Intergovernmental Data Exchange
Lessons from COVID-19

Charles Curran
10.26.23

This presentation discusses general developments and is not intended to provide legal advice.
Please consult with qualified counsel to address specific legal compliance and regulatory requirements.

Immunization Information Sharing Prior to COVID-19

- Pre-COVID-19 federalism landscape for Immunization Information Systems (IIS)
  - State operated registries, but with significant federal government funding and guidance on programmatic policy
  - State law governs IIS data inputs (reporting mandates, opt in/out), along with inter-jurisdictional sharing
- Federal public health focus on functional standards
  - Population data reporting for national-level analysis
  - STLT inter-jurisdictional exchange by IIS promoted (IZ Gateway)

Paradigm Shift for IIS Data Sharing in the COVID-19 Public Health Emergency

- Operation Warp Speed operational plan for distribution of federally-funded vaccines implemented centralized collection of vaccine administration data
  - Individually identifiable recipient information collected for purposes of second dose monitoring/support, safety assessment and “whole of government” response
  - IIS reporting to support newly-created federal databases storing both fully identifiable and limited data sets
- CDC emergency vaccine administration data sharing agreement (Fall 2020)
  - Successful vaccine development compressed time scale for state IISs to evaluate new DUA
  - Similar time limitations for operational implementation of IIS reporting, including application of privacy-preserving technologies

Issues Arising From the Emergency DUA for IIS COVID-19 Reporting

- Concerns over federal reporting of individually identifiable information from IIS
  - Resolving potential conflicts with state law requirements
- Questions about secondary use of data by federal agencies
  - Particular focus on potential immigration enforcement uses of data related to the undocumented
- Questions about governing de-identification standards
  - Affecting both individual and aggregate demographic data

Principal Challenges Addressed Pragmatically, but Some Issues Remain

- Pragmatic approaches resolve obstacles to transfer
  - Beyond the terms of the DUA, interpretative guidance and public policy statements addressed immigration enforcement data use
  - Amendments to the IIS reporting DUA or other operational modifications to data element reporting

- Post-COVID-19 confidence-building for future federal uses of IIS data
  - Some federal legislators have questioned whether federal access to individual vaccination status data makes possible its use for enforcement of mandates
  - New York has adopted legislation governing sharing of state IIS information with federal public health (NY S.6541A, Dec. 2022)

Some Key Common DUA Elements For Intergovernmental Exchange

- Scope of purposes for individual data access/use
  - Primary purposes & underlying authority (public health, research, e.g.)
  - Parameters of expanded public health emergency access & additional permitted purposes
- Approach to data de-identification
  - Standards for partial or full de-identification (whether prescriptive or expert-based)
  - Support for implementing technologies (privacy-preserving record linkage, e.g.)
- Limits on secondary data access/use
  - Inter-governmental transfers & law enforcement access
  - Public access rights, or uses ancillary to public health (AI training data, e.g.)
- Data rights - ownership; any consent issues affecting inputs
- Cybersecurity
- Governance

CDC Focus on Streamlining DUAs in Data Modernization Initiative

- CDC 2023 Public Health Data Strategy (April 2023)
- Newly-established Data Policy & Standards Division within the Office of Public Health Data, Surveillance, and Technology (OPHDST)
- Beyond harmonization of data definitions to further interoperability, a parallel focus on standardized data use agreements with STLT partners
  - Standard language for data protection and use of Core Data Sources
  - New syndromic data sharing agreement to enhance ER data sharing across STLT and CDC programs

Will DUA Streamlining be Affected by New Congressional Requirements?

- Congress has considered enhanced federal data authorities to promote more efficient sharing during emergencies and reduce delays in DUA negotiation
- Improving DATA in Public Health Act (S. 3913)
  - Would generally empower CDC to "*require the reporting of public health and health care data*" by health care providers, public health, STLTs, HIEs and HINs
  - CDC to prescribe the "*content, form, manner and frequency of the reporting . . . including necessary demographic data or other data elements that the Secretary determines is necessary for public health surveillance. . . .* "

Cooperative Data Federalism in Public Health Exchange – Status Quo

- Expanded data authorities in the Improving DATA Act were not included in the PREVENT Pandemics Act incorporated in the 2022 omnibus appropriations Act
- Omnibus reflects continued cooperative federalism (§§ 2211, 2213, e.g.)
  - Funding to promote voluntary standards adoption for public health data improvement
  - Continuity in allocation of data authorities between federal and STLT public health
  - Emphasis on privacy and de-identification in data exchange with federal government
- Congress' current approach continues to allow for flexible approaches to streamline inter-governmental DUAs and to pre-position for future epidemics

Looking Ahead: Simplified Data Exchange Frameworks, Supported by Increasingly Granular Technologies to Enforce Data Access Rights

- State/regional HIEs provide important points for integration for public health
- Platforms for national data exchange with standardized terms
  - Trusted Exchange Framework simplifies requirements for access for public health purpose
  - Interjurisdictional exchange via platforms with "flow down" requirements for downstream participants
- Emerging technologies can help reinforce DUA requirements
  - FHIR-enabled exchange (either individual level or bulk access) supports more fine-tuned access to data resources for public health
  - Deployment of privacy enhancing technologies (privacy-protecting record linkage, federated learning, e.g.)

Trends in General Privacy Legislation: Implications for Public Health Access and Use

Charles Curran
10.26.23

Federal Privacy Law – Still Waiting for a Harmonized Approach

- Prior approach of category-specific privacy laws and remedies
- A patchwork of sectoral laws adapted over decades
  - Health – HIPAA-regulated entities (not fully preemptive)
  - Other industry sectors or subject matters (GLBA, FERPA, GINA e.g.)
- Contrasts with European Union's comprehensive framework protecting both governmental and private sector data (GDPR)
  - Common definitions and obligations for sensitive & health data
- In response to the explosion in online data collection, Congress now focused on more broad regulation of commercial data use

General Federal Privacy Legislation Has Yet to Reach The Finish Line

- The American Data Privacy & Protection Act (ADPPA) advanced through committee in 2022 but failed to receive full Congressional vote
- Key features draw on European data protection law
  - Consumer rights of transparency, access, control & deletion
  - Obligations to minimize & reasonably limit data collection, use and transfer
  - Consent requirements for sensitive data collection or transfer (health, biometric, genetic, race/ethnicity, minors & precise geolocation)
- But not comprehensive: exempts currently regulated sectors (HIPAA, e.g.)
- Congress remains unable to resolve scope of pre-emption of state laws or whether to establish private rights of action to enforce violations

ADPPA – Collateral public health implications (if revived)

- Focus on private sector, exempts government agencies and their agents
- HIPAA-regulated entities exempt, but only to the extent they remain in compliance with privacy & security obligations
- But a narrow view of scope of public health data collection and use
  - Unlike research, public health not an explicitly permissible purpose
- Data transfers of sensitive data (health, race/ethnicity, e.g.) by non-government entities require affirmative express consent
  - Important implications for novel public health data sources
- No preemption of potentially stricter laws for state health privacy or governing public health activities

