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The Impact of Law on Syndromic Disease Surveillance Implementation

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Abstract

Context—Legal environments influence how health information technologies are implemented in public health practice settings. Syndromic disease surveillance (SyS) is a relatively new approach to surveillance that depends heavily on health information technologies to achieve rapid awareness of disease trends. Evidence suggests that legal concerns have impeded the optimization of SyS.

Objectives—1) Understand the legal environments in which SyS is implemented, 2) determine the perceived legal basis for SyS, and 3) identify perceived legal barriers and facilitators to SyS implementation.

Design—Multi-site case study in which 35 key informant interviews and five focus groups were conducted with 75 SyS stakeholders. Interviews and focus groups were audio recorded, transcribed, and analyzed by three coders using thematic content analysis. Legal documents were reviewed.

Setting—Seven jurisdictions (five states, one county, one city) that were purposively selected based on SyS capacity and legal environment.

Participants—Health department directors, SyS system administrators, legal counsel, and hospital personnel.

Results—Federal (e.g., HIPAA) and state (e.g., notifiable disease reporting) laws that authorize traditional public health surveillance were perceived as providing a legal basis for SyS. Financial incentives for hospitals to satisfy Meaningful Use regulations have eased concerns about the legality of SyS and increased the number of hospitals reporting SyS data. Legal issues were perceived as barriers to BioSense 2.0 (the federal SyS program) participation, but were surmountable.

Conclusions—The current legal environment is perceived by health department and hospital officials as providing a firm basis for SyS practice. This is a shift from how law was perceived when SyS adoption began and has policy implications because it indicates that major legal reforms are not needed to promote more widespread use of the technology. Beyond SyS, our study suggests that federal monetary incentives can ameliorate legal concerns regarding novel health information technologies.

Keywords

Syndromic disease surveillance; public health law; policy; public health practice; health departments

The success of health information technologies is influenced by the legal environments in which they are implemented.^{1–5} Syndromic disease surveillance (SyS) is a relatively new approach to public health surveillance that depends heavily on health information technologies and has been adopted by many local and state health departments in the United States (US).⁶ In order to achieve rapid awareness of disease trends, SyS automates multiple steps in the surveillance process—from the collection of electronically-stored health data to the application of statistical algorithms to identify unusual patterns of disease occurrence.

SyS differs from traditional infectious disease surveillance, which emphasizes reporting of specific diseases confirmed by laboratory testing (a process that can take days to weeks), in four key respects.⁷ First, SyS monitors constellations of symptoms or provisional diagnoses, typically using information from emergency department (ED) encounters, to track various syndromes (e.g., “vomiting and diarrhea,” “febrile respiratory illness”).⁸ Second, SyS typically involves reporting of demographic and illness information for *all* individuals who receive care at participating hospitals to health departments, instead of reporting just those with certain conditions.^{8,9} Third, while traditional infectious disease reporting is predicated on state-level legal mandates that all cases of notifiable disease be reported, SyS systems have largely involved voluntary participation of hospitals. Fourth, traditional case-based surveillance systems include each patient’s name and contact information to enable further investigation. In contrast, SyS systems do not collect names or contact information and instead obtain descriptive demographic information—such as zip code, gender, and ED encounter date.

SyS was founded, and grew, on the presumption that rapid detection of increases in syndrome incidence could enable a more prompt identification of, and response to, outbreaks and bioterrorist attacks than traditional surveillance systems.^{10,11} Investments in

SyS increased dramatically after 2001 in response to concerns about bioterrorist attacks and the practice expanded rapidly during the 2000s, largely with support from post-9/11 federal preparedness funding.¹⁰ By 2007, 83% of US states and territories had implemented some form of SyS system.⁶ Absent bioterrorist attacks, SyS has demonstrated variable utility in detecting and monitoring outbreaks and in characterizing the health impacts of other events of public health importance.^{6,12,13} SyS is commonly used to complement other approaches to monitoring seasonal viral infections (e.g., influenza and gastroenteritis), non-infectious conditions (e.g., asthma, injuries), the health impacts of natural disasters, and inform policy and planning decisions.²

