**POLICY INSIGHTS**

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**Patient Privacy and Public Trust:**

How Health Surveillance Systems Are Undermining Both

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**Introduction**

With funding primarily from Congress, state health departments have created a multitude of government patient-tracking systems. Increasingly, these systems are being linked together, creating individual health profiles and lifelong records.

The emergence of computerized medical records—and the federal requirement that physicians, hospitals and other health care professionals have interoperable electronic medical records or be penalized in 2015—has accelerated and facilitated government access to private patient data. Often without consent, patient data is collected from doctors, hospitals, and clinics—in some cases annually for lifelong monitoring.

But while most assume that patient privacy rights are protected by patient consent requirements, government health surveillance is characterized by a surprising lack of patient consent and little to no public awareness or discussion of the growing databases and registries. Even worse, the government seizure of data often happens at a time and in a place when individuals are in a vulnerable state—at the clinic or in the hospital.

Today, state government agencies collect illness, injury, hospitalization, diagnostic, medication, genetic, birth and death

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**Key Points:**

- State governments have created an array of government patient-tracking systems into which individuals have been placed without their consent.
- Federal requirements for computerized medical records, and the federal HIPAA privacy rule, have facilitated government access to patient data.
- States are linking databases together to create Child Health Profiles.
- Patient trust in doctors and hospitals may be harmed once patients realize health surveillance is taking place.
- This report focuses on four health surveillance systems found uniformly in all or most of the 50 states and Washington, D.C., including 51 online charts of state laws and rules, plus a table of raw data sent by state agencies: bit.ly/HealthSurveillanceReport.
- By law, state legislators can restore rights to patient privacy and consent.
data on individual citizens. This collection and connection of private medical records data occurs often without patient consent or knowledge—and sometimes without specific authority in state law.

These state collections of personal information include, but are not limited to, the following conditions or test results, which may exist in databases, registries or biobanks. States vary greatly in their collection of data. Although all states have one or more of the following collections of data, not every state maintains all of these collections. However, a single state example is given for each collection:

- Alzheimer’s disease (IL)
- Asthma (IN)
- Autism (DE)
- Brain or Spinal Cord Injury (IA)
- Birth defects (MN)
- Blindness (IN)
- Burn injuries (DE)
- Cancer (CA)
- Cerebral Palsy (MA)
- Chronic Disease Registry (IN)
- Diabetes Surveillance (CT)
- Disabled Persons (GA)
- Emergency room visits (IN)
- Health Status Monitoring/Environmental Health Program (ME)
- HIV testing (HI)
- Hospital discharge data (IL), including external-cause-of-injury codes
- Injury Reporting (DC)
- Morbid Obesity Surgery (IN)
- Newborn (genetic) screening test results (AZ)
- Newborn DNA Biobank (WA)
- Newborn hearing screening (NY)
- Obesity/Body mass index (MI)
- Occupational Disease Reporting (MA)
- Parkinson’s Disease (LA)
- Poisonings (IA)
- Sexually transmitted diseases (MO)
- Strokes/Cardiovascular Disease (TX-planned)
- Trauma registry (ID)
- Vaccinations (MS)
- Vaccine Pregnancy Registry (LA)
- Violent Injury (IL)
- Vital statistics (birth, death, marriage, divorce, adoption) – 50 states

This private data is not only routinely collected without patient consent, it is increasingly being linked together for analysis, research and tracking. For example, as part of its application for a federal Title V Maternal and Child Block Grant, Kansas reports:

“Kansas Maternal and Child Health (MCH) is building data infrastructure, epidemiological capacity, and products of analysis in order to carry out core public health assessment functions. We continue to improve Kansas MCH data capacity by: 1) improving data linkages between birth records and other data sets such as infant death certificates, Medicaid eligibility and/or paid claims files, WIC eligibility files, and newborn [sic] metabolic screening files; 2) improving access to hospital discharge data, Youth Risk Behavior Survey (YRBS) data, Birth Defects Surveillance System (BDSS) data, Pregnancy Risk Assessment Monitoring System (PRAM) data, and Children and Youth with Special Health Care Needs (CYSHCN) program data...”

Furthermore, the amount of government health surveillance just keeps growing. The U.S. Centers for Disease Control and Prevention (CDC) recently created the National Public Health Surveillance/Biosurveillance Registry for Human Health (NPHSB Registry), which they describe as,

“a comprehensive electronic catalog of over 280 CDC public health surveillance and biosurveillance assets related to human health. Launched in December 2012, the Registry provides information to foster collaboration among surveillance subject matter experts, and provides critical information about CDC’s surveillance capabilities to decision-makers as they address a wide range of public health preparedness and response issues that depend on effective coordination. ... The
Research Methods

The Citizens’ Council for Health Freedom began this research project in 2005, while operating as Citizens’ Council on Health Care. After requesting and receiving a letter of recommendation from HHS Secretary Michael Leavitt (Appendix A), we proceeded to query state health departments in all 50 states and Washington, D.C. A survey titled, “Privacy and Public Awareness of State Health Databases Project” (Appendix B) was distributed to state health departments by e-mail or fax with a request for response. We sought data on the specific numbers of individuals in the databases, whether patient consent was required, whether individuals could opt out, whether individual names were used, and other privacy-related information. An example of a response is included in this report (Appendix C).

After receiving little to no initial response to our e-mail inquiries, our interns began calling state health departments directly to get answers to the questions. Department responses varied from essentially, “We’re not going to tell you.” to “We’ll get you the data within the hour.” Some state workers expressed apprehension, wondering how the data they gave us would be used. For example,

“The CDC wasn’t familiar with you folks, but is ‘asking around’ and will get back to me. Please understand our caution considering all the horror stories little Programs like ours have gone through in the past.” (email, January 10, 2006)

“We are declining to do this survey . . [on newborn screening]” (email, March 16, 2006)

“Please do not expect a response to your survey. I am sorry but I am concerned about how the data will be used since there seems to be a bias toward anti-vaccination as I review your website.” (email, April 14, 2006)

“Our evaluation of the CCHC survey was that it does not support birth defects monitoring and prevention programs. Given our legislatively mandated mission is to conduct birth defects monitoring in support of birth defects prevention, we have decided not to participate in the survey.” (email, December 1, 2006)

Others expressed concerns related to the fact that many of those tracked by the state’s surveillance systems were unaware of the systems.

If a state refused explicitly or simply never responded, we sent certified letters to the heads of state health departments, and eventually to the governors. After this elicited only a few more responses, we decided to try to find answers to our questions online. When the results of this research seemed less than satisfactory, and occasionally in conflict with the answers provided by a state, we broadened the project to include the actual language of state statutes and rules, a truly arduous undertaking. The statute language in the report was updated several times in the course of completion, last in August 2012.

This report has taken far longer than imagined as various methods to secure a complete 50-state set of data were attempted and various interns and staff came and went. But even as state statutes change over the years, the current statutes will stand as an example of how intrusive public health surveillance around the United States has become in American lives.
registry is currently located on CDC’s intranet and available only to members of
the CDC community.” [Emphasis added.]

Our Report
This CCHF report explores the issue of government health surveillance by reviewing four state health data systems. These four state systems are found in all or most of the 50 states and D.C., and most have received federal funding:

- Birth defects surveillance systems
- Cancer registries
- Newborn screening databases
- Vaccination/Immunization registries

As a part of the federal funding requirement, or as a part of other federal law, state agencies overseeing these systems share aggregate data or private health information with various federal agencies, including the Centers for Disease Control and Prevention (CDC), the U.S. Department of Health and Human Services (HHS)—and even with the U.S. Department of Homeland Security.⁸

This report provides the following information on each surveillance system:

- Background
- Funding
- Uses
- Example of data collection
- Controversies
- Charts of applicable state statutes and rules

The charts of applicable statutes and regulations for all 50 states can be found at http://bit.ly/HealthSurveillanceReport.

The Demise of Privacy Rights
To build these four patient tracking systems, Congress, state legislatures, and state officials have dismissed three pillars of patient privacy protection.

Key Terms
Two sets of terms must be distinguished from each other. The first set of terms is database and registry. A database is simply a collection of records, or data that is searchable. However, statutory use indicates that a registry is a specific database of specific people with specific conditions.

For example, a newborn screening database is a collection of data on each baby screened for newborn genetic conditions. A registry is a collection of data on the children found through newborn screening to have a genetic condition or trait. Another example is the cancer registry. While hospitals have a database of their patients, many also have registries of all patients diagnosed with cancer. In short, every registry is a database, but not every database is a registry.

The second set of terms is data security and patient privacy. In the realm of government data systems, health officials regularly promise to protect patient privacy—but only after the government has accessed private data and placed it into a government database or registry. Assertions aside, the first privacy violation occurs when the government takes the data without patient consent. What officials are actually promising is data security. Once they have collected and stored the patient’s data, they promise not to let anyone else access it without their consent. Here are two examples of the loose use of these terms:

“State-by-state tracking of birth defects is usually carried out by state health departments, which apply public health science to establish monitoring programs that look for birth defects cases in the state and follow them, while protecting privacy through a centralized registry or database.”⁹

“All information reported to the New York State Cancer Registry is confidential, and strict procedures are in place to protect patients’ privacy. ... All research studies...with patient identifiers must be reviewed by the Health Department’s Institutional Review Board, which protects rights of privacy and informed consent.”¹⁰
First, they have forced doctors and hospitals to either report private patient data or open up patient records to government inspectors for data collection. This violates the consent and confidentiality requirements of the Hippocratic ethic and, therefore, the professional obligation of physicians and other health care professionals to patients. The Hippocratic Oath includes the promise, “Whatever, in connection with my professional service, or not in connection with it, I see or hear, in the life of men, which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret.”

