

Patchwork Privacy: How US Laws Put the Brakes on Data Science

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FEARLESS ON EVERY FRONT

Presentation Overview

- Outline
 - Ethical context for using existing data for public health purposes
 - [2017 WHO Guidelines on Ethical Issues in Public Health Surveillance](#)
 - Overview of federal privacy laws
 - Implications for leveraging existing data for public health purposes
 - International model (GDPR)
- Objectives:
 - Compare federal data protection laws across sectors.
 - Analyze how different federal data protection laws facilitate or impede the use of cross-sector data for public health purposes.

Resources to Navigate Federal Data Protection Laws

- 22 Snapshots of different federal laws protecting data
- Annotated list of resources and guidance
- Coming Soon: Interactive online database of legal data sharing resources

https://www.networkforphl.org/topics_resources/topics_resources/health_information_and_data_sharing/federal_privacy_laws/?blm_aid=21653

The Network for Public Health Law
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FEDERAL HEALTH Snapshot

HIPAA Privacy Rule

FEDERAL LAW: Health Insurance Portability and Accountability Act of 1996
Citation: 42 U.S.C. § 1324d, et seq.; 45 C.F.R. § 160.001, et seq.

THE LAW

What does the law do?
The HIPAA Privacy Rule protects the confidentiality of individuals' medical records and other personal health information.

EDUCATION Snapshot

Individuals with Disabilities Education Act (IDEA)

FEDERAL LAW: Individuals with Disabilities Education Act
Citation: 20 U.S.C. § 1400, et seq.

THE LAW

What does the law do?
IDEA provides the legal framework for ensuring that children with disabilities age 3-6 have access to a free appropriate public education.

EDUCATION Snapshot

Head Start Program

FEDERAL LAW: New Head Start Program Performance Standards
Citation: 42 U.S.C. § 9801, et seq.; 45 C.F.R. § 1303 Subpart C

THE LAW

What does the law do?
The Head Start program promotes school readiness for children, under five years old, from low-income families through education, health, social and other services. The program is administered by the U.S. Department of Health and Human Services.

Abbreviations

- 42 C.F.R. Part 2 - Substance Abuse and Mental Health Services Administration Confidentiality Provisions
- CIPSEA - Confidential Information Protection and Statistical Efficiency Act of 2002
- FERPA - Family Educational Rights and Privacy Act
- HIPAA - Health Insurance Portability and Accountability Act
- HHS - Department of Health and Human Services
- IDEA - Individuals with Disabilities Education Act
- NSLP - National School Lunch Program
- SBP - School Breakfast Program
- SMP - Special Milk Program for Children
- Title X - Population Research and Voluntary Family Planning Programs
- WIC - Women, Infants, and Children Supplemental Nutrition Program
- SNAP - Supplemental Nutrition Assistance Program
- VA - US Department of Veterans Affairs

WHO guidelines on ethical issues in public health surveillance

Ethical Foundations for Public Health Data Use

A Public Health Ethics Lens

Ethical Data Use for Public Health

- **Guideline 1. Countries have an obligation to develop appropriate, feasible, sustainable public health surveillance systems.** Surveillance systems should have a clear purpose and a plan for data collection, analysis, use and dissemination based on relevant public health priorities.

Obligation to conduct public health surveillance

WHO guidelines on ethical issues in public health surveillance

Ethical Data Use for Public Health

WHO guidelines on ethical issues in public health surveillance

- Guideline 11. Under certain circumstances, **the collection of names or identifiable data is justified.**

Justification for collecting Identifiable data

- Guideline 12. Individuals have an obligation to contribute to surveillance when reliable, valid, complete data sets are required and relevant protection is in place. **Under these circumstances, informed consent is not ethically required.**

Informed consent is not always ethically required

Ethical Data Use for Public Health

- 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.

↑
Obligation to share data with public health

- Guideline 16. With appropriate justification and safeguards, **public health agencies may use or share surveillance data for research purposes.**

↑
Use data for research purposes

WHO guidelines on ethical issues in public health surveillance

Federal Data Protection Laws and Cross Sector Data Sharing

- Federal agencies collect and use data for a variety of programs and initiatives across sectors.
- This data has significant potential to inform public health activities.

Legal Variation

- Unfortunately, there are different federal data protection frameworks depending on
 - Person or entity
 - Nature of the data
 - Why it was originally collected
 - Intended use or purpose

