveillance often relies upon a clinician's ability to discriminate chancroid from other genital ulcerative diseases and report cases to local health authorities, which is imperfect and limits the system's sensitivity. Furthermore, subject matter expert interviews determined that the national case notification data have limited usefulness at the national level. Finally, because chancroid is not a reportable condition in all jurisdictions as per our review, data reported through NNDSS do not and cannot capture all diagnosed cases in the nation, affecting the system's representativeness.

These findings follow those of similar studies conducted by CDC in the late 1980s and early 1990s, prior to the 1996 update to the case definition that is used currently. Similar to findings from this evaluation, an assessment of chancroid reporting after numerous, seemingly sporadic outbreaks during 1971–1980 found that chancroid diagnosis and reporting is unreliable; it is underreported and unrecognized by clinicians in some areas and often misdiagnosed or misclassified.[9] The authors also found it to be overreported in areas for reasons including clerical reporting mistakes.[9] Another study conducted in 1992, which assessed the decline in cases from the 1980s to 1990s, also found that problems with accurate diagnosis of chancroid and subsequent reporting of possible cases complicated the interpretation of surveillance data. In this case, the authors determined that chancroid was underreported because of the limited availability of culture media for *H. ducreyi* and a lack of a probable case definition.[10] The latter issue has since been addressed, but the first issue remains today.

Although NNDSS is implemented nationwide with a well-established infrastructure that allows for electronic transmission of case notification data to CDC, findings from this surveillance evaluation suggest that national case-based chancroid surveillance data continue to be difficult to interpret. Given the significant limitations of the surveillance system for chancroid, including poor data quality, reduced sensitivity, limited usefulness, and lack of representativeness, it is unclear if chancroid should remain on CSTE's nationally notifiable condition list (and be monitored at the national level). At the minimum, caveats to national rate estimates are needed to account for chancroid not being reportable in all jurisdictions, and data cleaning and quality assurance checks are needed to ensure data quality. It should be noted, however, that since the completion of this evaluation, CDC's annual STD surveillance report was revised as suggested.[23] Chancroid data were also added to quarterly case data review materials, which are provided to jurisdictions to support data cleaning prior to NNDSS data close out.

It is possible there is benefit to chancroid remaining on reportable condition lists at the local or state level. In jurisdictions where it is reportable, a recognized increase in cases locally might result in a redirection of programmatic resources allowing for investigation of clusters or outbreaks. However, given the low sensitivity of the case definition, it is possible that even if it remains a reportable condition, outbreaks may go undetected. Future discussions are planned with CSTE members and STD programs to better understand the utility of case-based surveillance for chancroid at the local, state, and national levels. Additionally, focusing efforts to develop a new gold standard based on nucleic acid amplification test (NAATs), including multiplex PCR for genital ulcer disease, and identifying laboratories where specimens can be readily submitted also holds merit: the wider availability of multiplex PCR testing is not only important to identify *H. ducreyi*, but also other conditions, like primary syphilis, which also suffer current diagnostic issues. Finally, investigation of alternative surveillance strategies to monitor the national burden of chancroid could be explored, such as use of administrative claims data (e.g., ICD-10 codes); however, rigorous evaluation of the alternative methods to understand strengths and limitations would be needed prior to implementation.

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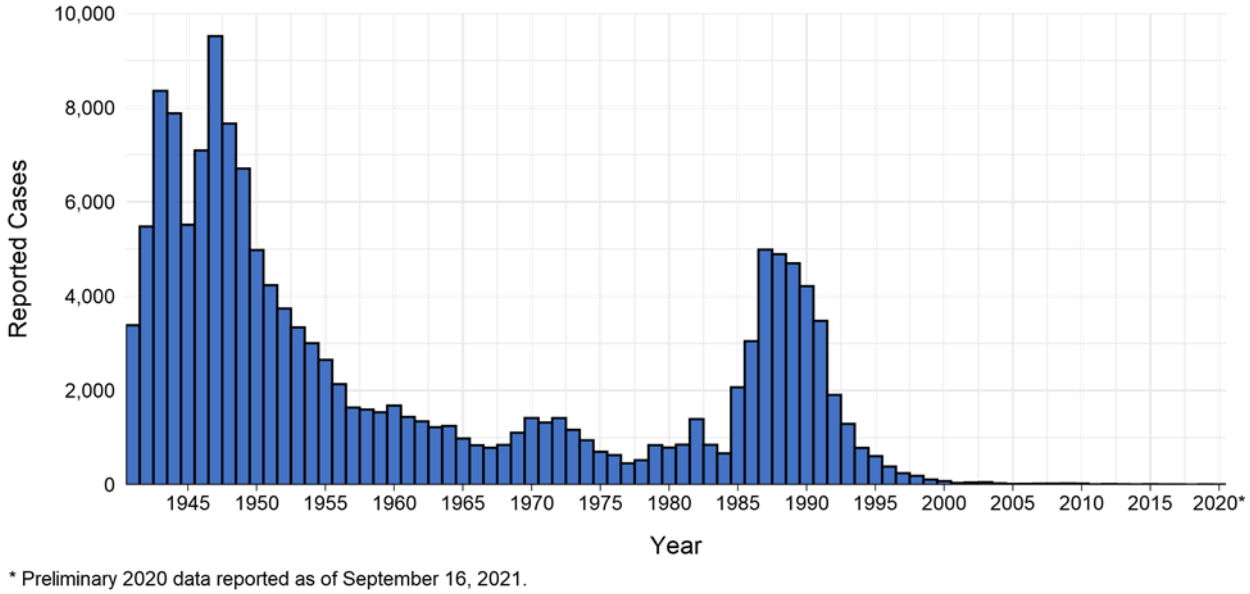

Figure 1: Number of reported chancroid cases — National Notifiable Diseases Surveillance System (NNDSS), United States, 1943–2020*

TABLE 1.

Number and percentage of chancroid case notifications, by demographic characteristic (N = 81) — National Notifiable Diseases Surveillance System (NNDSS), United States, 2011–2020 *

	Cases	
	n	**%**
Case status		
Confirmed	43	53
Probable	21	26
Suspect	16	20
Unknown	1	1
Sex		
Male	48	59
Female	33	41
Unknown	0	0
Race/ethnicity		
Non-Hispanic White	23	28
Hispanic/Latino	21	26
Non-Hispanic Black	15	19
Non-Hispanic Multiracial/Other	3	4
Unknown	19	23
Age, years		
<15	1	1
15–19	16	20
20–24	23	28
25–29	18	22
30–34	6	7
35–39	7	9
40–44	2	2
45–54	3	4
55+	5	6
Unknown	0	0
Region		
Northeast	16	20
Midwest	8	10
South	24	30
West	33	41
Unknown	0	0
HIV status		
Positive	0	0
Negative	11	14
Unknown	70	86
Sex of sex partners among male cases (n = 58)		

	Cases	
	n	**%**
Male partners only	2	3
Female partners only	4	7
Male and female partners	0	0
Unknown	52	90
Exchanged sex for drugs or money (past 12 months)		
Yes	0	0
No	10	12
Unknown	71	88
Injection drug use		
Yes	0	0
No	7	9
Unknown	74	91

* Preliminary 2020 data reported as of September 16, 2021.