As the University of Washington School of Medicine states on its “Ethics in Medicine” Web page:

Confidentiality provides the foundation for the physician-patient relationship. In order to make accurate diagnoses and provide optimal treatment recommendations, the physician must have relevant information about the patient’s illness or injury. This may require the discussion of sensitive information, which would be embarrassing or harmful if it were known to other persons.

The promise of confidentiality permits the patient to trust that information revealed to the physician will not be further disseminated. The expectation of confidentiality derives from the public oath which the physician has taken, and from the accepted code of professional ethics. The physician’s duty to maintain confidentiality extends from respect for the patient’s autonomy.

Second, the legal right of consent for accessing and using private data has often been replaced by the option of dissent. Under dissent laws, patients and parents are not asked whether their information can be used. Instead, if they figure out what’s going on and go to the trouble of taking action, they can stop the data collection and tracking. But in doing so, they leave behind a government record of dissent.

Third, constitutional rights against government intrusions, including the seizure of private property and personal information, have been widely ignored. For example, the Fourth Amendment says:

“The right of the people to be secure in their persons, houses, papers, and effect, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.”

And the Fifth Amendment says:

“No person shall be...deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use without just compensation.”

As Supreme Court Justice Louis D. Brandis stated in his dissent in Olmstead v. U.S. (1928):

“The makers of our Constitution understood the need to secure conditions favorable to the pursuit of happiness, and the protections guaranteed by this are much broader in scope, and include the right to life and an inviolate personality -- the right to be left alone -- the most comprehensive of rights and the right most valued by civilized men. The principle underlying the Fourth and Fifth Amendments is protection against invasions of the sanctities of a man’s home and privacies of life. This is a recognition of the significance of man’s spiritual nature, his feelings, and his intellect.”

The Option of Dissent

These systems have been aided by the use of, and confusion over, “opt-out” or “dissent” requirements. The “opt-out” requirement means the government agency can collect,
store, use and share the individual’s data unless the individual or parent discovers the intrusion, realizes his or her right to object, figures out the process to object, and takes action to formally do so. Opt-out assumes government has first dibs on the data, places a significant bureaucratic burden on individuals, and, creates a government record of the dissent.

An “opt-in” or “consent” requirement prohibits the government from collecting, storing, using or sharing a person’s data without voluntary written informed consent. Until there is a legal signature from the individual or parent, the government cannot even collect the data.

When given a choice – when consent is required prior to government access – members of the public usually choose privacy.

In 2005, Eurocat, a network of population-based registries of congenital anomalies—birth defects—in Europe, conducted a survey on registries’ implementation of informed consent. Eight of the registries had used consent at one point. One registry reported a drop in its participation rate, noting that it had received “less than 10 written consents in the entire year in which opt-in consent was instituted.” This was compared with 249 people added to the registry the year before they integrated consent.

As a result, the registry eventually dropped the consent requirement (opt-in) and offered a dissent option (opt-out). In short, when people refused to cooperate of their own volition, the registry forced them in.

Proponents of patient tracking dislike consent requirements. “Opt-out clauses eliminate the need for providers and surveillance program staff to obtain written consent from parents and contribute to more complete data collection,” reports the National Birth Defects Prevention Network.

State health departments often oppose both consent and dissent requirements. Public officials argue that such requirements consume agency time, energy and dollars and pose an impediment to high levels of public participation in the data system. Proponents of government access to vaccination data without consent have estimated financial costs for a consent-based system at $2.00 per child, or $0.29 per child for a dissent system.

Moreover, state agencies have used these terms loosely and inappropriately—and to their advantage. For instance, in Minnesota law, the birth defects surveillance system seemingly requires parent “consent.” However, the term “consent” (opt-in) is actually referring to a “dissent” (opt-out) process, and only partial dissent is allowed. Only “identifying” data may be removed. All other information will still be collected, stored, used and shared:

“Subdivision. 1. Hospitals and similar institutions. With the informed consent of a parent or guardian, as provided in subdivision 4, a hospital, medical clinic, medical laboratory, or other institution for the hospitalization, clinical or laboratory diagnosis, or care of human beings shall provide the commissioner of health with access to information on each birth defect case in the manner and at the times that the commissioner designates.”...

[Emphasis added]

“Subd. 4. Opt out. A parent or legal guardian must be informed by the commissioner at the time of the initial data collection that they may request removal at any time of personal identifying information concerning a child from the birth defects information system using a written form prescribed by the commissioner.”

Finally, federal dollars discourage consent requirements. For example, under the 1992 Cancer Registries Amendment Act, states must report to the CDC data on at least 95 percent of cancer cases diagnosed or treated in the state. The National Program of Cancer Registries (NPCR) “required the use of uniform data items and codes and record layouts” as determined by the North American Association of Central
Cancer Registries. The layout includes patient demographics and personal identifiers such as name, address and Social Security number.

**HIPAA: A Permission Slip for the Government**

The public has been greatly misled on privacy rights under the federal HIPAA privacy rule. The Rule is permissive, allowing broad sharing of private patient data without patient consent. The leading government and industry proponents of the HIPAA privacy rule—working together as the Working Group for Electronic Data Interchange (WEDI) — advanced the rule to enable a national system of computerized, interoperable, linkable medical records to be built.

The required HIPAA privacy rule was finalized six years after the Health Insurance Portability and Accountability Act of 2006 (HIPAA) was enacted. The rule became effective on April 14, 2003 despite more than 52,000 public comments written to the U.S. Department of Health and Human Services, with a majority of them asking for patient consent requirements. Federal and state health officials, and others — over 600,000 different entities — were given “significant latitude” to access private health information. As the Missouri Cancer Registry states,

> “HIPAA allows for the reporting of identifiable cancer data to public health entities such as the Missouri Cancer Registry. Neither written informed consent from each patient nor Business Associate Agreements are required to report data to a public health entity.”

HIPAA has no patient consent requirements for sharing of data. According to the CDC, “the [HIPAA] privacy rule expressly permits [protected health information] to be shared for specified public health purposes...Thus, the privacy rule provides for the continued functioning of the U.S. public health system.”

The rule allows government access for a variety of purposes including: “public health activities,” “health oversight activities,” “judicial and administrative proceedings,” and “law enforcement purposes.” Unless stronger state privacy laws forbid it, identifiable patient data can be released to government officials, “for the purpose of preventing or controlling disease, injury, or disability, including but not limited to public health surveillance, investigation, and intervention.”

Access increased to 2.2 million entities in 2009 when the Health Information Technology for Economic and Clinical Health Act (HITECH), which was part of the American Recovery and Reinvestment Act of 2009, gave 1.5 million “business associates” access without patient consent. The HIPAA “Notice of Privacy Practices” patients receive describes “how they may use and share your health information...” For all intents and purposes, the notice should be called a “Notice of Disclosure Practices.”

HIPAA allows state legislatures to write strong patient privacy laws—laws that acknowledge patient privacy rights; laws that acknowledge the primacy of privacy in the patient-doctor relationship and the patient’s need for trust. As Patrick W. O’Carroll, MD, MPH, a physician at the Centers for Disease Control and Prevention (CDC), writes, “Federal [privacy] legislation will not preempt stricter state laws.”

Yet most state legislatures have not enacted state privacy laws to counter the federal rule’s elimination of patient privacy rights. Instead most states have enacted government patient tracking and health surveillance systems to capture federal grant dollars.

**Four Surveillance Systems**

Four state surveillance systems are detailed below. The four included have been chosen because most states have them. Three
surveillance systems collect and store data on individuals starting shortly after birth (newborn screening, birth defects and vaccinations), and two systems include data collected on adults (cancer, and increasingly vaccinations). The vaccination registry is discussed first because it is considered to be one of the key building blocks of a national health data system.

The registry is also primarily called a vaccination registry in this report — rather than an immunization registry — because it registers vaccinations received, not immunity.

**Vaccination Registreries**

A state vaccination registry seems quite benign. However, vaccination registries—now popularly called immunization registries or more recently immunization information systems (IIS)—are viewed by many in health care as platforms for comprehensive health surveillance on the American public:

- “[I]mmunization registries represent innovative technologic solutions to the challenge of monitoring health problems and health care access on a population basis.”

- “For public health officials, immunization registries integrate immunization services with other public health functions.”

- “In particular, [the National Immunization Program at the CDC] ‘supported the concept of integrating state-based registries within more comprehensive information systems at the state level.’”

- All Kids Count (part of the Robert Wood Johnson Foundation) “was interested in learning if immunization registries could provide the infrastructure to support tracking and sharing of patient-based information within the broader health system.”

- Immunization registries are needed “as a source of experience for the development of electronic medical records.”

