Intractable? Identifying Consensus Policy Opportunities to Address Legal and Ethical Challenges in National Public Health Surveillance from State and Local Epidemiologist Leaders.

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Background

Nearly all US jurisdictions that conduct syndromic surveillance to monitor public health threats send their data to the National Syndromic Surveillance Program (NSSP), operated by the Centers for Disease Control and Prevention (CDC).[1] However, Data Use Agreements (DUAs) between the state/local and federal government do not permit federal access below HHS-region level (absent jurisdictional consent).[2,3] **Figure 1**. Consequently, a Syndrome X incidence increase in HHS Region 6 could reflect:

- An isolated incidence increase in LA
- Unrelated incidence increases in LA and NM
- A related incidence increase in LA in AR

Current CDC access permissions do not permit distinguishing these alternatives and limit CDC's capacity to provide support for interjurisdictional public health threats and responses. [1,4]

This limitation was a significant challenge for the national response to COVID-19 because federal agencies could not access available data to see how the pandemic was developing across state lines.[1,4] In 2021, a new version of the DUA was introduced to permit greater federal access, but this DUA has not been adopted widely.[3]

Methods

NSSP DUAs (2018, 2021) between state/local governments and CDC NSSP were analyzed to: 1) determine whether DUA provisions are consistent with 2017 World Health Organization's (WHO) ethical guidance;[5] and 2) to determine the extent that legal provisions address (fully, partially, or omitted) policy opportunities identified by state and local epidemiologist leaders in a 2021 study.[4]

Figure 1: Routine federal access to state and local NSSP data is limited to HHS-region level data

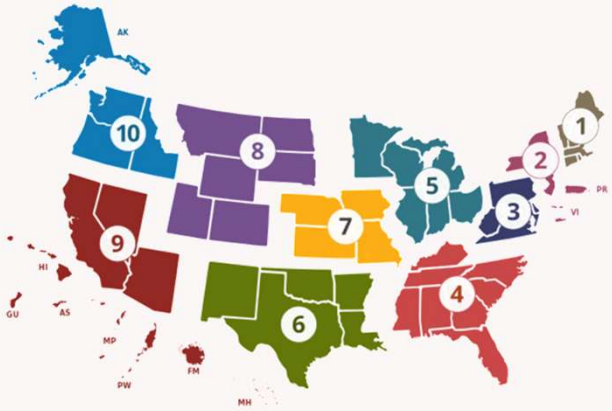

Table 1: Comparison of NSSP DUA terms (2018, 2021) with select WHO Ethical Guidelines for Public Health Surveillance.[5]

Select WHO Ethical Guidelines for Public Health Surveillance	2018 DUA	2021 DUA
G2. Obligation to develop mechanisms to ensure ethical surveillance	✓	✓
G4. Obligation to ensure that the data collected are of sufficient quality	✓	✓
G6. Obligation to support governments that lack adequate surveillance resources	✓	✓
G8. Obligation to identify, evaluate, minimize and disclose risks for harm	✓	✓
G10. Obligation to ensure that identifiable data are appropriately secured	✓	✓
G13. Obligation to effectively communicate surveillance results to relevant audiences	?	?
G14. Obligation to share data with other public health agencies	✗	✓
G15. Obligation to timely share data in a public health emergency	✗	✓
G16. Public health agencies may use or share surveillance data for research purposes	✓	✓
G17. Surveillance data should not be shared with agencies that are likely to use them to take action against individuals or for uses unrelated to public health.	—	—

✓ : at least one DUA term that is **compatible** with the WHO Ethical guideline
✗ : at least one DUA term that is **incompatible** with the WHO Ethical guideline
? : compliance with WHO Ethical guideline up to state or local DUA signees
— : WHO guideline not addressed in DUA

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Results

The NSSP DUAs are in apparent conflict with the two WHO ethical recommendations for sharing public health surveillance data between public health agencies. **Table 1**. The absence of a restriction on sharing data with agencies likely to take action against individuals (WHO Guideline 17) is also notable given the recent Supreme Court decision in *Dobbs v. Jackson*.[6] Nonetheless, the NSSP DUAs contain many terms that establish important prerequisites for ethical public health surveillance.

Notably, NSSP DUAs at least partially address all but three of the policy opportunities identified by state and local epidemiologist leaders (i.e., audit process, access restriction standards, breach responsibility). **Table 2**.

Discussion/Conclusion

Imminent public health data modernization efforts require careful examination of existing legal and ethical challenges in public health surveillance.[1,4] Critically, these findings suggest that these challenges are not intractable. In fact, federal, state, and local partners may be closer to agreement than they might realize. Moreover, several consensus policy opportunities (i.e., data analysis collaborations and developing communication protocols) provide a promising path forward.[1,4]

Relationships are critical to data sharing.[1] Unfortunately, the relationships between state, local, and federal partners were strained when NSSP data was accessed by the White House COVID-19 task force in early 2020 without following DUA terms.[4] Consequently, reaching an agreement may be more difficult after the pandemic response than before.[1] Regardless, policy changes are required to bring US public health surveillance within WHO ethical guidelines.

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Citations

1. C.D Schmit, B. Willis, E. Teel, D. Washburn, (2022). *Draft Report - Review of Federal Access Policies for State National Syndromic Surveillance Program Data: Findings and Recommendations*.
2. CDC, *National Syndromic Surveillance Program Data Sharing and Use Agreement*. (2018).
3. CDC, *National Syndromic Surveillance Program Data Sharing and Use Agreement* . (2021).
4. C.D. Schmit, B. Willis, H. McCall, A. Altabbaa, D. Washburn, (2022). *Views on Increased Federal Access to State and Local National Syndromic Surveillance Program Data: A Nominal Group Technique Study with State and Local Epidemiologists*, (under review).
5. World Health Organization. (2017). *WHO Guidelines on Ethical Issues in Public Health Surveillance*. http://apps.who.int/iris/bitstream/10665/255721/1/9789241512657-eng.pdf
6. *Dobbs v. Jackson Women's Health Organization* (2022)

Table 2: Comparison of policy opportunities generated by state and local epidemiologists and NSSP DUA terms (2018, 2021).[2,3,4]

Identified Rule, Restrictions, Guidelines or Codes	Mean importance Likert score*	Aggregate rank score **	CDC DUA-Ver 2.0 Mar. 20, 2018	CDC DUA-Ver 3.0 Feb. 23, 2021
Involving state and local partners in data analysis	4.93	22	◒	◒
Create communication protocols between CDC and STLTs	4.53	17	◒	◒
Make DUA applicable to all federal recipients of NSSP data	4.53	8	◒	◒
Restrict data access for specific purposes or events	3.73	8	●	●
Audit and documentation process for data access and analysis	4.33	7	○	○
Create standards for removing access	4.07	7	○	○
Restrict data access to specific users (i.e., not groups)	3.53	6	◒	●
Allow optional participation in greater federal access	4.00	5	●	●
Establish restrictions on data publication	4.13	5	◒	◒
Include procedure for DUA renewal	4.07	2	◒	●
Require training on code of conduct	3.67	2	◒	◒
Clarify breach responsibility	4.07	1	○	○

*Likert scores were scored 1-5 with Very Important = 5, Important = 4, Moderately Important = 3, Slightly Important = 2, Not important = 1
**For the rank score, items ranked 1, 2, and 3 were assigned scores of 3, 2, and 1 respectively. The aggregate rank score is the sum of all respondents' ranking scores.
●: DUA terms fully address issue; ◒: DUA terms partially address issue; ○: DUA does not address issue.