Filling the Vacuum: The State Privacy Law Tsunami

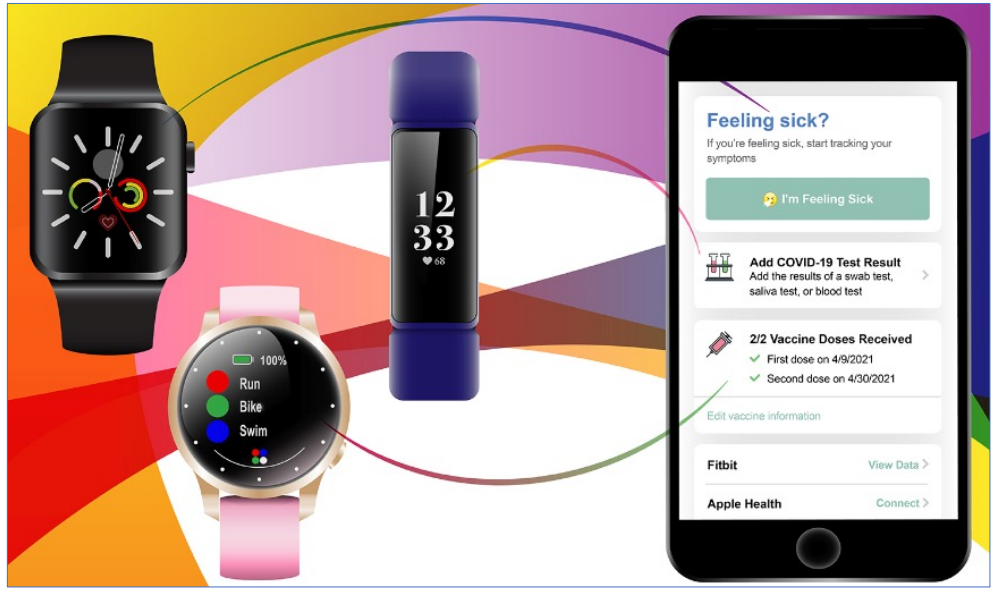
- California was a first mover in 2018, but state general consumer privacy law adoption is accelerating in the absence of Congressional action
  - Five states by end of 2022 and eight more states this year
  - In 2023, two states have adopted health-specific privacy laws (WA/NV)
- Consumer privacy principles similar to ADPPA, varying state-by-state
  - Rights of transparency, access and control; proportionality or minimization
  - Broad definitions of sensitive data (like ADPPA)
  - Emphasis on non-HIPAA health data (consumer apps, e.g.) & reproductive health data post-Dobbs (precise geolocation, e.g.)
  - In some states, enhanced remedies included private rights of action
- The new state laws generally exempt government agencies and HIPAA-regulated entities, as well as non-profits (with a few exceptions)
- Also generally exempt public health data use (although exemption scope varies)

State (effective date)	Law	Sensitive Personal Data Definitions (including Health)	Sensitive Data Use Permission	HIPAA Entities or Data Exempt?	Non-profits Exempt?	Scope of Public Health Exception
Virginia (Jan 1, 2023)	Virginia Consumer Data Protection Act	Reveals mental/physical health diagnosis; race/ethnicity; precise geolocation & genetic/biometric data	Consumer consent required for sensitive data processing	Covered entities & HIPAA PHI	Yes	Info used only for public health activities/purposes authorized by HIPAA
California (July 1, 2023)	California Consumer Privacy Act (as amended)	Information concerning health; race/ethnicity; precise geolocation & genetic/biometric data	Rights to limit use and disclosure of sensitive data (w/rulemaking)	Covered entities & HIPAA medical info (also medical info regulated by CA law)	Yes	Reidentification permitted for HIPAA §512 public health purposes; research studies in public interest
Colorado (July 1, 2023)	Colorado Privacy Act (+ implementing regulations)	Reveals mental or physical condition or diagnosis; race/ethnicity; & genetic/biometric data	Consumer consent	PHI processed by covered entities	No, when data held for 100K+ consumers	For public interest in public health, with safeguards and professional oversight
Connecticut (July 1, 2023)	Connecticut Personal Data Privacy Act (as amended)	Reveals mental or physical condition diagnosis; race/ethnicity; precise geolocation & genetic/biometric data	Consumer consent	Covered entities & HIPAA medical info	Yes	For public health activities per HIPAA; community & population health; & public interest (with safeguards)
Utah (Dec 31, 2023)	Utah Consumer Privacy Act	Reveals mental/physical condition, diagnosis & treatment; race/ethnicity; specific geolocation & genetic/biometric data	Notice & consumer opt out	Data collected by licensed health care providers; HIPAA PHI	Yes	Information used only for public health activities and purposes under HIPAA
Florida (July 1, 2024)	Florida Digital Bill of Rights	Reveals mental or physical health diagnosis; race/ethnicity; precise geolocation & genetic/biometric data	Consumer consent	Covered entities & HIPAA PHI	Yes	Information used only for public health activities and purposes authorized by HIPAA
Oregon (July 1, 2024)	Oregon Consumer Privacy Act	Reveals mental or physical condition/diagnosis; race/ethnicity; precise geolocation & genetic/biometric data	Consumer consent	Covered entities & HIPAA PII	No	Information used only for public health activities and purposes described by HIPAA
Texas (July 1, 2024)	Texas Data Privacy & Security Act	Reveals mental/physical diagnosis; race/ethnicity; precise geolocation & genetic/biometric data	Consumer consent	Covered entities & HIPAA PHI	Yes	Information used only for public health activities & purposes authorized by HIPAA

State (effective date)	**Law**	**Sensitive Personal Data Definitions (including Health)**	**Sensitive Data Use Permission**	**HIPAA Entities or Data Exempt?**	**Non-profits Exempt?**	**Scope of Public Health Exception**
Montana (Oct 1, 2024)	Montana Consumer Data Privacy Act	Reveals mental/physical condition; race/ethnicity; precise geolocation & genetic/biometric data	Consumer consent	Covered entities & HIPAA PHI	Yes	For public health activities per HIPAA; community & population health; & public interest (with safeguards)
Delaware (Jan 1, 2025)	Delaware Personal Data Privacy Act	Reveals mental or physical condition/diagnosis; race/ethnicity; precise geolocation & genetic/biometric data	Consumer consent	HIPAA PHI	No	For public health, community/population health authorized by HIPAA, & where provided by covered entity
Iowa (Jan 1, 2025)	Consumer Data Protection Act	Includes mental or physical condition/ diagnosis; race/ethnicity; precise geolocation & genetic/biometric data	Notice & consumer opt out	HIPAA PHI	No, when data held for 100K+ consumers	Information used only for public health activities and purposes authorized by HIPAA
Tennessee (July 1, 2025)	Tennessee Information Protection Act	Includes mental or physical condition/diagnosis; race/ethnicity; precise geolocation & genetic/biometric data	Consumer consent	Covered entities & HIPAA PHI	Yes	Information used only for public health activities and purposes authorized by HIPAA
Indiana (Jan 1, 2026)	Consumer Data Protection Act	Reveals mental or physical health diagnosis; race/ethnicity; precise geolocation & genetic/biometric data	Consumer consent	Covered entities & HIPAA PHI	Yes	Information used only for public health activities and purposes as authorized by HIPAA
Washington (Mar 31, 2024)	Washington My Health, My Data Act	Linked or linkable info identifying past, present & future mental/physical health status, including reproductive, genetic & biometric data; precise geolocation info	Consent for consumer health data use & sharing	Covered entities & HIPAA PHI	No	Information used only for public health activities and purposes described by HIPAA; limited data sets
Nevada (Mar 31, 2024)	Nevada Consumer Health Privacy Law	Linked or linkable info identifying past, present & future mental/physical health status, including reproductive, genetic & biometric data; precise geolocation information	Consent for consumer health data use & sharing	Covered entities	No	Information used only for public health activities and purposes described by HIPAA, regardless of whether info subject to HIPAA