- “IIS were the public health program that led the way for linkage with the health care delivery sector. IIS possess most of the attributes of a clinical information system (e.g., person-centric records capturing a longitudinal history of care delivered to a child and also supporting decisions at the point of care). Consequently, when states begin thinking about a suitable integration platform for public health systems and a platform for linkage to [electronic health records], they often conclude that the immunization registry is their most robust platform and the most logical point at which to begin extending the data model to include other programmatic data.”

In January 2013, the CDC reported 84 percent (19.2 million) of U.S. children younger than six years old participated in immunization information systems during 2011. The term “participate” implies consent, but many parents gave no consent prior to data on their children and themselves being shared.

**Background**

Early efforts to develop infant vaccination tracking systems began in the 1960’s but “failed because systems were primarily manual, expensive to maintain, and not integrated with the broader public health delivery.
Delaware created the first functional vaccination registry in 1974. Called VacAttack, it was based on submissions of encounter data. State policy required schools and day care centers to report vaccination histories and required providers “who received vaccines through the federal Vaccines for Children program to report to the registry.”

In 1980, the National Immunization Program (NIP) at the Centers for Disease Control and Prevention, established an “Automated Immunization Management System.” Later in the same decade, San Antonio established a “mainframe based registry of vaccinations given in the public sector.”

Significant steps were taken in the 1990’s. In 1991, an expert panel convened by the CDC recommended a national immunization registry. Meanwhile, the Robert Wood Johnson Foundation met with NIP to consider financial support. After these discussions, the Robert Wood Johnson Foundation began to fund vaccination registry development nationwide.

The foundation established the All Kids Count (AKC) program, approving $9.3 million in funds for registry planning grants. In 1992, 23 state and local health departments received $150,000 grants each. Over the next 13 years, RWJF invested $30 million to work with 38 state and local health agencies in the development and establishment of vaccination registries.
On July 23, 1997, government registration of each child’s vaccinations received a boost. President Clinton issued a presidential directive to the Department of Health and Human Services:

I’m directing Secretary Shalala to start working with the states on an integrated immunization registry system...it may have something to do with whether their children live or die. And we have to do it and do it right.55

In July 1999, the American Immunization Registry Association was formed to facilitate registry development.56 57 In 2000, the U.S. Department of Health and Human Services added vaccination registries to the Healthy People 2010 agenda with goal of having “95 percent of children under the age of six years in a population based immunization registry.”58

By 2004, 11 million U.S. children under the age of six (out of 23 million total) were registered in an Immunization Information System (IIS).59 Children are often entered into the state’s registry by linking with electronic birth certificates in the state’s vital records division or with the state newborn genetic testing programs.60

Today, all fifty states have immunization registry projects61 — defined as “confidential, population-based, computerized information systems that attempt to collect vaccination data about all children within a geographic area.”62

Under the 2009 HITECH Act, doctors that want to receive federal “meaningful use” incentive payments for purchasing and using digital record systems must demonstrate “meaningful use” of electronic medical records by exchanging immunization data with public health agencies. “One option is to exchange data with an [Immunization Information System],” states the American Immunization Registry Association. 63

Adults are also being targeted for tracking. For example, in February 2010, the Texas-based Immunization Partnership asked state lawmakers to include all Texans in the state’s registry. They argued that the inclusion of every Texan was “…vital to a robust public health system, that a complete registry of those shots would help navigate major health crises.”64

Several states, including Illinois, Maine, Ohio, Rhode Island, and Texas are investigating the use of vaccination registries for obesity (body mass index) surveillance. 65

According to the 2004 Immunization Registry Annual Report, 20 percent of states receiving federal funds (12 of 56 grantees) included individuals from birth to under 23 years old in the registry. About 70 percent (37 of 56 grantees) included all ages in the registry.66

Vaccination registries can stand alone, but increasingly they are integrated into health information exchanges (HIEs). For example, in San Diego, California, data in the registry will be directly imported into the HIE, eventually giving “other providers, schools, childcare organizations and other stakeholders in the county” access to vaccination data. 67

Funding

State vaccination registries are expensive. In addition to state funding, the CDC funds 56 programs (50 states, 5 cities, and the District of Columbia).64 A 2002 study to predict the true cost of developing and maintaining an electronic vaccination registry put it this way: “As of September 1997, more than three hundred registries were in development, supported by at least $142 million in 317d Federal categorical immunization grant funds and more than $200 million in other public, private, and foundation funds. ... Early research using data from some of these registries found costs ranging from as low as $0.65 to as high as $217 per child per year.”69 [Emphasis added.]

These grant funds came from:
• The Robert Wood Johnson Foundation, which “has provided an estimated $20 million for registry development.”

• The federal “317 program” grants to fund immunization operations and infrastructure.

• The CDC’s National Immunization Program, which since 1994 “has allocated $181.9 million for the development and implementation of a nationwide network of community- and state-based immunization registries to its 64 immunization grantees … that receive federal immunization funds under the Public Health Service Act.” 70

The 2002 study also found the following:

• The cost of building vaccination registries is predictable and independent of the hardware/software combination employed.

• The effort requires four man-years of technical effort or approximately $250,000 in 1998 dollars.

• An additional three-quarter man-years is needed for annual maintenance.

• Data entry required 82.7 man-hours per 1,000 record entries.

• Registries that use only data entry personnel rather than more expensive nurses and doctors had a per-chart entry cost of $0.11.

• Costs for maintaining a registry were approximately $5,100 per end user per three-year period. 71

The projected annual cost of operating a nationwide network of state vaccination registries is $78 million for children from birth to five years of age ($100 million per year for children birth to six years of age).72 Additionally, clinics must purchase software, receive training, and do the work of data entry. One study found an increased cost of $0.56 per shot after the registry was implemented due to an additional 3.4 minutes per shot for registry activities.73 There are no studies on the cost of entering historical (past) vaccination data to populate the database.74

Vaccination registry projects receive funding from both public and private sources. The sources for all funding of registries is as follows:

- Federal; 56%
- State; 19%
- Private; 12%
- Local; 8%
- In-kind; 12%
- Other; 5%

Chart made from statistics found in Public Health Informatics and Information Systems, Patrick W. O’Carroll, page 474.

For example, Illinois’ governor proposed a budget in 1999 that included a “$1 million increase to continue the development of a childhood immunization tracking system (TOTS)”.76

In another example, the Minnesota Department of Health secured a $300,000 grant from the Robert Wood Johnson Foundation in 1997—after the department’s state vaccination registry proposal was defeated during the 1996 legislative session. The grant was awarded to the Minnesota Department of Health (MDH), the Southwest Minnesota Immunization Information System (SIIS) and the University of Minnesota for joint development of a model registry for the state77 —despite the legislature refusing to authorize it and despite no law authorizing MDH to create one. A push to establish a statewide Minnesota network of regional registries got a boost in 2000 with $300,000 funding from MDH and Blue Cross Blue Shield of Minnesota.79
In 2000, Congress was asked “...to fund a confidential, online immunization record for every child at birth.” The national registry would have cost approximately $125 million annually tracking each child’s vaccinations through the age of six. However, the CDC was already providing approximately $50 million **each year** toward the implementation of state-based registries. The national registry was not enacted.

Recently, the National Center for Immunization and Respiratory Diseases (NCIRD) began an “IIS Sentinel Site” program, providing supplemental funds to select vaccination registries to “track patterns in immunization practices and assess vaccination coverage among children less than 19 years of age” in their sentinel site geographic regions. The six sentinel sites are in Michigan, Minnesota, North Dakota, New York City, Oregon, and Wisconsin.

**Uses**

The stated purpose of vaccination tracking systems is to ensure that the approximately 11,000 children born each day receive required vaccinations against vaccine-preventable diseases such as measles, pertussis and tetanus. As explained in *Progress in Development of Immunization Registries*, a report written by the CDC in 2000,

> “Registries are an important tool to increase and sustain high vaccination records of children from multiple providers, generating reminder and recall vaccination notices for each child, and providing official vaccination forms and vaccination coverage assessments.”

Registries have been used to share vaccination data broadly, to conduct research on use of polio vaccine, and to recall children who received invalid doses of a vaccination. According to the CDC, vaccination registries do the following:

- Provide an accurate, official, consolidated copy of a child’s vaccination history for parents.
- Prevent unnecessary or duplicative vaccinations.
- Assist with timely vaccination if the family moves or switches health care practitioners.
- Make vaccine recommendations.
- Manage vaccine inventories.
- Reduce paperwork.
- Reinforce the concept of medical home.
- Control vaccine-preventable diseases.
- Identify high-risk and under-immunized populations.
- Prevent disease outbreaks.
- Link with other health databases.
- Target interventions and resources.
- Make sure providers are following up-to-date immunization practices.
- Integrate with other public health functions.

**Integrity Issues**

To meet these claims, the vaccination registry data must be accurate and up to date. Yet, registries have ongoing problems of data integrity.