Building SyS Systems in an Uncertain Legal Environment

Despite increases in the number SyS systems being operated by health departments, evidence suggests that legal concerns have been substantive barriers to optimizing the utility of SyS and its broader adoption.^{14–18} In 2002 and 2003, two national conferences explored the status and future of SyS implementation.^{14,15} At both, uncertainties about the legal terrain surrounding SyS were identified. In 2004, in light of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule taking effect the prior year, the Association of State and Territorial Health Officials (ASTHO) convened a taskforce on HIPAA and SyS.¹⁶ The taskforce found that interpretation of HIPAA and the legal authority to conduct SyS varied dramatically, that hospitals often opted not to participate in SyS systems because of concerns about violating the Privacy Rule, and that the prospect of sharing SyS data between state/local health departments and the federal government posed many challenges. Also in 2004, a survey of health department and hospital officials found that 54% identified health information privacy concerns as barriers to SyS implementation and that 23% explicitly identified the HIPAA Privacy Rule as a concern.¹⁷

In 2007, in response to these legal concerns, an expert panel was convened by the International Society for Disease Surveillance to examine the legal basis for SyS implementation.¹⁸ The panel interpreted the HIPAA public health reporting exemption as a safeguard against concerns regarding the Privacy Rule, but acknowledged that many legal ambiguities about HIPAA existed and that “the current legal framework for syndromic surveillance does not provide clear guidance to public health practitioners.”¹⁸(p.4)

Federal Initiatives with Potential to Change the Legal Environment Surrounding SyS

Two recent federal initiatives have great potential to change the legal environment surrounding SyS: investments in electronic health records (EHRs) and redesign of the federal SyS program, BioSense. First, the Health Information Technology for Economic and Clinical Health (HITECH) Act provides substantial financial incentives for hospitals to adopt EHRs. Effective October 1, 2010, the magnitude of this incentive has ranged from \$2 million to \$6.4 million per hospital per year.¹⁹ As a condition for receiving these payments, however, hospitals must demonstrate “Meaningful Use” of EHRs.²⁰ Participation in a SyS system is one of the three options that hospitals can select to satisfy the Meaningful Use

Public Health Reporting requirement.^{20,21} This regulation, in effect, offers a monetary incentive for hospitals to send SyS data to health departments.

Second, in 2011, the CDC launched a redesign of BioSense, the federal SyS program. In contrast to the original version of BioSense, in which hospitals were recruited to send SyS data directly to the CDC, BioSense 2.0 (now referred to as the “BioSense Platform” under the new National Syndromic Surveillance Program)²² more actively engages health departments in the SyS reporting process. Under BioSense 2.0, health departments can opt to participate and share SyS data with CDC via ASTHO using an Internet-based cloud platform. To participate in BioSense 2.0, health departments enter into a data use agreement (DUA) with ASTHO, which manages the platform through a contract with Amazon Web Services. The DUA contains an indemnification clause that requires, to the extent permitted by applicable state law and practice, the health department to indemnify ASTHO in the event of a data breach.

This arrangement potentially creates a new level of legal complexity because of the use of a proprietary cloud-based information management service and a non-governmental intermediary organization (i.e., ASTHO). BioSense 2.0 also, however, offers a new monetary incentive for health departments. Through the CDC BioSense 2.0 Cooperative Agreement, about 25 awards have been issued to participating health departments annually, each averaging approximately \$250 000.²³ This funding opportunity comes at a time when health departments have otherwise experienced sustained cuts in preparedness funding.²⁴

Study Purpose

Within the context of these developments and the potential of SyS systems to capitalize on the widespread adoption of EHRs and enhance national health security, the objectives of the current study were to: 1) understand the current legal environment in which SyS is implemented, 2) determine the perceived legal basis for implementing SyS, and 3) identify perceived legal barriers and facilitators to SyS implementation.

METHODS

We used a multi-site case study design that combined focus groups, key informant interviews, and review of legal documents.^{25,26} We used this approach because it is well-suited for producing a holistic understanding of complex and unstudied legal issues.²⁷ The Drexel University IRB approved the study.