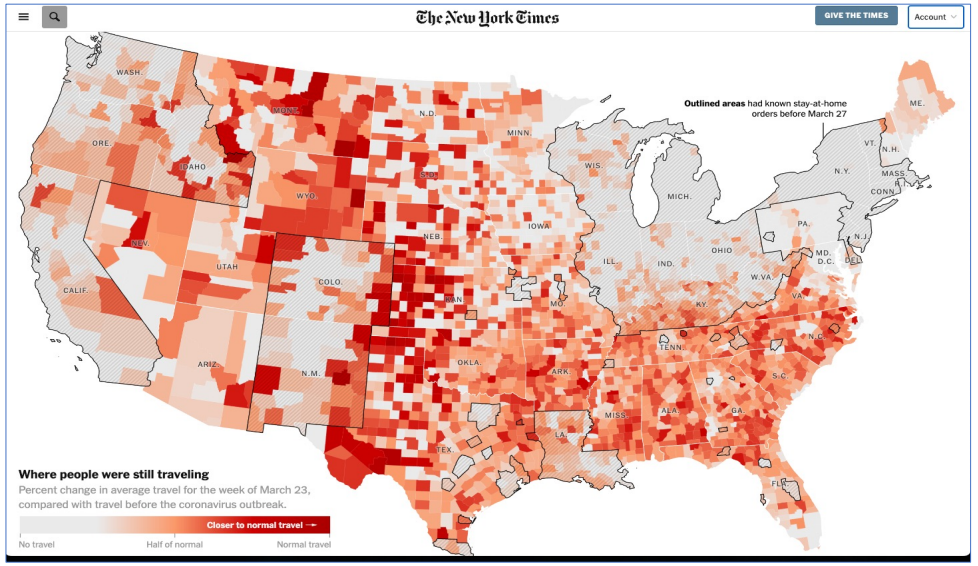
Public Health Implications of New State Laws – Good News (Mostly)

- New laws generally leave intact traditional public health data reporting
  - HIPAA-regulated entities can still transfer PHI as required or permitted by law, without express consent requirements
  - PHI similarly exempted in all states (except Nevada)
  - For non-HIPAA entities, public health exemptions also apply
  - Exemptions for health research also provide comfort
- Likely effects on non-traditional public health data originating in a commercial context, and that now require consumer consent for transfer
  - Supplemental demographic/environmental data; identity resolution data
  - Novel online data (search, social, Internet of Things, geolocation)
  - Wearables & health apps



- Wearables, clinical data and COVID-19
- Scripps Research DETECT project

COVID-19 Symptom Tracker (ZOE, Massachusetts General Hospital *et al.*)



App & Wifi-derived data: "Where America Didn't Stay Home Even as the Virus Spread"

Public Health Implications of New State Laws – Effects in Corner Cases

- For non-exempt data falling outside public health exception, affirmative consent for collection or transfer (health info, race/ethnicity or children's data)
- Variations in de-identification standards (different than HIPAA framework)
- Private rights of action like WA's can create potential deterrent effects to private sector data sharing (outside HIPAA context)
- Additional emerging AI regulation (e.g. VA/CO opt outs for automated processing that results in "*legal or similarly significant effects*"; CA disclosure requirements for automated data "*inferences*")

Preserving and Enhancing Public Health Data Access

- PHA analysis of state law for transfers and DUAs should be expanded to include potential applicability of new comprehensive privacy laws
    - Prior analysis useful for data sources for future emergencies
- State legislation wave continues (particularly for protection of minors)
- Public health can educate policymakers preemptively on appropriate exemptions that preserve public health use
- Against a backdrop of changing public expectations for data transparency and control, opportunities for trust building through public education about health and equitable benefits arising from STLT/federal data collection and use, and heightened awareness of rigorous privacy controls

Questions? charlescurranconsulting@gmail.com

Intergovernmental Public Health Data Exchange

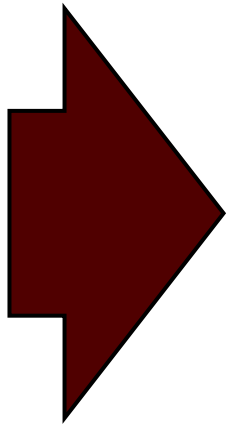
Cason Schmit, JD
Assistant Professor
Program in Health Law and Policy, Director
Department Health Policy & Management
Texas A&M University School of Public Health

TEXAS A&M UNIVERSITY

Data Sharing & Traditional Federalism

- Federalism → division of power between different governmental levels
- Data are power

- Data sharing can be viewed as a marketplace for governmental power
  - **Data are non-rivalrous**
    - Data shared are not lost
  - **Data as a complementary good**
    - More data are more valuable



Data sharing is an amplification of power

Fahey, B. A. (2022). Data Federalism. Harvard Law Review, 135(4), 1007. https://harvardlawreview.org/2022/02/data-federalism/

Governance of “the Intergovernmental Data Market”

- “Congress has largely declined to structure and regulate” intergovernmental data exchange

- Increases the importance of data use agreements (DUAs), memoranda of understanding (MOUs), contracts, and other agreements
  - “a kind of domestic treaty between the federal government and states or cities.”