For example, vaccination data is often missing from the registry. A 2008 study found that data in the registry only agreed with data in the child’s medical record in 59 percent of cases examined. Notably, the parent’s report of vaccination status agreed with the medical record in only 62 percent of cases. Thus, the study concluded that the registry is similar in accuracy to parental recall of vaccination status — and neither is accurate enough to rely on for decisions.
A similar finding was reported earlier in a 2002 study of Boston’s vaccination registry. Researchers found 59 percent of the studied registry records with at least one data error.\(^9\)

**Duplication**

Another integrity problem surrounding vaccination registries is duplication. “Duplicate registry records pose a serious challenge to the integrity of registry databases. While many population-based registries have methods in place for ensuring that only one record exists on each individual, there are no criteria for assessing the effectiveness of these methods,” writes Rob Linkins, then head of the CDC’s National Immunization Program.\(^9\)

**Example of Data Collection**

The Indiana Children and Hoosiers Immunization Registry Program (CHIRP) procures immunization data from all Indiana health departments, the Regenstrief Institute, and from Medicaid claims.\(^9\) The Regenstrief Institute, a tax-exempt organization in Indianapolis, provides a case study of how the private sector has partnered with the government to advance public health data surveillance systems, including vaccination registries. Their public health goal aligns with government surveillance objectives: “Link clinical activities and public health activities to improve the population’s health (Pluck reportable cases from the [data] streams).”\(^9\)

One proposed definition of “population health” is “the health outcomes of a group of individuals, including the distribution of such outcomes within the group.” Thus health care is viewed from the group level, not the individual level. Population health is a driving force in the development of a national medical records system, called the Nationwide Health Information Network (recently renamed the eHealth Exchange):

“…in addition to enabling health information to follow an individual and to be available for clinical decisions, it had been envisioned that the Nationwide Health Information Network would take, with appropriate safeguards, health care information beyond direct patient care to improve population health. CDC has been a critical partner at the table with other federal agencies to ensure that the Nationwide Health Information Network can be used to support ongoing efforts at state and national levels to improve surveillance of disease.”\(^9\)

**Controversies**

The establishment of vaccination registries is not without detractors. Concerns have included the collection and use of the data by health officials; the creation of lists of those who refuse vaccinations; the use of clinic vaccination rates to score the performance of doctors\(^9\); the use of such scores to financially penalize doctors, and the potential refusal of health plans to cover an unvaccinated or under-vaccinated individual.

Some wonder whether immunization registries are a “good idea or too big brother?” \(^9\) For example, the National Vaccine Information Center specifies that the registries will become “a national government operated vaccine tracking registry system that will tag all citizens with a national ID number at birth and track their movements throughout life for the express purpose of enforcing vaccination with all government-endorsed vaccines.”\(^9\)

How broad these controversies become is yet to be seen. Today, most of the public is unaware of the state vaccination tracking systems or the more sweeping surveillance goals of its proponents. Becoming aware of the systems will give members of the public an opportunity to react to the realities of surveillance and the information necessary to choose to remain in it, avoid it or dismantle it.

**Cancer Surveillance**

**Background**

State cancer registries, sometimes called...
The integrated Child Health Information System is also called a child health profile system.

From Registries to Profiles

In 1996, the Health Resources and Services Administration (HRSA) at the U.S. Department of Health and Human Services released a strategy statement recommending the development of a "Maternal and Child Health Information System." In 1998, the Genetics Services Branch of HRSA established grants to develop an integrated Child Health Information System (CHIS). As the Public Health Informatics Institute notes:

"The concept of the Child Health Profile is one that was developed by HRSA/MCHB is [sic] promoted through the activities of the Connections CoP [Community of Practice, a group established as part of the Robert Wood Johnson Foundation's All Kids Count immunization registry initiative]. The profile is the term we utilize to describe the consolidated record that would be available to authorized users."

The integrated CHIS is also called a child health profile system. The CHIS began with data from newborn genetic screening, newborn hearing screening, immunizations, and birth and death certificates. The initial federal HRSA/MCHB Title V Special Projects of Regional and National Significance (SPRANS) grants to 25 states were directed toward merging newborn genetic screening data with other maternal and child health data systems.

In 2001 and 2002, federal officials visited seven states. A sourcebook of five lessons, including "Data are for sharing," was published. And in 2003, a federal work group was convened, resulting in nineteen principles, twenty-two core functions and eight desirable functions of the CHIS, including:

- Establish a government health record for each infant within two weeks of birth.
- Establish a unique identifier for or a process to individually identify all children that all participating programs can use to cross-link information.
- Track the individual from screening through confirmation of diagnosis and initiation of therapy.
- Track long-term follow-up care into adulthood.
- Record additional information as it becomes relevant to the health of the child and the programs participating in the data system.

Utah’s Child Health Advanced Records Management (CHARM) Program, which includes vaccination data, has been heralded as an example of how the child health profiles can be created:

"CHARM is ... leveraging funding and incremental successes to achieve a long-term vision for a statewide integrated system. ... Privacy and confidentiality concerns will be addressed and governed by data sharing and confidentiality agreements between public health and private providers. ...

"CHARM development and operations are primarily supported by grants from federal agencies including the Centers for Disease Control and Prevention Early Hearing and Detection Intervention cooperative agreement, the HRSA Genetic Services and Data Integration Planning and Implementation Grants, the HRSA State Systems Development Initiative, and the HRSA MCH Block Grant. ..."

"Integrating the state’s public health care databases will provide immediate access to information that is stored in specific databases to track and monitor health status for children. ..."

Other child health information systems link to state blood lead testing programs; the Women, Infants and Children (WIC) database; newborn developmental testing; newborn hearing screening, and the data collection system of the government’s home visiting program.
tumor registries, have a long history. In 1926, a Massachusetts doctor began a bone sarcoma registry, one of the earliest registries established for a specific type of cancer. That same year, the first hospital-based cancer registry was established in New Haven, Connecticut.¹⁰⁹

Nine years later, in 1935, Connecticut also created the first population-based cancer registry in the United States. In 1956, the American College of Surgeons required a cancer registry for any approved cancer program.¹¹⁰

Congress got involved in 1971, enacting the U.S. National Cancer Act, which provided the National Cancer Institute (NCI) with funding for research, detection, and treatment of cancer. Two years later, the Surveillance, Epidemiology and End Results (SEER) program of NCI established the first national cancer registry program.¹¹¹ In 1992, U.S. Public Law 102-515 established the National Program of Cancer Registries (NPCR) through the Cancer Registries Amendment Act.¹¹² By 1993, many state laws made cancer a reportable disease.¹¹³

The NPCR has been administered by the CDC since 1994. Prior to NPCR, there were ten states without cancer registries, and the states that had registries were short on funding, resources, and legislative support.¹¹⁴ By 1999, SEER had amassed data “on more than 2.5 million cancer cases.”¹¹⁵ Together NPCR and SEER “collect data for the entire U.S. population.”¹¹⁶

State cancer surveillance systems collect data on each incidence of cancer, date of diagnosis, source of information, the industrial or occupational history of individuals with cancer, the type of cancer diagnosed, the location of the cancer in the body, the disease stage, and the type of treatment received by the patient.¹¹⁷ This data can also be broadly linked to other systems (see graph below).

To be sure no patient is missed, the data on each cancer case is reported to the state’s central cancer registry from numerous medical facilities.

Information provided by Strengthening State Cancer Registry Data by Linking to Public and Private Sources, Joseph Lipscomb, PhD http://www.iom.edu/~/media/Files/Activity%20Files/Disease/NCPF/2009-OCT-5/Lipscomb-Strengthening-StateCancerRegistryDatabyLinkingtoPublicandPrivateSources.pdf

By 1999, SEER had amassed data on more than 2.5 million cancer cases.
These facilities include:

- Hospitals
- Physicians’ offices
- Therapeutic radiation facilities
- Freestanding surgical centers
- Pathology laboratories

The NPCR began collecting cancer data in 2001. Cancer data from 96 percent of the United States’ cancer cases is collected annually and entered into the NPCR Cancer Surveillance System. Using this data, the surveillance system facilitates studies in rare cancers, cancer in children, cancer care quality, and cancer among specific minority populations. Cancer surveillance systems also plan to link with other administrative and clinical databases, such as Medicare, Medicaid, and insurance claims. (see graph on previous page.)

NPCR supports an informatics infrastructure for electronic cancer registry reporting. This has been dubbed the “NPCR Advancing E-cancer Reporting and Registry Operations (NPCR-AERRO) project.” The cancer surveillance infrastructure consists of a complex network of hospitals, clinics, laboratories, health departments, non-governmental organizations, and government agencies.

The introduction to the Maine Cancer Registry (MCR) manual on data standards gives a sense of the extensive involvement of outside organizations in collection of cancer data:

“The MCR strives to maintain compliance with the standards for abstracting and coding practices promoted by the national groups, including NPCR, the National Cancer Institute’s Surveillance, Epidemiology and End Results (SEER) Program, the North American Association of Central Cancer Registries (NAACCR), the American Joint Committee on Cancer (AJCC), and the American College of Surgeons (ACoS), including the Commission on Cancer (COC). These standards facilitate data exchange and allow for a “big picture” analysis of cancer in the United States.”

Funding

The 1998 National Program of Cancer Registries law gave state cancer registries $30 million for fiscal year 1994 and “such sums as may be necessary for each of the fiscal years 1995 through 2003.” Using those funds, NPCR “supports cancer registries in 45 states, the District of Columbia, Puerto Rico and the U.S. Pacific Island Jurisdictions.” The program also conducts special research projects, examining cancer patterns within specific populations.