(A few) Federal Data Protection Laws

Federal Legal Framework	Citations	Sector	Focus
42 C.F.R. Part 2	42 U.S.C. § 290dd- 2, 42 C.F.R. Part 2	Health Care	Mental/Behavioral Health
Child and Adult Care Food Program	42 U.S.C. § 1758(b)(6); 7 C.F.R. §§ 226.2, 226.23	Social Service	Nutrition Programs
CIPSEA	44 U.S.C. § 3501 Note Sec. 501, et al.	Population data	Statistical Data
Confidentiality of Certain VA Medical Records	38 U.S.C. 7332; 38 C.F.R. §§ 1.460-1.499	Veterans	Health Care
VA Medical Quality Assurance Records	38 U.S.C. § 5705; 38 C.F.R. §§ 17.500-17.511	Veterans	Quality Assurance
FERPA	20 U.S.C. § 1232g; 34 C.F.R. Part 99	Education	Student Records
Head Start	42 U.S.C. § 9801, et seq.; 45 C.F.R. § 1303 Subpart C	Education	School Readiness
HHS Privacy Act Regulations	5 U.S.C. § 552a; 45 C.F.R. Part 5b	Federal Health Plans	Health Care
Higher Education Act	20 U.S.C. § 1092b; 34 C.F.R. Part 5b	Education	Student Loans
HIPAA	42 U.S.C. § 1320d et al., 45 C.F.R. Parts 160 and 164	Health Care	Services and Payment
Homeless Management Information Systems	42 U.S.C. § 11360a; 24 C.F.R. §§ 578.7, 578.57, 578.103	Social Service	Homelessness
IDEA, Part B	20 U.S.C. § 1400; 34 C.F.R. Part 300	Education	Disability Programs
IDEA, Part C	20 U.S.C. § 1400; 34 C.F.R. Part 303	Education	Early Intervention Services
Medicaid Information Safeguards	42 U.S.C. § 1396a(a)(7); 42 C.F.R. Part 431, Subpart F	Federal Health Plans	Participant Information
NSLP and SBP	42 U.S.C. § 1758(b)(6); 7 C.F.R. §§ 245.2, 245.6	Social Service	Nutrition Programs
Protection of Pupil Rights Amendment	20 U.S.C. § 1232h; 34 C.F.R. Part 98.	Education	Data Collection
SNAP	7 U.S.C. Ch. 51; 7 C.F.R. § 272.1	Social Service	Nutrition Programs
Special Milk Program	42 U.S.C. § 1758(b)(6); 7 C.F.R. §§ 215.2, 215.13a, 245.6	Social Service	Nutrition Programs
Summer Food Service Program	42 U.S.C. § 1758(b)(6); 7 C.F.R. §§ 225.2, 225.15	Social Service	Nutrition Programs
Title X	42 U.S.C. Ch. 6A, Subch. VIII; 42 C.F.R Part 59, Subpart A	Social Service	Family Planning
VA Claims Confidentiality Statute	38 U.S.C. § 5701; 38 C.F.R. §§ 1.500-1.527	Veterans	Claims
WIC Confidentiality Provisions	7 U.S.C. § 2018; 7 C.F.R. § 246.26	Social Service	Nutrition Programs

How is identifiable information defined?

Federal Legal Framework	Not Defined	Unspecified information about individuals	Direct Identifiers	Indirect Identifiers	Deduction/ Inference	De-identification Standards
42 C.F.R. Part 2			X		X	Yes
Child and Adult Care Food Program		X				Aggregate or summary data
CIPSEA			X	X	X	No
Confidentiality of Certain VA Medical Records			X		X	No ^{1,3}
VA Medical Quality Assurance Records			X ¹	X ¹		No
FERPA			X	X	X	Yes
Head Start		X	X			No
HHS Privacy Act Regulations			X			No
Higher Education Act	X					No
HIPAA		X			X	Yes
HMIS		X	X	X		No ³
IDEA, Part B			X		X	No
IDEA, Part C			X	X	X	No ³
Medicaid Information Safeguards			X ²			No
NSLP and SBP		X				Aggregate or summary data
Protection of Pupil Rights Amendment		X	X			No
SNAP	X					No
Special Milk Program		X				Aggregate or summary data
Summer Food Service Program		X				Aggregate or summary data
Title X		X				Aggregate or summary data
VA Claims Confidentiality Statute	X ¹					No ^{1,3}
WIC Confidentiality Provisions		X				No

¹ VA guidance applies the HIPAA identifiability standards

² States have flexibility to determine what information is protected.

³ Federal de-identification guidance exists.

Identifiability Defined by Deduction or Inference

- FERPA
 - “information that, **alone or in combination, is linked or linkable** to a specific student that **would allow a reasonable person in the school community**, who does not have personal knowledge of the relevant circumstances, to identify the student with **reasonable certainty**.”
- 42 CFR Part 2
 - “information by which the identity of a patient... **can be determined with reasonable accuracy** either directly or by reference to other information.”
- HIPAA
 - “a **reasonable basis** to believe the information **can be used to identify** the individual.”
- CIPSEA
 - “**permits** the identity of an individual to whom the information applies to be **reasonably inferred** by either direct or indirect means.”