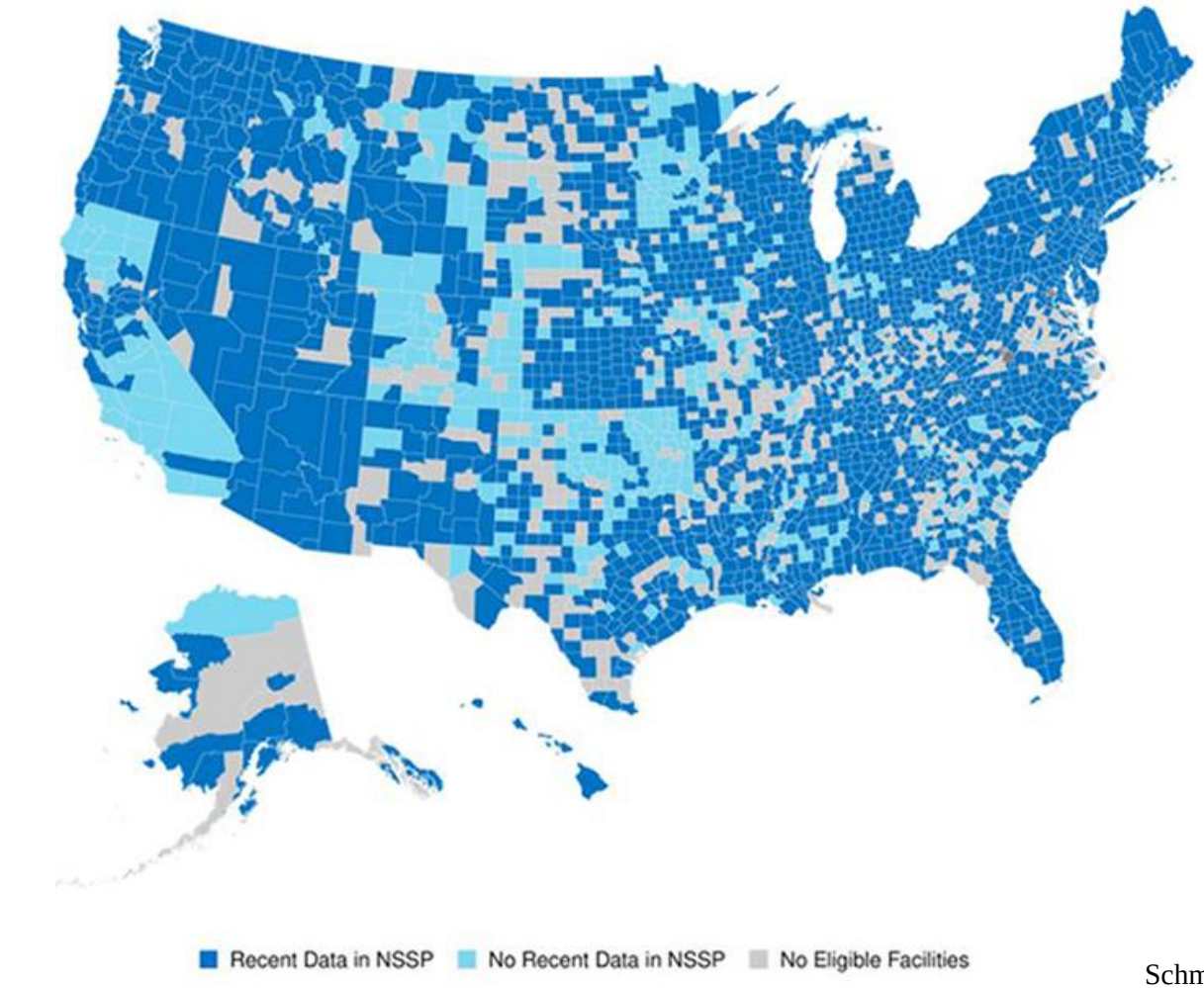
Fahey, B. A. (2022). Data Federalism. Harvard Law Review, 135(4), 1007. https://harvardlawreview.org/2022/02/data-federalism/

Focus: Syndromic Surveillance (SyS)

- Impelled by the 9/11 terrorist attacks (anthrax), SyS was funded/implemented as an early detection tool
- Advantages:
  - Near-real time situational awareness,
  - Supporting tool to help explain
- Use cases:
  - Health care needs after major disasters
  - Characterize extent of drug-related overdoses
  - Monitor for early signs of outbreaks
  - Respond to foodborne outbreaks

https://www.cdc.gov/nssp/images/nsspinfo/Final_NSSP-Infographic.pdf

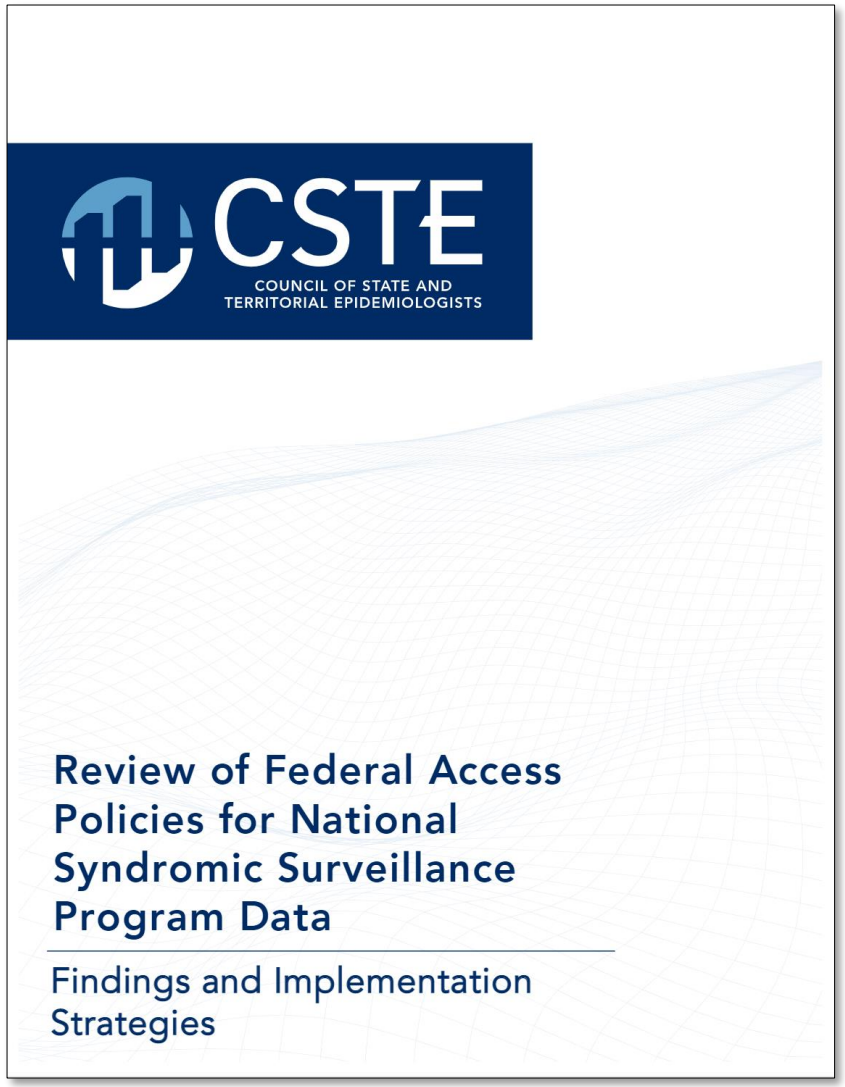
Syndromic Surveillance



https://www.cdc.gov/nssp/participation-coverage-map.htm
https://www.cdc.gov/nssp/images/nsspinfo/Final_NSSP-Infographic.pdf

Schmit, C. D., Willis, B., McCall, H., Altabbaa, A., & Washburn, D. (2023). Views on increased federal access to state and local National Syndromic Surveillance Program data: a nominal group technique study with state and local epidemiologists. *BMC Public Health*, *23*(1), 431.

Syndromic Surveillance DUAs



Schmit, C., Willis, B., Teel, E., & Washburn, D. (2023). "Review of Federal Access Policies for State National Syndromic Surveillance Program Data: Findings and Implementation Strategies." Council of State and Territorial Epidemiologists. https://hdl.handle.net/1969.1/197493

Schmit, C. D., Willis, B., McCall, H., Altabbaa, A., & Washburn, D. (2023). Views on increased federal access to state and local National Syndromic Surveillance Program data: a nominal group technique study with state and local epidemiologists. *BMC Public Health*, *23*(1), 431. https://doi.org/10.1186/s12889-023-15161-5

Schmit, C. D., Willis B, & Teel E. (2022). Intractable? Identifying Consensus Policy Opportunities to Address Legal and Ethical Challenges in National Public Health Surveillance from State and Local Epidemiologist Leaders. *APHA 2022 Annual Meeting and Expo*. https://oaktrust.library.tamu.edu/handle/1969.1/196995

Data Collection Activities

- Environmental Scan
- Workgroup of State & Local Epidemiologists Leaders (x2)
  - Nominal Group Technique
- Key Informant Interviews
  - Thematic analysis
- Survey on Policy Approaches

Analysis of SyS Data Access Policies

- SyS DUAs
  - 2018 DUA (restrictive)
  - 2021 DUA (more permissive, not widely adopted)
- SyS DUA Analysis
  - Are the DUAs compatible with WHO ethical guidelines?
  - Do the DUAs address desired protections/guardrails for greater access?