NPCR has partnered with the National Cancer Institute’s Surveillance, Epidemiology, and End Results (SEER) registry program. In 2001, SEER began providing additional financial support to California, Kentucky, Louisiana, and New Jersey – four NPCR-supported state registries. In 2010, greater Georgia joined SEER bringing 28 percent of the U.S. population under SEER. According to the NAACCR, NCI shares funding of these five states with the Centers for Disease Control and Prevention.

Uses

Public health officials use cancer registry data to track patients, treatments, and outcomes, as well as to conduct research, including research on the links between cancer and genetics and cancer and the environment. As noted by the National Cancer Institute, the term “environment” includes “not only air, water, and soil, but also substances and conditions in the home and workplace. It also includes diet; the use of tobacco, alcohol, or drugs; exposure to chemicals; and exposure to sunlight and other forms of radiation.”

The National Cancer Institute also states:

“Because most cancers are thought to be caused by a combination of factors related to genetics and environment (including behavior and lifestyle), studies of suspected cancer clusters usually focus on these two issues. Genetic factors are inherited, that is, passed from parents to
children. However, establishing a genetic-environmental interaction (significant and valid evidence that a specific genetic factor leads to an increased chance that a particular environmental exposure will result in cancer) requires studies of large populations over long periods of time.”

Furthermore, the data is used for research focused on evaluating the effectiveness of cancer prevention, control, and treatment. According to the CDC, data from centralized cancer registries can be used to:

- Monitor cancer trends over time.
- Determine cancer patterns in various populations.
- Provide complete state and national cancer incidence (i.e., number of cancers diagnosed in a population).
- Provide cancer information to the health care community and the public.
- Guide comprehensive cancer control planning and evaluation of cancer control programs (e.g., determine whether prevention, screening, and treatment efforts are making a difference).

**Figure 13: NPCR-AERRO Hospital: Business Use Case Diagram**

The CDC diagram on the previous page, intended to make a business case for hospitals using electronic reporting for cancer cases, shows those who report the cases (labeled “actors”), the various functions in reporting and merging of data, and the recipients of cancer registry data, including researchers.  

Example of data collection

In Washington State, there are two types of cancer data collection. The Fred Hutchinson Cancer Research Center’s cancer surveillance system captures cancer data from the 13 counties surrounding Puget Sound and sends it to the state cancer registry. Outside the Puget Sound area, cases are submitted directly to the registry.

The state cancer registry obtains cancer data from hospitals, other health care facilities, ambulatory surgical centers, pathology laboratories, freestanding radiation and oncology centers, medical clinics, and health care providers. Patient information collected includes but is not limited to:

- Name (last, first, middle)
- Address at time of diagnosis
- Sex
- Race
- Spanish/Hispanic origin
- Birthdate
- Age at time of diagnosis
- Social Security number
- State or country of birth
- Usual occupation, or if retired, primary occupation before retirement
- Primary payer
- Diagnostic information
- Date first seen for diagnosis or treatment of this cancer
- Primary site of originating tumor
- Laterality (if applicable)
- Date of each diagnosis
- Stage of disease at diagnosis
- Date of initial treatment or decision not to treat
- First course of treatment information
- Description of all treatment given
- Date of last contact
- Vital status at time of last contact
- Name and address of facility or National Provider ID number
- Other items necessary to meet reporting requirements as provided annually

Before submitting cancer data to the Washington registry, the cancer surveillance system performs quality control and case consolidation. With many entities required to report, duplications abound. The Pennsylvania Cancer Registry receives “over 100,000 reports of cancer cases annually. After accounting for duplicates, this translates into nearly 76,000 newly diagnosed cases every year.”

Controversies

Controversies include the registration of cancer patients in government tracking systems without their consent. In addition, the following four issues could emerge as patients become aware of the surveillance systems:

Research without patient or parent consent

The most universal and generally used patient identifier in the registry is the patient’s name, with “lifetime follow-up” considered “an important aspect of the cancer registry.” The CDC reports various research functions using patient data in cancer registries:

- Determining cancer patterns in various populations.
- Setting priorities for allocating health resources.
- Advancing clinical, epidemiologic and health services research.
- Providing information for a national database of cancer incidence.
Possible lifestyle interference

A group of researchers studied the causes of cancer in the world using site-specific mortality data from the World Health Organization. They concluded that, “Primary prevention through lifestyle and environmental interventions remains the main way to reduce the burden of cancers.” Specifically mentioned are smoking, alcohol use, and low intake of fruits and vegetables, along with obesity and being overweight. Individuals may become concerned at how their data may be used to push objectionable policies that inhibit lifestyle choice and increase costs for personal choices.

New York City Mayor Michael Bloomberg’s decision to limit soda to 16 ounces per cup—ruled unconstitutional on July 30, 2013—serves as a prime example of intrusive public policies. Indeed, the Fred Hutchinson Cancer Research Center, the contractor for cancer data collection in Washington state, explains it this way on its Web site:

“Using large populations as their ‘laboratory,’ our public-health researchers look for links between cancer and its possible triggers, from diet and lifestyle to environmental and genetic factors. Identifying such cancer causes can lead to better cancer-detection methods and new ways to help people adopt healthier lifestyles to minimize or avoid their risk of getting the disease in the first place.”

Creating a national health data system

According to the CDC, the registries will enhance the exchange of electronic data and advance the government’s controversial Nationwide Health Information Network (NHIN)—recently renamed the eHealth Exchange—which is funded primarily by the 2009 Recovery Act (“stimulus”). The CDC Web site on cancer registries notes:

“This effort supports the U.S. Department of Health and Human Services’ mandate to develop a national health information infrastructure, and, as part of that infrastructure, to develop the electronic health record.”

Geo-mapping patients

In Minnesota, researchers are working to match patient cancer data to precise geographic coordinates. At least 14 states can provide cancer data at the neighborhood level. No patient consent is yet required under law and the federal HIPAA privacy rule does not prohibit it. Conclusions made from research using these geo-coded cancer surveillance systems will soon be able to identify the distinct and unique geographic location of an individual — potentially bringing the violation of patients’ privacy to the front steps of their homes.

Birth Defects Surveillance Systems

Background

The earliest state legislation requiring the reporting of birth defects took place in New Jersey in 1926. The first population-based birth defects surveillance system was established in 1967 in Atlanta, Georgia and is currently administered by the CDC. Called the Metropolitan Atlanta Congenital Defects Program (MACDP), the birth defects registry was established by the CDC, Emory University, and the Georgia Mental Health Institute in the wake of the “thalidomide tragedy.”

Like many government programs, the purpose of birth defect surveillance systems has expanded. According to guidelines for surveillance, “The purposes and objectives established by state birth defects surveillance programs are constantly evolving. Some objectives are traditional, such as those having to do with the epidemiologic purposes of surveillance; others have emerged more recently, serving to broaden the scope of surveillance.”

Despite almost 90 years of reporting, according to the March of Dimes, 70 percent of the causes...
of birth defects are unknown. The CDC was directed by Congressional legislation in 1996 to establish the Centers for Birth Defects Research and Prevention. In 1998, Congress passed the Birth Defects Prevention Act of 1998, which authorized the CDC to:

“(1) collect, analyze, and make available data on birth defects;

(2) operate regional centers for applied epidemiologic research on the prevention of birth defects; and

(3) inform and educate the public about the prevention of birth defects.”

It specified that the Secretary of the U.S. Department of Health & Human Services:

(A) shall collect and analyze data by gender and by racial and ethnic group, including Hispanics, non-Hispanic whites, Blacks, Native Americans, Asian Americans, and Pacific Islanders;

(B) shall collect data under subparagraph (A) from birth certificates, death certificates, hospital records, and such other sources as the Secretary determines to be appropriate; and

(C) shall encourage States to establish or improve programs for the collection and analysis of epidemiological data on birth defects, and to make the data available.

By 2004, at least 45 states, Washington, D.C., and Puerto Rico either had or were developing birth defects registries.

Some of these registries may have been created without legislative approval. For instance, it is not clear if the CDC had authority under Georgia law to collect birth defect data or conduct research. Instead, it appears to have been an executive decision by state regulators. As one report states:

“...the Georgia Department of Human Resources (DRH) has given MACDP the authority, renewed annually, to conduct active surveillance of birth defects in metropolitan Atlanta with and on behalf of the Georgia Division of Public Health (DRH)”

Today, the March of Dimes is a leading advocate in the birth defects registry movement. State chapters advocate for registries in all fifty states. They do not support parent consent. As the Wisconsin Chapter of the March of Dimes testified to the state legislature on a bill to move the state Department of Health and Family Services (DHFS) from an opt-in (consent) to an opt-out (dissent) program for birth defects surveillance:

“This bill will specifically enhance the current [birth defects surveillance] program by:

• “Implementing presumed parental consent. This provision would require parents (of children with birth defects) to opt-out of the reporting program instead of opting-in, which is current law. This will allow for more widespread collection of data and allow the system to be linked to other health-related databases. Such linkage is necessary to ensure complete data and avoid duplicate reporting.

• “Expanding the program to include stillbirth data and vital records. This data is critical to the identification and scientific investigation of birth defects and their ultimate prevention.

• “Expanding the definition of ‘birth defect’ to include malformations.