Case Study Site Section

In accordance with recommendations for multi-site case study research,^{25,26} we purposively selected seven case study jurisdictions that were known, *a priori*, to vary in SyS capacity and legal environment (Table 1). We selected jurisdictions at both state- and local-levels because SyS systems, and the laws that affect them, exist at both these levels. Case study jurisdictions were selected in consultation with the International Society for Disease Surveillance (ISDS), an organization that aims to advance SyS practice, and a project advisory group of SyS practitioners that serve in SyS leadership capacities and national and local levels.

Data Collection

First, we developed a preliminary interview guide in collaboration with ISDS and the advisory group. We then conducted two telephone-based focus groups with local/national SyS practice workgroups during which we solicited feedback on the interview guide and research questions. The focus group guide was developed in consultation with ISDS and the advisory group. After revising and piloting the interview guide, we conducted telephone-based interviews with three types of stakeholders in the seven case study jurisdictions: health department officials, health department legal counsel, and hospital officials. Respondents in each jurisdiction were identified through our advisory group and a snowballing strategy in which interview respondents identified other key informants within their jurisdiction. At the recommendation of key informants, we conducted additional interviews with national SyS experts.

As data collection neared saturation (i.e., when the interviews were not yielding new information),²⁸ we conducted three additional telephone-based focus groups with local/national SyS practice workgroups. During these focus groups, we presented our results and elicited feedback about the extent to which the findings resonated with participants' practice experiences. In total, we conducted 35 key informant interviews (many of which were group interviews with multiple respondents) and five focus groups. In total, we heard from 75 individuals. All focus groups and interviews were conducted in 2015–2016, audio recorded, and transcribed. On average, focus groups were approximately one hour in duration and interviews were 30 minutes.

In addition to focus group and interview data, we collected relevant legal documents (e.g., federal, state, and local statutes and regulations, DUAs). These documents were identified by interview respondents, the project advisory group, and scholarship on the legal aspects of SyS.^{14–18} Legal documents were not limited to those of the case study jurisdictions.

Data Analysis

Interview and focus group transcripts were imported into NVivo 10, a qualitative data management program, for analysis. First, three members of the project team read the transcripts, wrote memos about themes in the data, and inductively generated preliminary coding categories. The coders then met with the larger project team to discuss themes observed and develop a coding framework. Three coders then re-read and coded the transcripts, meeting regularly to discuss coding decisions and refine code definitions. Key themes were then identified through an iterative process using analytic techniques such as coding matrixes and quote tables.^{29,30} In accordance with recommendations by Creswell,²⁹ we used two strategies to ensure validity. First, we sought to identify divergent findings that were counter to emergent themes. We then used a member checking strategy in which we presented our results to the three local/national SyS practice workgroups and elicited feedback on the perceived validity of our findings. Legal documents were reviewed by a project team member with legal training to provide objective legal analysis documents identified by interview respondents.

RESULTS

We identified legal mechanisms that currently facilitate SyS implementation and found that federal monetary incentives influence how laws are interpreted (Figure 1). Three primary areas of findings emerged: the perceived legal basis for SyS, the impact of Meaningful Use regulations, and legal barriers to BioSense 2.0 participation.

Federal, State, Local Laws Provide A Firm Legal Basis for SyS

Most respondents saw no major legal barriers to conducting SyS. As stated by one hospital infection control specialist, “I don’t feel like there’s any illegality to it.” (Respondent 1.4) To the contrary, federal, state, and local laws were perceived as facilitating SyS implementation, although the specific legal mechanisms cited varied between jurisdictions. Four legal sources were repeatedly mentioned as providing support for SyS: 1) the exemption of the HIPAA Privacy Rule for reporting to public health agencies; 2) broad authority to conduct public health surveillance granted by state statutes; 3) modifications to existing laws and regulations to explicitly authorize SyS; and 4) statutory mandates for hospitals to provide SyS data to health departments (Table 2).