Alignment with Public Health Ethics

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

Alignment with Desired Policy Guardrails

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.

Federalism: federal, state & local relationships

- Absent a federal statutory framework, trust and relationships remain among the most important factors to data sharing between public health partners
  - Trust and relationships were strained during COVID-19
    - "It is important that any rules/policies/guidelines are emergency proof, so they don't just get thrown out the window in the event of an emergency."
    - "I think the NSSP program itself … has been an amazing steward of the data, but the system around it has become less trustworthy"

Schmit, C., Willis, B., Teel, E., & Washburn, D. (2023). "Review of Federal Access Policies for State National Syndromic Surveillance Program Data: Findings and Implementation Strategies." Council of State and Territorial Epidemiologists

Questions?

schmit@tamu.edu

TEXAS A&M UNIVERSITY

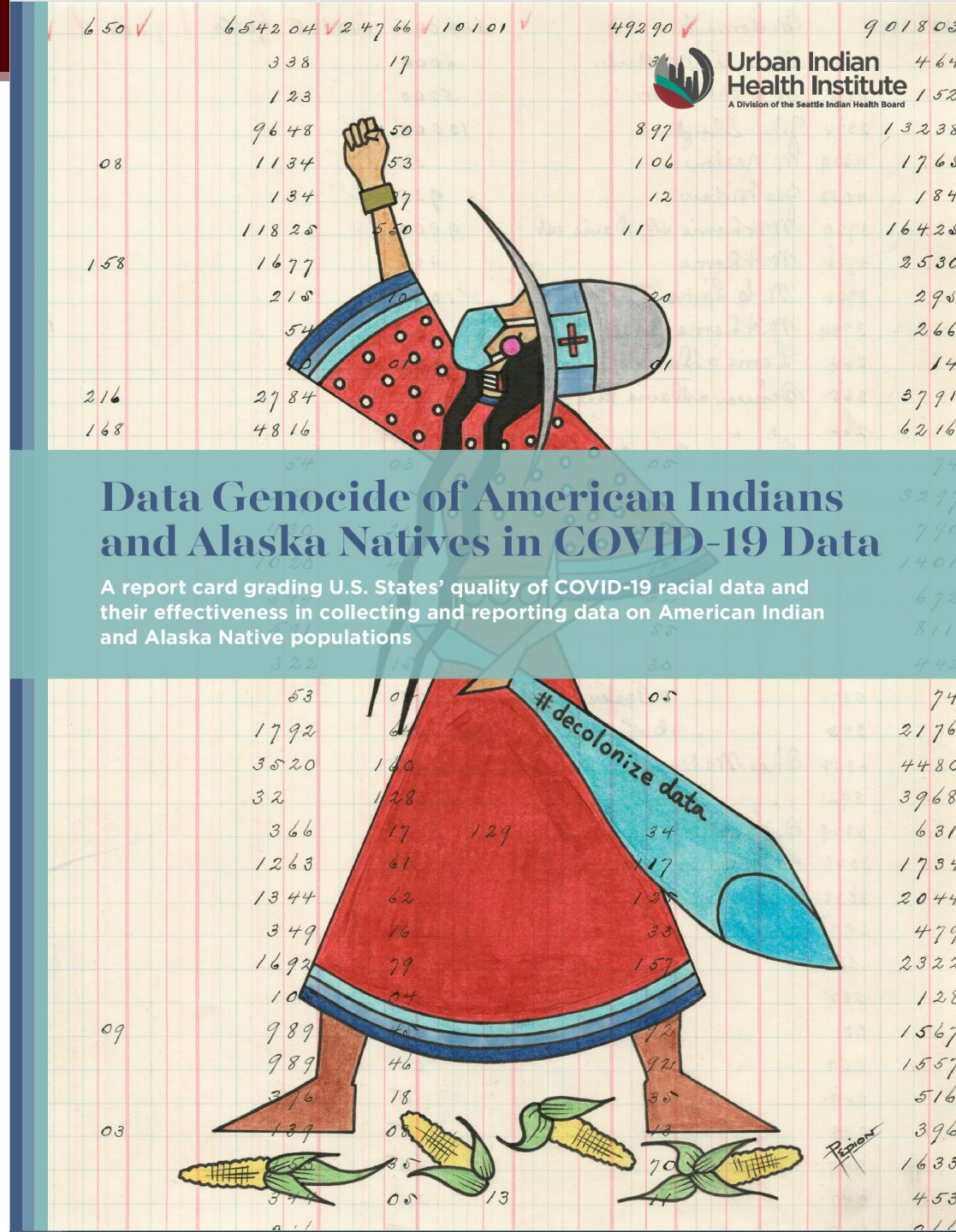
Data Federalism Concerns

- Fehey's focus on law enforcement data uses:
  - **Purpose**: Collecting data to prosecute individuals
  - **Concern**: Liberal data sharing infringing civil liberties.

- Contrast with public health data uses:
  - **Purpose**: Collecting data to help individuals and their communities
  - **Concern**: Insufficient data inhibits public health efforts

Ex: Insufficient Data Sharing with Tribes

- Inadequate data sharing from federal/state governments and their Tribal public health partners severely restricts their public health capacity