The Problem with Inference or “Reasonable Person” Identifiability

- Actually very difficult to apply
- Safe harbor de-identification standards (e.g., HIPAA) are low risk and easy to use



Federal Legal Framework	Data Use Exceptions	
	Public Health	Research
42 C.F.R. Part 2	No	No
Child and Adult Care Food Program	No	No
CIPSEA	No	Yes
Confidentiality of certain (VA) medical records	Yes	Yes
VA Medical Quality Assurance Records	Yes	Yes
FERPA	No	Yes ¹
Head Start	No	Yes
HHS Privacy Act Regulations	No	Yes ²
Higher Education Act	No	Yes ³
HIPAA	Yes	Yes
Homeless Management Information Systems	No	Yes
IDEA, Part B	No	Yes ¹
IDEA, Part C	No	Yes ¹
Medicaid Information Safeguards	No	No
NSLP and SBP	No	No
Protection of Pupil Rights Amendment	No	No
SNAP	No	No
Special Milk Program	No	No
Summer Food Service Program	No	No
Title X	No	No
VA Claims Confidentiality Statute	Yes	Yes
WIC Confidentiality Provisions	No	No

Data Use Exceptions for Public Health and Research

¹ Limited to educational studies

² Several HHS components list research as a permitted purpose

³ Restricts non-governmental research

But that's not all...

- Tremendous variation and complexity in state laws dealing just with health information



EDITOR'S CHOICE

Falling short: how state laws can address health information exchange barriers and enablers FREE

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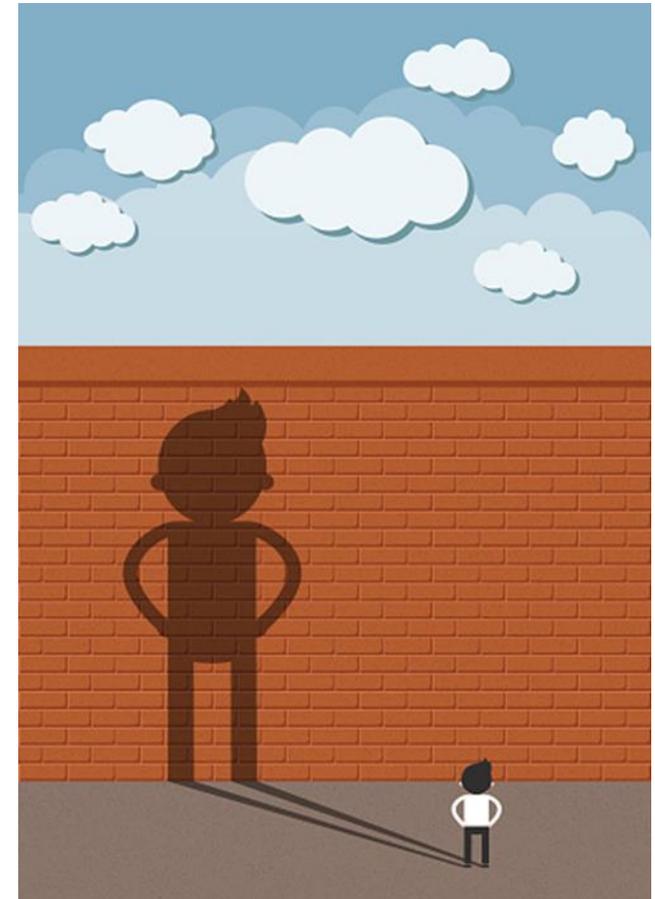


Persistent Data Sharing Barriers

- Unfortunately, effectively leveraging this cross-sectoral data for public health purposes has remained elusive in part because the **United States lacks a unified framework for sensitive data protection** (i.e., privacy, confidentiality, and security).
- Legal data sharing barriers can be both real and perceived
 - Real legal barriers → a law restricts a use or disclosure
 - Perceived legal barriers → belief that a law prohibits a use or disclosure
 - BOTH are actual barriers!

Implications of Legal Uncertainty

- Precautionary data stripping
 - I.e., removal of useful data elements
- At best, legal uncertainty increases transaction costs for data sharing
- At worst, legal uncertainty impedes legal data uses



Model for an alternative approach

The European Union's General Data Protection Regulation (GDPR)

GDPR(EU)

- “[A]pplies to the processing of **personal data** ... which form part of a filing system or are intended to form part of a filing system.”
- “**personal data**’ means any information relating to an identified or **identifiable natural person**; an identifiable natural person is one who **can be identified, directly or indirectly, in particular by reference to an identifier...**”



Applies broadly
to all data

GDPR and Public Health

- Recital #54
 - “The processing of special categories of personal data **may be necessary for** reasons of public interest in the areas of **public health without consent** of the data subject”
- Article 9
 - “1.Processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data ..., [health data or sexual activity data] shall be prohibited.
 - **2.Paragraph 1 shall not apply** if one of the following applies: ...
 - **(i) processing is necessary for reasons of public interest in the area of public health**”

GDPR Article 5: Principles relating to processing of personal data

- “Personal data shall be: ...(b) collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes;
- further processing for archiving purposes in the public interest, **scientific or historical research purposes or statistical purposes shall**, in accordance with Article 89(1), **not be considered to be incompatible with the initial purposes”**



Conclusions

- Inconsistent federal statutes and regulations place different restrictions on how sensitive administrative data can be used.
- Understanding these federal laws is critical to understand how to leverage cross-sectoral data for public health purposes.
- The EU GDPR provides a workable model for a unified approach to data protection while permitting data to be used to promote population health.
- What are the ethical implications of the US data protection framework?

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