With regard to HIPAA, most respondents interpreted SyS as being covered under the Privacy Rule’s exemption for data reported by hospitals in response to a request from a public health authority. As described by one state health department official, “Since the very beginning, we didn’t hear any complaints at all [related to HIPAA].” (Respondent 1.2)

With regard to traditional notifiable disease surveillance authority as codified in state statutes or administrative rules, the majority of respondents perceived them as covering SyS. Although SyS is different from traditional reporting in that it entails sending data for all encounters rather than just for specified diseases, most respondents did not interpret this distinction as significant. As a health department lawyer stated: “[SyS] is different in that it’s not diagnosis-specific, but it’s still surveillance. It’s still the same concept and still the same purpose.” (Respondent 4.3)

With regard to amendments to existing disease reporting rules, two of the jurisdictions amended their rules to add ‘disease clusters’ to the list of notifiable diseases that are reportable to the health department. These changes were made to explicitly authorize SyS and ease hospitals’ legal concerns. As one respondent described, “Since we amended the communicable disease rule to include the collection of syndromic data, [hospitals] have not been too concerned with legal issues.” (Respondent 5.2) In another jurisdiction, a respondent described that a modification of the state health department’s poster of notifiable diseases to include mention of “any cluster of illness” was perceived as authorizing SyS.

Finally, in two jurisdictions, statutes were amended to mandate that hospitals send SyS data to the health department. These mandates were implemented at the request of hospitals to ameliorate legal concerns. As stated by one health department official, “[The hospitals] said, ‘you know what would really help is if you could pass a regulation.’” (Respondent 3.1) Health department officials perceived these mandates as being effective at increasing the number of hospitals reporting SyS data, however they were slow to take effect.

Meaningful Use Regulations Accelerate Hospital Reporting of SyS Data

Funding from the HITECH Act for Meaningful Use of EHRs was identified as a major facilitator of SyS implementation because it substantially increased the number of hospitals sending data to health departments (Table 3). Several respondents perceived the payments as hospitals' primary motivation to report SyS data. In the words of one health department official, to receive this funding, "[the hospitals] are ready to get their syndromic check box checked off." (Focus group participant 1)

Many respondents contrasted the pre-Meaningful Use environment, which was characterized by prolonged negotiations over the terms of DUAs and discussions about the legal basis for SyS, with the post-Meaningful Use environment, in which hospitals are eager to send SyS data and sign agreements with little hesitation. As one health department official stated, "They wouldn't have done it otherwise—they wanted the money." (National expert 1) The financial incentives for satisfying Meaningful Use regulations were also recognized as a major reason for hospitals to relax their legal concerns. As a health department official noted, "With Meaningful Use, the legal question has been really set aside." (Respondent 2.1)

However, the influence of Meaningful Use incentives raised concerns for several health department respondents. Because financial incentives were perceived as the primary motivator for hospital participation in SyS, some respondents feared that participation would decline after Meaningful Use incentives end. Some respondents expressed concern that Meaningful Use regulations lack a mechanism to ensure the quality of SyS data. Others feared that the outsourcing of SyS responsibilities to third-party vendors could weaken interpersonal relationships between health department and hospital personnel.

Legal Barriers to BioSense 2.0 Participation Exist, But Are Surmountable

A number of respondents perceived aspects of the DUA between the health department and ASTHO as impeding BioSense 2.0 participation (Table 4). As a respondent stated, "We'd really like to participate, and if we are able to come to an agreement regarding the DUA we will." (Respondent 2.1) Respondents in two jurisdictions believed that they were unable to sign the DUA, and thus participate in BioSense 2.0, because of the indemnification clause related to data breaches. Some respondents felt that the qualification for compliance with state law did not provide adequate assurance. As one state health department official explained, "The [state] Constitution forbids state agencies from entering into indemnification clauses." (Respondent 2.2)

Respondents also expressed concerns about lack of clarity in the DUA about access to SyS data. One health department official expressed concern about the role of Amazon, the vendor that houses the data. The department's legal counsel stated,

"The bigger issue from my perspective was who can see [the data]. They have these IT people at Amazon who have backdoor access to the whole system. We don't know who they are. That was the part that was uncomfortable." (Respondent 4.2)

Some respondents expressed apprehension more broadly about sharing SyS data with the federal government. Specifically, these respondents were concerned that data could be

accessed through Freedom of Information Act (FOIA) requests after they reached the federal-level.