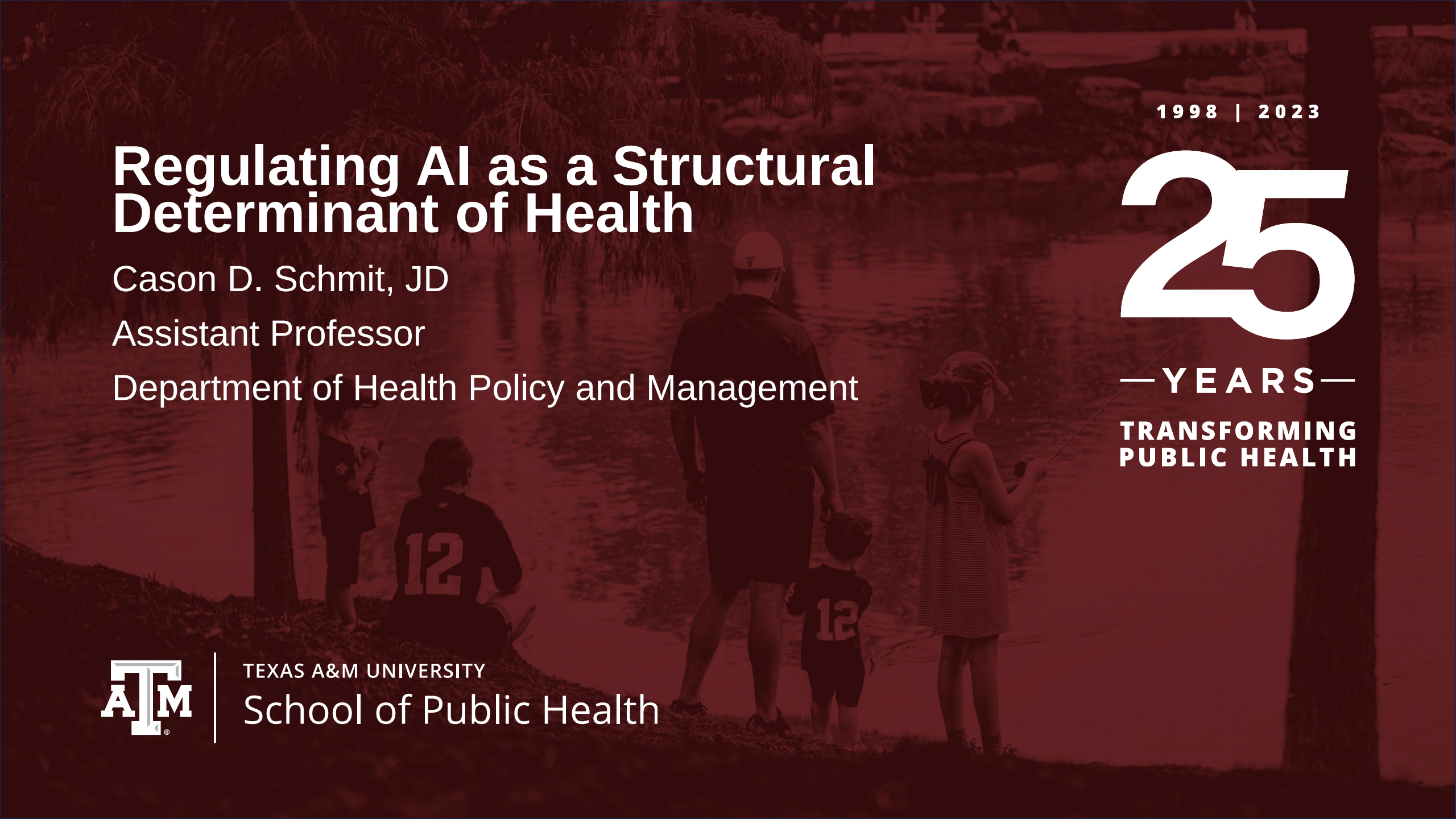


Reconciling These Different Concerns

- 2017 WHO Guidelines on Ethical issues in Public Health Surveillance
  - **Guideline 14.** With appropriate safeguards and justification, those responsible for public health surveillance have an *obligation to share* data with other national and international public health agencies.
  - **Guideline 17.** Personally identifiable 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.

The Bottom Line

- DUAs are critical to the governance of data flowing between US public health agencies.
- DUA provisions have massive impact on the capacity of federal, tribal, state, local, and territorial health departments



1998 | 2023

25 YEARS

TRANSFORMING PUBLIC HEALTH

Regulating AI as a Structural Determinant of Health

Cason D. Schmit, JD

Assistant Professor

Department of Health Policy and Management

TEXAS A&M UNIVERSITY

School of Public Health

Roadmap

25 YEARS | TRANSFORMING PUBLIC HEALTH | 1998 | 2023

- What is artificial intelligence (AI)?
- Why should public health professionals care about AI governance?
- What are the different approaches to AI governance?
- How can public health experts improve the public health relevance of existing AI governance efforts?

What is Artificial Intelligence (AI)

25 YEARS | TRANSFORMING PUBLIC HEALTH 1998 | 2023

- AI system is*
  - “an engineered or machine-based system that can, for a given set of **human-defined objectives**, generate outputs such as **predictions, recommendations, or decisions** influencing real or virtual environments. AI systems are designed to operate with varying levels of autonomy (Adapted from: OECD Recommendation on AI:2019; ISO/IEC 22989:2022).”

***No universally recognized definition of AI**

NIST AI Risk Management Framework: Second Draft August 18, 2022

AI: a Structural Determinant of Health

- AI will affect virtually all facets of everyday life. It can:
  - Identify social media content likely to prolong engagement
    - (and add to alarming mental health challenges and despair among youth).
  - Identify consumers likely to successfully repay bank loans
    - (and exacerbate disparities in wealth and homeownership).
  - Aid employers in identifying productive job candidates
    - (and systematically discriminate against minority applicants).
  - Automate many tasks that require substantial human effort
    - (and eliminate employment opportunities).
  - Create new sharable content and media
    - (incl. deepfake videos designed to deceive individuals and communities).
  - Predicting where crimes might occur and who might commit them
    - (and exacerbate existing biases and inequities reflected in existing data).

AI plays a significant role in controlling economic, political, or social determinant of health.

AI: a Structural Determinant of Health

25 YEARS | TRANSFORMING PUBLIC HEALTH 1998 | 2023

- AI will affect virtually all facets of everyday life. It can:
  - Identify social media content likely to prolong engagement
    - (and **FIX** alarming mental health challenges and despair among youth).
  - Identify consumers likely to successfully repay bank loans
    - (and **FIX** disparities in wealth and homeownership).
  - Aid employers in identifying productive job candidates
    - (and **NOT** discriminate against minority applicants).
  - Automate many tasks that require substantial human effort
    - (and **FIX** employment opportunities).
  - Create new sharable content and media
    Flag deepfake videos designed to deceive individuals and communities).
  - Predicting where crimes might occur and who might commit them
    - (and **reduce** existing biases and inequities reflected in existing data).

AI plays a significant role in controlling economic, political, or social determinant of health.

AI: a Public Health Tool

25 YEARS | TRANSFORMING PUBLIC HEALTH 1998 | 2023

- Potential Public Health Applications
  - Support surveillance
  - Precision public health
  - Learning Health Systems
  - Optimize resource allocation
- Of course, public health information infrastructure has a long way to go before it can capitalize on AI's promise

Challenges Regulating AI

- Creating a legal definition for AI
  - The “AI Effect” – where past “AI” applications are no longer considered “AI” once commonplace.
- Pacing problem
  - Technological development *FAR* outpaces regulators’ ability to update statutes or regulations
    - EX: “The faster cycles of innovation and the speed of change for medical device software would benefit from a new regulatory approach.” U.S. Food & Drug Administration (FDA) (2022)
  - How do we know how to maximize benefits or minimize risks when we do not know what the benefits and risks of future AI applications are?
- Expertise

Hard v. Soft Laws

- Two broad approaches for AI governance
  - Traditional or “Hard” Laws
    - Statutes and Regulations
      - These are the bread and butter of public health law
  - Soft Laws
    - Voluntary rules or standards that are created to guide practices within an industry or sector
      - Less common in public health law

Pros and Cons with Hard and Soft Law Governance of Emerging Technology

- Traditional (Hard) Laws
  - Pros
    - Enforcement
  - Cons
    - Insufficient expertise
    - Inflexible, blunt
    - Slow to adapt
- Soft Laws
  - Pros
    - Available Expertise
    - Flexibility
    - Quick to adapt
  - Cons
    - Enforcement

A Third Way?