• “Permit DHFS to contract with a qualified third party to develop preventive strategies for birth defects. Currently, the registry must be analyzed for preventative strategies only by the department.”
Funding
In addition to comprehensive birth defects tracking systems, the CDC is providing funding for defect-specific registries. For example, in fiscal year 2011, 47 states plus various U.S. territories received almost $7.5 million for development, maintenance and enhancement of a surveillance system for newborn hearing screening. Eighteen states have received funding to create disability surveillance systems, and the CDC funds 17 spina bifida registries (e.g. Pennsylvania received $79,547), and hemoglobinopathy registries (e.g. California received $545,442). Even autism surveillance has been funded in a few states (e.g. $324,870 to Colorado, $900,000 to Michigan, $478,976 to New Jersey, $344,170 to North Carolina and $478,975 to Wisconsin).

There are separate funds for birth defects research. For example, in fiscal year 2011, Massachusetts received $1,050,000; Iowa received $825,000; and North Carolina and Utah each received more than $1.3 million. These four states belong to the Centers for Birth Defects Research and Prevention (CBDRP), a collaboration between the CDC and nine state birth defects surveillance registries across the U.S. These centers conduct center-specific research projects, enhance their state’s birth defects surveillance systems, and participate in the National Birth Defects Prevention Study (NBDPS).

The NBDPS, “the largest population-based study ever conducted on the causes of birth defects,” covers an annual birth population of 482,000 and includes cases identified from these nine states. The study identifies and analyzes children with birth defects, as well as “control” infants who do not have birth defects. As part of the study, the CBDRP is collecting cheek cells from infants and parents to identify genetic factors and...
conducting interviews with infant mothers on pregnancy, medical history, occupational and environmental exposures, lifestyle, behavioral factors, physical activity, diet, and medication use. Although state collection and researcher analysis of infant’s data is not voluntary, mothers can choose not to participate in the DNA collection (cheek cells) and the interviews.

All CBDRP case records include the following data:

- Basic demographic information
- Specific written diagnoses
- 6-digit diagnostic codes
- Birth-related information
- Cytogenetic data
- Complications of birth
- Prenatal data
- Pregnancy history
- Family history
- Other risk factor information

Specific numbers for total spending on state birth defects registries are difficult to find. The CDC reports that there are 41 states with birth defects tracking programs, but they provide funding for only 13 states and Puerto Rico:

<table>
<thead>
<tr>
<th>State</th>
<th>Federal BDS Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arizona</td>
<td>$180,000</td>
</tr>
<tr>
<td>Colorado</td>
<td>$180,000</td>
</tr>
<tr>
<td>Florida</td>
<td>$200,000</td>
</tr>
<tr>
<td>Illinois</td>
<td>$827,057</td>
</tr>
<tr>
<td>Kentucky</td>
<td>$180,000</td>
</tr>
<tr>
<td>Louisiana</td>
<td>$185,000</td>
</tr>
<tr>
<td>Michigan</td>
<td>$200,000</td>
</tr>
<tr>
<td>Minnesota</td>
<td>$175,000</td>
</tr>
<tr>
<td>New Hampshire</td>
<td>$160,000</td>
</tr>
<tr>
<td>New Jersey</td>
<td>$200,000</td>
</tr>
<tr>
<td>Ohio</td>
<td>$180,000</td>
</tr>
<tr>
<td>Oklahoma</td>
<td>$185,000</td>
</tr>
<tr>
<td>Puerto Rico</td>
<td>$175,000</td>
</tr>
<tr>
<td>Rhode Island</td>
<td>$160,000</td>
</tr>
<tr>
<td>TOTAL</td>
<td>$3,187,057</td>
</tr>
</tbody>
</table>

Despite CDC grants, state birth defects registries have faced an uncertain financial future as budget cuts have persisted throughout numerous states. However, many efforts have been made to continue maintaining these state-based surveillance systems. In 2003, Oklahoma faced several budget cuts, requiring the state to shift the costs of its registry to other state funding sources in order to maintain the program’s activities. Linking the state’s birth defects registry to environmental issues is another method states have used to acquire funding.

Uses

Although registries have been in existence for some time, the cause of most birth defects remains unknown. Therefore, birth defects registries primarily provide state policy makers, health care providers, and researchers with basic information about birth defect incident rates. Health officials argue that the registries will allow them to spot trends and increase access to services for families of affected children.

The information in birth defects registries is often paired with studies of genetics, molecular biology, etiologic investigations (investigations on the cause of the disease), and environmental exposures. When paired together, registry proponents claim this information may eventually uncover the causes of birth defects, reduce infant morbidity and mortality, and prevent future causes.

Example of data collection

States use active or passive surveillance to capture birth defect data. Active surveillance involves registry staff combing through medical records at strategic data sources, such as clinics and hospitals. Passive surveillance relies on hospitals and clinics to report the data to the state. Birth defects surveillance is just the beginning. The CDC reports:

“The diversity of approaches — particularly methodologies used to generate timely data, applications to monitor prevention activities, and projects to improve access...”
to health services and early intervention — provides useful resources for developing surveillance systems for other childhood diseases.¹⁷⁸ [Emphasis added.]

The Texas birth defects registry “monitors all births”¹⁷⁹ and uses active surveillance. The registry was established in 1993 in an effort to “identify and describe patterns of birth defects in Texas and collaborate with others in finding causes of birth defects, working towards prevention, and linking families with services.”¹⁸⁰ Registry staff routinely visit the hospitals and birthing centers where affected children have been delivered and treated. While at the hospitals and birthing centers, staff members look through logs to find potential cases. They also examine medical records to identify patients with one or more birth defects. Once identified, staff members abstract applicable information onto a special form. Typically, as demonstrated in Michigan, abstracted information includes:

- Child name and address
- Sex
- Medical record number
- Medicaid number
- Social Security number
- Mother’s name and Social Security number
- Diagnosis
- Admission and discharge dates
- Discharge status
- Procedure [treatment] codes¹⁸¹

Data sources for state birth defects registries include vital records from the State department of health, hospital and clinic records, administrative databases, prenatal diagnosis centers and clinical examination findings.¹⁸² The Association of State and Territorial Health Officials (ASTHO) reports sources of birth defects surveillance in the graph seen below.¹⁸³

**Controversies**

Birth defects registries have generated various concerns, including the lack of parent consent. Another concern discovered by this study is the possible inappropriate collection of data. For example, Florida has identified approximately 70,000 infants with a major birth defect between 1998 and 2007; however, the state registry contains demographic and clinical data

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**Table 1. Most Common Partners and Data Sources with Systematic Data Exchange (n=30-33)**

The most frequently reported response for each partner or data source is highlighted in dark orange.

<table>
<thead>
<tr>
<th>Partner or Data Source</th>
<th>Routine Bi-Directional Data Exchange</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Early Hearing Detection and Intervention (EHDI)</td>
<td>34.4%</td>
</tr>
<tr>
<td>Children with Special Health Needs</td>
<td>31.3%</td>
</tr>
<tr>
<td>Delivery Hospitals: Discharge Reports</td>
<td>21.9%</td>
</tr>
<tr>
<td>Birth Certificate</td>
<td>18.8%</td>
</tr>
<tr>
<td>Delivery Hospitals: Chart Review</td>
<td>18.8%</td>
</tr>
<tr>
<td>Metabolic/Newborn Genetic Screening</td>
<td>18.2%</td>
</tr>
<tr>
<td>Vital Records: Death Certificates</td>
<td>15.6%</td>
</tr>
<tr>
<td>Pediatric/Tertiary Care: Other</td>
<td>15.6%</td>
</tr>
<tr>
<td>Pediatric/Tertiary Care: Specialty Outpatient Clinic</td>
<td>15.6%</td>
</tr>
<tr>
<td>Vital Records: Fetal Death</td>
<td>12.5%</td>
</tr>
</tbody>
</table>

*Note: Categories are not mutually exclusive; not all states responded to all partner or data source categories.

**N/A** indicates that the state does not have the corresponding program (e.g., does not have local health departments).
for at least 2,135,000 live births.  

Another concern surrounding birth defect surveillance systems is the presumption that government patient-tracking systems can be established without legislative authority:

> “Although most states have established such registries through legislative action, it is not always required and some states may be able to establish a registry through rulemaking, generally by adding birth defects to a list of information that the state health department tracks.”

As seen with cancer and vaccination registries, there is also a concern over creating child health profiles by linking birth defects data with other government surveillance systems. The National Office of Public Health Genomics says the purposes of birth defects surveillance systems are:

> “...best accomplished through surveillance systems that use multiple data sources, have accurate and precise diagnostic criteria, perform timely data analysis and dissemination, use personal identifiers for follow-up and data linkage, and guarantee confidentiality.” [Emphasis added]

The collection of DNA for the National Birth Defects Prevention Study (NBDPS) heightens the concerns about data linkages, particularly with the newborn genetic screening database (see next page). “Biologic samples (cheek cells) are collected from mother, father and baby to provide samples of DNA” and surveillance data and parent interviews are compiled for approximately 35 categories of birth defects.  

Finally, birth defects registries may also raise moral quandaries. For instance, might data in the registries lead to pressure on parents to terminate a pregnancy if one or more children are already affected by a birth defect, or if the parent’s newborn screening results indicate the possibility of a child born with a genetic defect?