Despite these concerns, most jurisdictions did participate in BioSense 2.0 and those that did not were in the final stages of negotiating the terms of the DUA. Two main themes emerged related to motivations for BioSense 2.0 participation: financial incentives and altruistic desires to protect public health. Several respondents stated that cuts in federal preparedness funding had strained their health department's epidemiologic capacity and that the CDC's BioSense 2.0 Cooperative Agreement awards enabled them to hire and retain key personnel. As with the Meaningful Use incentives, the magnitude of this financial benefit was sufficient to ameliorate legal concerns. As illustrated by a quote from an official in a state that was hesitant to participate in BioSense 2.0 because of legal concerns, "If we do get those monies, we will participate." (Respondent 6.3) In addition to the monetary benefits of BioSense 2.0 participation, respondents across jurisdictions articulated desires to share SyS data with the CDC for the good of public health. As one respondent noted, "I think it's less about what it does for us and more about what it does to inform the national picture of what's going on." (Respondent 2.1)

DISCUSSION

Law and policy are currently perceived as facilitators, more than barriers, to SyS implementation in the US. This represents a major shift from the early 2000s when the legal environment was perceived as presenting formidable challenges. Our study suggests that legal concerns related to SyS have eased over time and that federal monetary incentives have been powerful drivers of this change.

In particular, Meaningful Use incentives for EHRs have assuaged hospitals' legal concerns about SyS, thereby increasing the volume of SyS data being sent to health departments. Although evidence of the impact of Meaningful Use regulations on clinical practice is limited,^{31,32} our findings indicate that they have been effective in encouraging SyS implementation. The extent to which increases in the number of hospitals reporting SyS data translate into improved surveillance capacity, however, is not yet known and will likely be contingent upon the ability of health departments to receive, analyze, and make effective use of the data.³³ Federal funding through the Public Health Emergency Preparedness Cooperative Agreement substantially enhanced health departments' SyS capabilities post-9/11, but declines in this funding might threaten these gains.²⁴ Moreover, while regulatory and funding facilitators may be necessary, they are unlikely sufficient to realize the full potential of technological innovations that increase the amount of electronic health information at the disposal of health departments.

Some respondents appeared to have incomplete information about legal aspects of BioSense 2.0. One area where potentially unfounded concerns were identified was in relation to the prospect of BioSense 2.0 data being accessible to the public via FOIA requests. Although all federal agency records are potentially subject to FOIA requests³⁴ there are nine exemption categories that prohibit disclosure of certain types of records.³⁵ Most relevant to BioSense 2.0 is the exemption for information that is prohibited from disclosure by another law. Under

this exemption, personally identifiable SyS information reported to BioSense 2.0 could not be disclosed because it is protected under HIPAA.¹⁶ An exception under the FOIA for information involving matters of personal privacy, including health information, would also likely apply. Another area of possible misunderstanding involved the applicability of the indemnification clause in the ASTHO DUA. The DUA stipulates that the indemnification clause applies to the extent permitted by applicable state law and practice. Therefore, it would not conflict with state constitutional provisions that prohibit government agencies from entering into such arrangements. Training and education resources, such as those from ASTHO and ISDS, could help clarify the legal environment surrounding SyS implementation.

Implications for Policy & Practice

Federal and state laws are perceived as providing a firm legal basis for health departments to implement SyS systems. This has implications for policy and practice because it indicates that major legal reforms are not needed to promote more widespread use of SyS. The finding that Meaningful Use incentives have increased the amount of SyS data being sent to health departments highlights the potential of policies (e.g., budgetary decisions, grant opportunities) that enhance the capacity health departments to analyze SyS data. In jurisdictions where hospitals remain hesitant to report SyS data, despite Meaningful Use incentives, health department officials might consider working with elected officials to mandate that hospitals report SyS data. In two jurisdictions, we found that such mandates came about at the request of hospitals because they were perceived as providing a legal assurance.