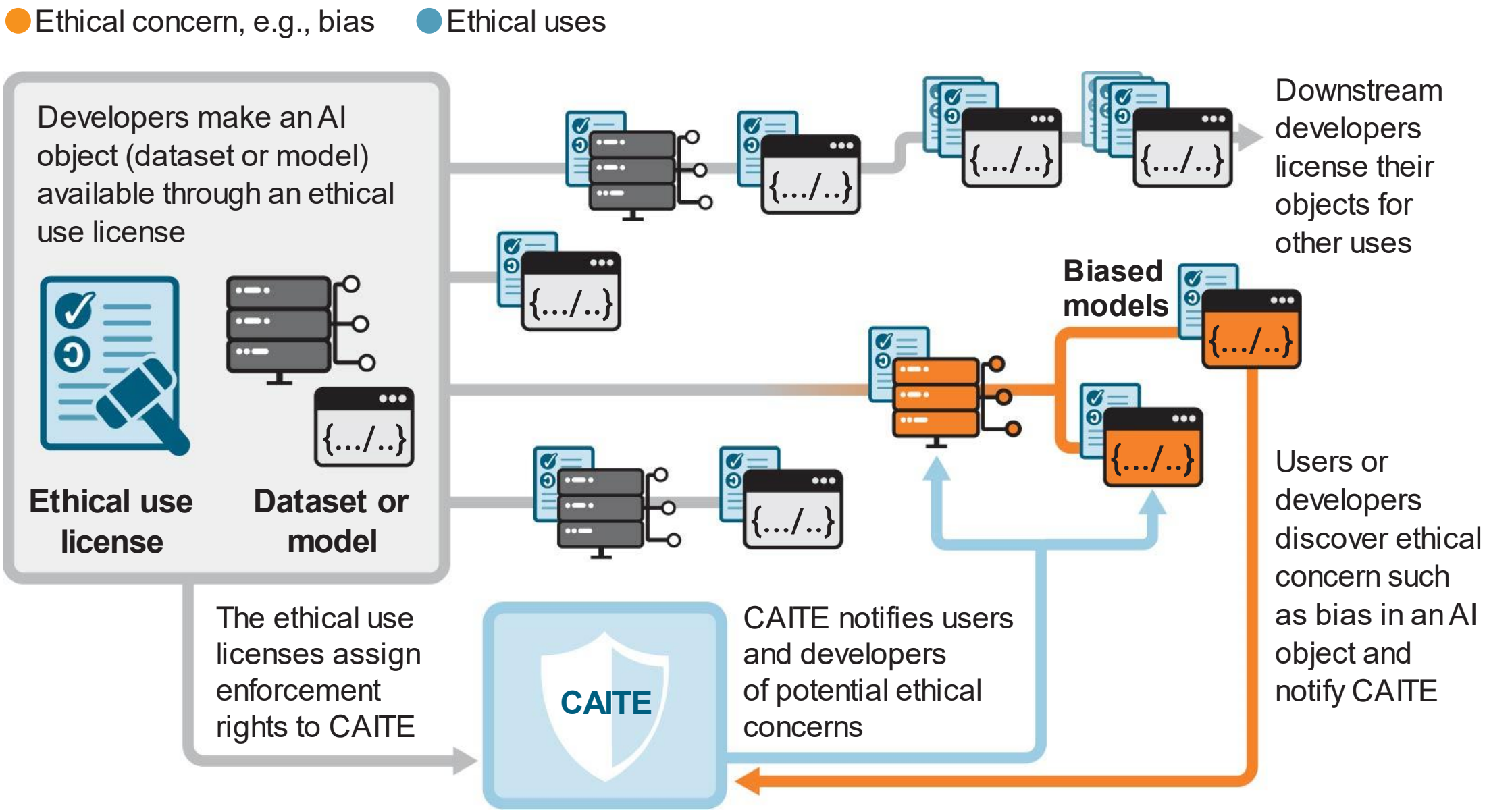
- Collaborative Governance
  - Governments incorporating soft law standards and guidance into a hard law regulatory framework.
  - With collaborative governance, government regulators have added hard law carrots and sticks to soft law standards.

Example: Collaborative Governance

- **The Joint Commission (TJC)—**both state and federal regulators incorporate TJC accreditation status for a variety of functions.
    - Texas exempts TJC-accredited hospitals from annual inspections,
    - The federal Medicare statute permits CMS to deem certain accredited healthcare facilities as compliant with Medicare certification requirements.

Policy Innovations

- Quasi-governmental AI regulator
  - CD Schmit, MJ Doerr, JK Wagner. "Leveraging IP for AI Governance." Science. 2023; 379(6633): 646-648. DOI: 10.1126/science.add2202.


Ethical concern, e.g., bias
Ethical uses
Developers make an AI object (dataset or model) available through an ethical use license
Ethical use license
Dataset or model
Downstream developers license their objects for other uses
Biased models
Users or developers discover ethical concern such as bias in an AI object and notify CAITE
The ethical use licenses assign enforcement rights to CAITE
CAITE
CAITE notifies users and developers of potential ethical concerns

Benefits of Our Approach

- Traditional (Hard) Laws
  - Pros
    - Enforcement
- Soft Laws
  - Pros
    - Available Expertise
    - Flexibility
    - Quick to adapt

Current AI Governance Efforts

- International
  - European Union AI Act (under deliberation; HARD*)
    - Risk-based framework
      - Rules are more stringent for more risky AI applications
  - China
    - “Global AI Governance Initiative”
      - “healthy, orderly and safe” development of AI
  - United Nations
    - High-Level Advisory Body on Artificial Intelligence
    - UN Tech Envoy is convening a Multistakeholder Advisory Body on AI to explore Global AI Governance Frameworks (SOFT without enforceable treaty).

https://www.europarl.europa.eu/news/en/headlines/society/20230601STO93804/eu-ai-act-first-regulation-on-artificial-intelligence
https://www.scmp.com/news/china/diplomacy/article/3238360/belt-and-road-forum-china-launches-ai-framework-urging-equal-rights-and-opportunities-all-nations
https://www.un.org/techenvoy/ai-advisory-body

Current AI Governance Efforts

- United States (federal)
  - NIST AI Risk Management Framework (SOFT)
  - White House Blueprint for an AI Bill of Rights (SOFT)
  - Biden-Harris Admin. “Secures Voluntary [AI] Commitments” 7/21/2023 (SOFT)
  - FDA Marketing Submission Recommendations for a Predetermined Change Control Plan for AI/ML-Enabled Device Software Functions (Draft guidance; SOFTISH)
  - (Bill) American Data Privacy and Protection Act, 117th Congress (2021-2022) (Not under active consideration; HARD)