For example, the National Birth Defects Prevention Network’s 2012 report on selected birth defects included the maternal age of mothers who had children diagnosed with trisomies 13, 18, and 21. Florida’s birth defects surveillance reports provide a look at the economic pressures that could lead doctors, government officials, health plans, hospitals, and others to pressure parents to abort a child when a defect is suspected. Florida estimates the costs for just four birth defects in the table below.

As Chuck Colson, former host of a Christian worldview radio commentary called “Breakpoint,” once wrote:

<table>
<thead>
<tr>
<th>Birth Defect</th>
<th>Cases per Year</th>
<th>Hospitalization/repair costs</th>
<th>Annual cost</th>
<th>Lifetime costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spina bifida</td>
<td>70</td>
<td></td>
<td>$636,000/case (“societal”) for a total of $44.5 million per year</td>
<td></td>
</tr>
<tr>
<td>Down’s syndrome</td>
<td>280</td>
<td></td>
<td>$126 million (“medical, non-medical and indirect”)</td>
<td></td>
</tr>
<tr>
<td>Orofacial cleft</td>
<td>290</td>
<td>$21,090 (first two years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastrochisis repair</td>
<td>75</td>
<td>$108,000 (in 1992)</td>
<td>$8.1 million</td>
<td></td>
</tr>
</tbody>
</table>

“As genetic screening and other technologies become increasingly available, the abortion of defective babies goes from being an option to being an explanation — in the name of ‘public health’.”\(^{193}\)

**Newborn Screening Databases**

**Background**

Newborn screening is a government testing program “included in the broader definition of genetic screening.”\(^{194}\) Annually, more than 4 million infants are tested in the U.S. by state health departments for newborn genetic disorders. In 2001, newborn screening programs received 5.3 million blood spot specimens for analysis—33 percent higher than the reported births because 8 programs required two specimens for every newborn.\(^{195}\)

For most babies, the collection of newborn blood takes place between 24 and 48 hours after birth. The newborn’s heel is punctured by a hospital or clinic worker and blood is squeezed from the heel until the drops saturate three to five circular areas on a filter-paper card. These are called newborn dried blood spots (DBS). Basic demographic information — varying from state to state — is recorded on the blood spot card.\(^{196}\)

The card is then sent to the state health department’s laboratory, or a private laboratory under contract with the state, for processing. The results are sent to the baby’s doctor to be recorded in the child’s medical record. The hospital laboratory does not do the actual testing or report the results, and not all states do their own testing. Some states choose to use a centralized laboratory, such as the New England Newborn Screening Program at the University of Massachusetts Medical School, which conducts newborn genetic testing for five New England states.\(^{197}\)

Although the baby’s blood specimen could be destroyed as early as two weeks after the screening as was the former practice in Louisiana,\(^{198}\) state governments increasingly retain the blood spot specimen for secondary purposes — without parent consent. As newborn screening expert Bradford Therrell notes in his paper reviewing the status of state newborn screening programs:

> “Whereas previously these specimens were viewed as primarily useful for program
quality assurance and perhaps as final testing material that could be reanalyzed in cases of late or misdiagnosed conditions, they have become increasingly important as possible sources for genetic research. This is of particular importance because newborn screening specimens represent the most comprehensive population testing program currently in operation, and specimens are obtained from essentially every newborn.\textsuperscript{199}

Newborn screening began in the early 1960s with the intent of decreasing or eliminating the effects of mental retardation.\textsuperscript{200} Special-interest advocacy played a key role in initiating mandatory phenylketonuria (PKU) screening legislation.\textsuperscript{201} This early legislation typically included funding for lab testing and follow-up services, justifying government spending on the basis of preventive care and the resulting reduction of health care expenses.

The scope of newborn screening programs has broadened as scientific and medical knowledge and technology have advanced. The hope of newborn screening proponents is that early diagnosis of genetic conditions will reduce morbidity and mortality.\textsuperscript{202}

Although the HHS Secretary’s Advisory Committee on Heritable Disorders in Newborn and Children make recommendations for newborn genetic screening tests, each state is responsible for the design and implementation of its own newborn screening program. The committee’s uniform screening panel recommends that every newborn be screened for thirty-one core disorders and twenty-six secondary disorders.\textsuperscript{203} The disorders screened for by states are typically established in state statutes or through state regulation, often with the state health department having the authority to change them at their own discretion. State statutes also regulate the following:

- Payment for newborn screening.
- The provision of medical foods for treatment of a disorder.
- Privacy and confidentiality issues.
- Parent education about the screening process.
- Contracting services.
- Lab standards.
- Storage, use, and disposal of blood spots.\textsuperscript{204}

Individual state screening data is ultimately captured by a national system. Through 2012, it was collected by the National Newborn Screening Information System (NNSIS), which was hosted by the National Newborn Screening and Genetics Resource Center (NNSGRC). The NNSIS provided a “…secure, Internet-based, real-time, information collection and reporting system for capturing state and territorial newborn screening information.”\textsuperscript{205}

In 2012, the NNSGRC lost its federal grant. The Newborn Screening Technical assistance and Evaluation Program (NewSTEPs), a Association of Public Health Laboratories (APHL) program funded through a cooperative agreement with the Genetic Services Branch of the federal Health Resources and Services Administration, was then created to provide “quality improvement initiatives, an innovative data repository and technical resources for newborn screening programs.”\textsuperscript{206}

Funding

The Government Accountability Office (GAO) reported in 2003 that states spent over $120 million on newborn genetic screening in fiscal year 2001, with fees covering 64 percent of state expenditures.\textsuperscript{207} Lab expenses accounted for 74 percent of the states’ expenses, while administration and follow-up costs accounted for 26 percent.\textsuperscript{208} A 2007 survey of all 51 newborn screening departments discovered 90 percent of fees are paid by parents or a third
party payer. 209 Furthermore, 61 percent of state programs received some federal grant funds, 33 percent received state appropriations, and 24 percent obtained direct reimbursement from Medicaid. The fee varies significantly from state to state. For instance, in October 2006, the following states charged these amounts:

<table>
<thead>
<tr>
<th>STATE</th>
<th>Newborn Screening Fee, October 2006</th>
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<tbody>
<tr>
<td>Alabama</td>
<td>$139.33</td>
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<tr>
<td>California</td>
<td>$78.00</td>
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<tr>
<td>Florida</td>
<td>$15.00</td>
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<td>Kansas</td>
<td>No fee</td>
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<tr>
<td>New Hampshire</td>
<td>$40.00</td>
</tr>
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<td>New York</td>
<td>No fee</td>
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<tr>
<td>Rhode Island</td>
<td>$110.00</td>
</tr>
<tr>
<td>South Dakota</td>
<td>$99.99</td>
</tr>
<tr>
<td>Texas</td>
<td>$19.50 each screen</td>
</tr>
<tr>
<td>Washington</td>
<td>$67.50</td>
</tr>
</tbody>
</table>

Uses

Newborn screening data consists of identifiable patient and parent demographic details, the child’s dried blood spots on a filter-paper card and the newborn screening genetic test results.

Genetic test development

More blood is collected from the baby’s heel than is typically needed for the testing. When the dried blood spots (DBS) are used for testing, they are “punched,” creating holes of various sizes in the DBS. Health officials and others often consider the unused portions of the blood spots available for secondary uses, such as for validating newborn screening laboratory instruments, developing new newborn screening tests, and assessing genetic connections to disease. 211

Biomonitoring

Additionally, these dried blood spots have recently been recognized as a source for detecting HIV 212 and for biomonitoring – evaluating the newborn’s blood for various substances found in the air, earth, water, and the mother’s home and work environments. Thus, the CDC says it is

“combining its biomonitoring expertise with its newborn screening expertise to examine the possibility of using newborn screening dried blood spots to measure exposure to environmental chemicals, such as pesticides and metals. The benefit of using dried blood spots is that researchers will be able to determine which environmental chemicals are actually in newborns.” 213

The findings could then be used to make certain judgments and push certain policies, whether or not the claims about the harms caused by such chemicals are accurate. There can be significant disagreement among experts. For instance, the FDA banned the use of bisphenol A (BPA) in baby bottles, 214 but the EPA says the exposure levels are much too low to affect the human body. 215

Genetic research

The newborn’s dried blood spots are considered a rich source of DNA. Fully 19 states have laws and regulations that allow researcher access to newborn genetic information with ten states giving specific access to the baby’s blood specimen. 216 Although 33 states have genetic privacy laws, public health agencies that conduct newborn screening are exempt from the law in 22 states. 217 Only one state, Alaska, extends personal property rights to DNA, 218 however the law exempts newborn screening from its protections. 219

Collected from almost every baby, these blood specimens are ideal candidates for use in genetic research, according to newborn screening policy researchers. 220 Newborn screening tests for genetic disorders primarily by testing for various analytes in the newborn’s dried blood spots. But analytes have a short life span of validity: “Stability of other non-DNA biomarkers for [newborn screening] vary with each specific analyte and may start to degrade within a few months.” 221 This leaves the child’s
DNA as the only remaining usable substance in the newborn’s dried blood spots. Researchers note, “Stability studies show that genomic DNA is stable in dried blood spots stored on filter paper at ambient tropical conditions for at least 11 years.”

Example of data collection

There are two types of data collection in newborn screening: the newborns’ dried blood spots and the newborns’ genetic test results.