Limitations

Our study has two main limitations. First, our results are not necessarily generalizable to all jurisdictions in the US. Although we conducted focus groups with SyS stakeholders from across the country, interviewed national experts, and consult with a national advisory group throughout the project, our study primarily focused on seven jurisdictions. Second, although we reviewed legal documents, we did not conduct a full legal analysis or a comprehensive mapping of laws relevant to SyS. This represents a priority area for future research.

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Figure 1. Legal Mechanisms and Monetary Incentives Facilitating the Implementation of Syndromic Surveillance Systems

Note. HIPAA = Health Insurance Portability and Accountability Act of 1996; SyS = syndromic surveillance; ASTHO = Association of State and Territorial Health Officials; CDC = Centers for Disease Control and Prevention; CMS = Centers for Medicare & Medicaid Services.

Table 1

Characteristics of Seven Case Study Sites

State with limited experience conducting SyS before electing to seek funding from, and participate in, BioSense 2.0
State with well-established SyS system that is participating BioSense 2.0
State that is not participating in BioSense 2.0, at least in part because of concerns about the terms of the data use agreement
State that has announced intention to accept SyS data from hospitals seeking to fulfill the population health requirements for Meaningful Use
State that mandates hospital participation in SyS
City
County

Table 2

Perceived Legal Basis to Conduct Syndromic Surveillance

Theme	Illustrative Quotes
HIPAA Privacy Rule	<p>“[The hospitals] knew that HIPAA allowed for them to provide personally identifiable information to state public health agencies and that they could do that voluntarily for surveillance purposes.” (Respondent 1.3)</p> <p>“[The hospitals] understand the laws and HIPAA, and the fact that public health generally is exempt from HIPAA when it’s dealing with a notifiable disease, or a [cluster of illness].” (Respondent 2.3)</p>
Broad state legal authority for public health surveillance	<p>“There’s enough flexibility in the state law that allows the public health officers to collect what they need to collect for the purposes of public health.” (Site G, 1)</p> <p>“From our perspective, the way that surveillance and public health practice legal authority exists in our state, it’s broad enough that we really didn’t face a whole lot of issues... Syndromic is covered in the interpretation.” (Respondent 2.5)</p> <p>“From a legal standpoint, in our state, the laws and the regulations around the gathering of the information by local health officers permits us to pretty much ask for anything we think has public health value.” (National expert 1)</p>
Modifications to existing laws and regulations to explicitly include syndromic surveillance	<p>“We’ve actually added some additional items to our state’s administrative code to explicitly allow us to do syndromic surveillance.” (Focus group participant)</p> <p>“We just restated it in the rule that any illness or condition or encounter information was authorized, even if it did not meet the definition of a reportable illness or condition. (Respondent 5.1)</p> <p>“So for our state, on our notifiable disease poster, under ‘Report Immediately,’ it lists ‘Any Clusters Illness.’ (Respondent 2.2)</p>
Mandates that require hospitals to report syndromic data to health departments	<p>“It was clear that the larger hospitals felt more comfortable in a mandatory system that mandated them to provide syndromic information to us.” (Respondent 1.3)</p> <p>“We got legislation passed to mandate hospitals to report... They wanted some legal coverage for providing us the data, so we got the legislation passed.” (Focus group participant)</p> <p>“It’s usually just the presence of that [mandatory reporting] law that seems to spur [hospital] people on.” (Respondent 3.3)</p> <p>“There was interest in speeding up the number of hospitals sending emergency department data to the system and [the hospitals] felt that by mandating it, it would happen faster... Hospitals don’t want to do something they’re not absolutely required to do even if it’s for the benefit of public health because they have so many pressures on them.” (Respondent 1.1)</p>