Current AI Governance Efforts

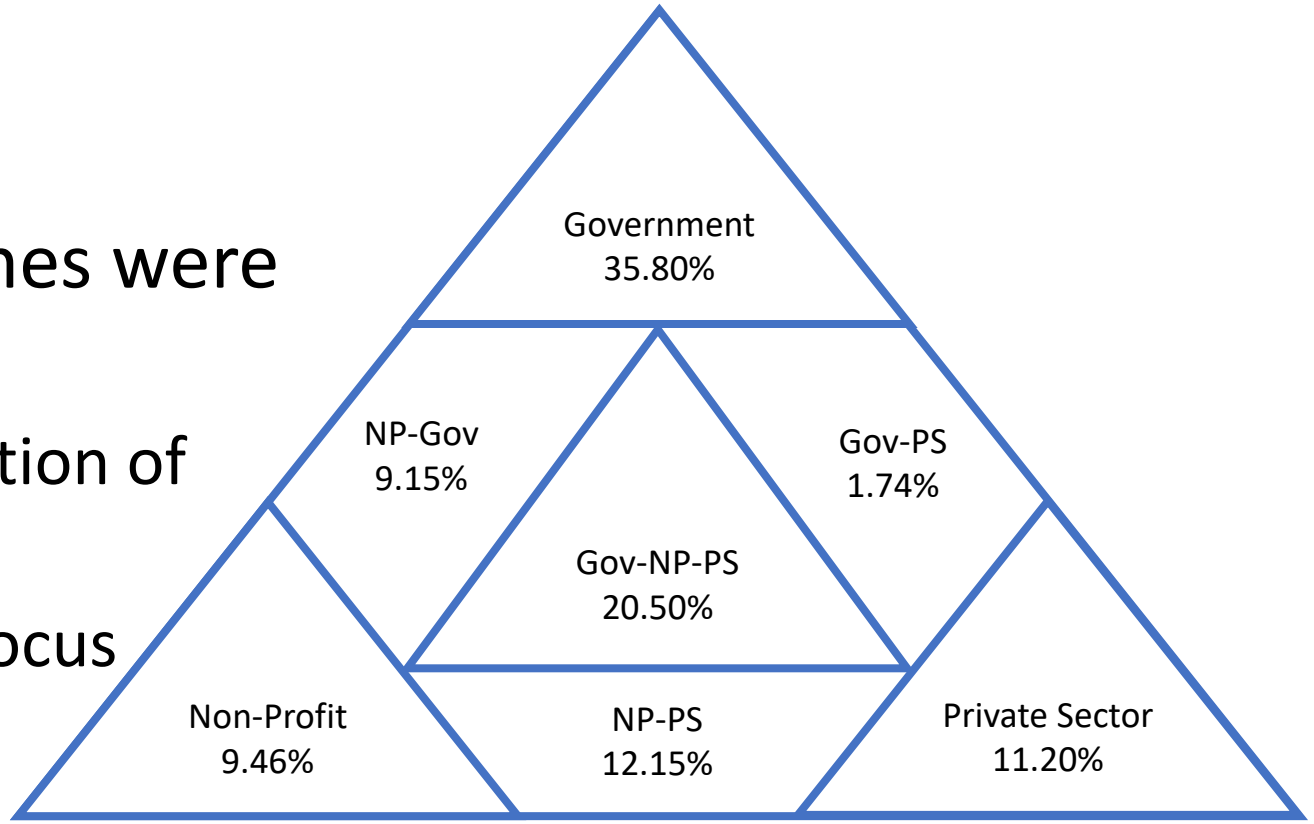
25 YEARS | TRANSFORMING PUBLIC HEALTH 1998 | 2023

- United States (Enacted state laws)
  - No general AI legislation
  - Categories of AI legislation
    - AI as part of data protection/privacy laws
      - CA, CO, CT, DE, IN, MT, OR, TN, TX, UT, VA
    - Specific AI applications (e.g., hiring, advertising, profiling)
      - CO, CT, DE, GA, IL, MT, NY, OR, TN, TX, UT, VA
    - AI committee, task force, resolutions
      - AL, CT, HI, IN, TX
    - AI is not a person
      - ND

https://epic.org/the-state-of-state-ai-laws-2023/
https://www.federalregister.gov/documents/2022/08/22/2022-17752/trade-regulation-rule-on-commercial-surveillance-and-data-security

Current AI Governance Efforts

- Soft Law
  - Gutierrez and Marchant (2021) systematic review of 638 soft law frameworks.
  - 5 out of 78 identified themes were health related
    - Present in only a small fraction of identified frameworks
    - **None** had a public health focus



How Can PH Perspectives Improve AI Governance?

- Social determinants of Health
- Harm Reduction
- Public Health Ethical Principles
  - Common Good Benefits
  - Equity
- One Health
- Health in All Policies

Social Determinants of Health

25 YEARS | TRANSFORMING PUBLIC HEALTH 1998 | 2023

- **AI Governance Challenge**: Assessing the risks of harm from bias, discrimination, inequity, and civil liberty infringements from AI applications.

- Recognizing the impact of social, environmental, and political factors on the health of communities radically reframes the AI risk assessment calculations.
- Useful to understand that the risks of certain AI harms (e.g., race-based discrimination, inequity) have adverse impacts that extend to the health and wellbeing of entire communities and populations.
  - Existing scientific knowledge of social determinants of health is essential to operationalize fairness in AI

Harm Reduction

- **AI Governance Challenge**: Unavoidable risks

- Harm reduction could be an important guiding principle for AI soft law standards for risks that are difficult to eliminate.
- For example: enforcement discretion or regulatory "safe harbor" for developers that adhere to current "soft law" standards for responsible AI development.
  - Scalable standards from garage developers to global corporations.
  - Provides flexibility to innovate while enabling protections from the greatest risks.

Public Health Ethics

25 YEARS | TRANSFORMING PUBLIC HEALTH 1998 | 2023

- **AI Governance Challenge**: Protections that Balance Population-Scale Harms & Benefits

- Traditional information technology regulatory approaches (e.g., notice and consent for privacy protection) are likely to be highly deficient to protect against AI harms
- Public health has developed an ethical framework for addressing activities that have population-level effects

One Health

- **AI Governance Challenge**: AI Disrupting System Dynamics

- One Health represents the idea that humans are intimately connected to—and their health is intrinsically intertwined with—that of non-human animals, plants, and the environment.

- Deliberately approaching AI through use of a One Health lens could enable a meaningful recognition of an international human right to health by enabling integrated, transformative policy interventions to impel responsible AI across diverse sectors of society (and diverse data ecosystems) and better address complex health threats.

Health In All Policies

- **AI Governance Challenge**: Addressing AI as a Determinant of Health

- Health in All Policies is a collaborative approach that factors public health considerations in policy development and decision making. The Health in All Policies approach—which "identifies the ways in which decisions in multiple sectors affect health, and how better health can support the achievement of goals from multiple sectors"—is highly relevant for AI policy development that primarily exists outside health sectors.28 As is, the population health impact of AI appears to be largely absent from the 638 soft law AI frameworks analyzed by Gutierrez and Marchant.25

Final Thoughts

25 YEARS | TRANSFORMING PUBLIC HEALTH 1998 | 2023

- AI governance is a pressing public health issue
- Public health perspectives are essential to ensure that AI social benefits are maximized and risks are minimized
- AI governance developed without public health participation could impede public health AI applications and deny governments the legal tools to manage a structural determinant of health.

"Public Health Informatics Depends On Engagement With Privacy Legislation", Health Affairs Forefront, October 28, 2022. DOI: 10.1377/forefront.20221027.571505

Acknowledgements

- Megan Doerr, SageBionetworks
- Jennifer Wagner, Penn State University