Table 3

Perceived Impacts of Meaningful Use Regulations on Syndromic Surveillance

Theme	Illustrative Quotes
Easing legal concerns of hospitals	<p>“With Meaningful Use, it’s different. Ever since we declared wanting [the data] for Meaningful Use, hospitals have been okay with whatever we want to do with it.” (Focus group participant)</p> <p>“Since Meaningful Use, we do not seem to be getting a lot of requests for DUAs.” (Respondent 2.1)</p> <p>“Because of Meaningful Use, we just say [to hospitals], ‘you know, thanks for participating in Meaningful Use. Here are the things that you need to do. You need to sign this DUA.’ And the vast majority [of hospitals] sign it without any hesitation.” (Respondent 6.3)</p>
Increasing the number of hospitals reporting and volume of syndromic data	<p>“I think it’s been very helpful in accelerating uptake and getting new [hospital] to sign on.” (Respondent 6.5)</p> <p>“Meaningful Use has been an enabler to encourage additional facilities to send their data... and improves the ability to conduct near real time surveillance.” (Respondent 1.1)</p> <p>“Meaningful Use seems to be the main motivator. That removes all the barriers and then we try to really inform [the hospitals] about public health.” (Respondent 6.3)</p> <p>“We have the opportunity to receive more comprehensive data, and we are certainly enrolling more providers at a speed with which we were not approaching prior to the onset of the Meaningful Use program.” (Respondent 2.1)</p>
Concerns/Challenges	<p>“We are concerned that as Meaningful Use funding wanes, so will the cooperation.” (Focus group participant)</p> <p>“We have seen persistent data quality issues that have not been resolved... And when I contact the hospital I say, ‘What are the plans for resolving this?’ They ask, ‘Does this affect our Meaningful Use status?’ And no, we don’t have the ability to change their status. So their next answer is ‘Oh we’ll just get to it when we get to it.’ There are no mechanisms to force change under Meaningful Use.” (Respondent 6.4)</p> <p>“We have a little bit more of a disconnect between the practitioners of infection control at the hospitals and our program... We had hands-on knowledge of who they were and what they did and the personnel involved... A lot of that has fallen by the wayside, and the disconnect has really been brought about by folks seeing this as a requirement that they need to meet their Meaningful Use attestation requirements, and not always circling around and making the handshake back with the programmatic folks.” (Respondent 2.1)</p>

Table 4

Perceived Legal Barriers and Facilitators to BioSense 2.0 Participation

Theme	Illustrative Quotes
Concerns about terms of ASTHO DUA	<p>“Obviously we had to delete the part where we agreed to indemnify [ASTHO], because we’re not allowed to do that. There was a sentence about how [the state] agrees to indemnify and hold harmless ASTHO against all claims. Legally we’re not allowed to do that, but they were fine with taking that out. I’m just surprised that any state could agree to that.” (Respondent 4.2)</p> <p>“It wasn’t clear the extent to which ASTHO was going to have access to identifiable data, so that was a little bit of an issue.” (Respondent 6.2)</p> <p>“Some of the language around who [ASTHO] would share the data with was a little bit too vague for us.” (Respondent 6.3)</p>
Concerns about sharing data with the federal government	<p>“But I think part of the reason why we’re reluctant to put anything identifiable, other than the fact that we don’t exactly know who has access to it, is the whole FOIA possibility.” (Respondent 4.2)</p> <p>“As far as the data flowing up to the federal level, I wish that federal agencies would be more open to the receipt of aggregate data... That would greatly, I think, ease the legal impediments because a lot of times a health department can share data in aggregate form without needing a DUA.” (Respondent 1.1)</p> <p>“That was a hell of a negotiation because the hospital attorneys rightfully understood that state law could not bide the federal agency because you’ve got a supremacy clause constitutional issue with state law abiding federal officials, but they were very concerned about giving all that data to CDC and then what would they do with it and how were we gonna be able to limit their use of proprietary information.” (Respondent 1.3)</p>
Factors that ease legal concerns	<p>“We didn’t have the funding to keep [our original syndromic] system going, so we were anxious to implement BioSense.” (Site E, 2)</p> <p>“You know at some point when you look across the country and you see hurricanes, tornadoes, blizzards, [the CDC] has a role to play and if it helps them do their job better, then that’s a good thing.” (Respondent 3.1)</p> <p>“Yeah, I think the reason [for BioSense participation] is altruism plus grant money.” (Respondent 3.3)</p>