The child’s dried blood spots are kept for at least one month, with many states retaining them for three to six months. According to our research, in 2012, at least 18 states reported keeping the child’s blood spots for ten years or longer. Some states keep them indefinitely. In a “Proposed ‘White Paper,’” researcher Brad Therrell and his cohorts include the diagram shown above.

States also keep a database of all children’s genetic test results. They may also have a state registry that contains the results of only those children found to have a heritable (genetic) condition. When we initially began this project, we asked state health officials to give us the number of individuals in their newborn screening database. Some provided the number of children tested (database). Others gave the number of children that had tested positive for a genetic condition (registry).

As an example of a registry, the Minnesota state registry of confirmed cases of newborn disorders is maintained by the Minnesota Department of Health. According to state regulations, the registry is updated not more than annually through direct contact with the patient. During this interaction, the health department determines the patient’s address and need for medical treatment services, educational materials, and counseling related to their disease. The minimum data on each patient includes:

- Patient name
- Gender
- Date of birth

• Place of birth
• Parents’ names
• Current address of patient
• Diagnosis
• Name and address of physician
• Other data the commissioner deems necessary for follow-up services.

Controversies
Our organization’s discovery of state storage, use, and sharing of genetic test results and newborn DNA has brought forth national issues of consent, privacy, and ownership. Parents in Texas and Minnesota have filed and won lawsuits against state health agencies for government storage, use, and sharing of newborn DNA. Neither state department of health had legislative authority to do so, and Minnesota law specifically forbids unconsented storage, use and dissemination under the state genetic privacy act. Minnesota law also only allowed storage of test results for the children found with a genetic condition, but the Department had created a database of all children tested. On November 16, 2011, the Minnesota Supreme Court ruled that the state may only store test results for 24 months unless parents provide written consent for longer storage.

Issues of Consent and Privacy
DNA serves as the unique identifier of each individual. In newborn dried blood spots, the individual’s unique identity, indeed the person’s entire genetic code, becomes available for state dissection, assessment, and exploitation. Consent is also important given the fact that “…collections of surplus, stored samples have become immensely attractive to researchers in medical genetics and the biomedical sciences.” Researchers also recognize that removing identifying information
from DNA does not protect the genetic privacy of the individual, saying, “[I]t may become increasingly difficult to deidentify biological specimens in the future.”

In April 2009, two months after our organization helped nine families sue the Minnesota Department of Health, the American College of Medical Genetics and Genomics, which has a federal contract to develop a National Newborn Screening Translational Research Network including a “reliable repository of residual dried blood spots that is either virtual or physical and comprised of those stored by state newborn screening programs and other resources,” claimed the following:

“A very small but very vocal minority has begun to argue for the destruction of residual newborn screening dried blood spot filter cards after screening has been completed. Their arguments are based on unsubstantiated and highly exaggerated privacy concerns. Such destruction of dried blood spots would significantly and negatively impact the quality and development of newborn screening programs.”

However, on November 16, 2011, the nine families won in the Minnesota Supreme Court. A year earlier, Texas families had won their case leading to the destruction of 5.3 million newborn dried blood spot cards.

Studies prove that parents oppose research using newborn DNA without consent. A 2009 study by Dr. Beth Tarini and others was conducted specifically because “a Minnesota advocacy group recently called for stored [newborn screening] samples to be destroyed, claiming these samples had been stored without parental consent.”

The Tarini study, called “Not Without My Permission: Parents’ Willingness to Permit Use of Newborn Screening Samples for Research,” found parents strongly opposed to state government storing or using the baby’s DNA for research without their knowledge or consent. If parent permission were obtained, 76 percent of parents were “very or somewhat willing” to permit use of the child’s DNA for research. If permission were not obtained, only 28 percent were willing. More than half (55.7%) were “very unwilling.”

The lawsuits and growing public awareness and angst over government storage and secondary use of newborn bloodspots also led to a study of all 50 state laws on baby DNA. The 2011 study reported in the journal Pediatrics found that “some states that retain [dried blood spots] may be acting outside the scope of their legal authority,” and reported:

- Fifty states operate newborn screening programs.
- Forty-nine states mandate newborn screening.
- Eighteen states have not addressed state retention of newborn DNA.
- Fourteen states allow release of confidential information without parent consent.
- Forty percent of state health departments retain newborn bloodspots at least a year.
- Four states claim newborn DNA as state government property.
- Eight states require parents be given information about retention of newborn DNA.
- Six states require parent consent in certain circumstances for research using the DNA.
- Three states allow child who become adults to require destruction of their DNA.
- One state prohibits newborn DNA from being used for research purposes.
- No states require parent be informed of the type of research that can be done.
• No states provide a mechanism for parents to find out what research has been done with their child’s DNA.\textsuperscript{236}

The study concludes:

“The maintenance of public trust in these important programs is paramount, yet state laws often are silent with respect to the education of parents about [dried blood spots] and parental control over their retention and use... The lack of transparency on the part of states in retaining [dried blood spots] may undermine the public’s trust in state newborn screening programs and the research enterprise.”\textsuperscript{237}

**DNA Ownership**

DNA ownership is also an issue. The Council of Regional Networks for Genetic Services, writing guidelines for state retention of newborn blood spots, notes:

“Ownership of the DNA in a residual [dried blood spot] is also an issue especially given the current informed consent process used by more programs (i.e., legally required with attention given only to dissent). Without informed consent about specific sample use, DNA ownership and use is an issue. Sample ownership and use may be an issue even with informed consent. Saving [dried blood spots] for use in the identification of a person may ultimately infringe on the rights of the individual.”\textsuperscript{238}

In the wake of the lawsuits over newborn blood spot storage, proponents of state storage and use of newborn DNA have tried another tack, a modified version of government ownership. Some suggest that states be “stewards” of the child’s DNA, keeping it in government storage, but only allowing it to be used or shared with either parent consent or what could be called, “community consent”:

“State [newborn screening] programs are charged with being responsible stewards of these specimens—stewardship is defined as the caretaking responsibility in which responsibilities and policies are clearly defined to ensure appropriate uses of [newborn screening] specimens.”\textsuperscript{239}

“[S]tewardship means taking responsibility for the care and well-being of something that is valued ... It entails the science, art, and skill of responsible and accountable management of resources. A steward assumes responsibility for the donor’s intent, the manner in which resources are used, and the outcomes from their use.”\textsuperscript{240}

“Once an [Institutional Review Board] review is complete, there should be a secondary review by a group more oriented toward stewardship and with a stronger community influence. Review by groups with multiple people who represent the community from which samples have come can make sure that the interests of all stakeholders are represented.”\textsuperscript{241}

These statements are problematic for several reasons. First, there is no “donor” for which stewards can assume intent because newborn screening is a government-mandated testing program. The baby’s DNA has not been donated. It has been taken by the government, using hospital staff, at a time of great physical and mental exhaustion for parents – within forty-eight hours after the birth of a child. Parents have described this period as a “fog.”\textsuperscript{242}

Most parents have no idea the genetic testing was even done.\textsuperscript{243}

Second, members of community groups represent themselves. They neither know nor can assert the preferences of the multitudes of individuals whose DNA has been retained by state government. Furthermore, it is impossible for a small group of decision makers to “make sure that the interests of all stakeholders are represented.” The more than 4 million children born each year and their parents who may not even want the child’s DNA stored or used will
not have their rights respected or protected when DNA is stored under “stewardship.”
Third, anonymized genetic data can be reidentified, and should not be used without the consent of the individual to whom it belongs or of their parents while the child is young.

An Israeli scientist recently proved that he could easily re-identify people whose DNA was used for research using publicly available databases. He called it a “‘wow’ feeling.”

Ann Cavoukian, Ph.D., Information and Privacy Commissioner in Canada once said, “It is impossible to completely anonymize DNA since there is always a means to identifying the tissue or the sample.” This was underscored in a conversation about the use of newborn DNA that took place at a newborn screening workshop in Washington, D.C.:

“[Al] Fleischman and several other speakers raised the issue of whether anonymous samples containing DNA could be linked to individuals. They acknowledged that this could occur. For example, [S] Terry pointed out that additional data could be obtained to link the DNA in an anonymized sample to a particular person and such identification will become increasingly possible in the future. Fleischman observed, however, that creating such linkages would require the use of other databases. Careful data and sample access agreements with researchers can make it inappropriate and unethical for people to make such linkages.”

The Need for Transparency and Consent

The majority of Americans are in at least one of these four surveillance systems. For example, parents of children who are not adopted are typically included in the newborn screening database. Parents’ names and addresses are often included in the vaccination registry. Information on mothers is also in the birth defects registry. And almost every newborn is included in the newborn screening and vaccination databases, perhaps for life. Yet these systems are only four of many more surveillance systems being built by state agencies, primarily with federal dollars.

The need for transparency is great. The public does not yet realize that having a medical condition may mean individuals become involuntary subjects of government tracking and analysis. The public does not know that their medical records or their children’s medical records could have been used for medical and genetic research, and in some cases, their DNA used, shared or sold for analysis— all without their consent. Most American do not yet know about the Nationwide Health Information Network funded through the American Recovery and Reinvestment Act of 2009, an act that will force their doctors and hospitals to use interoperable medical records accessible under the federal law to 2.2 million entities nationwide.

The public has a right to know. Protection against government intrusion was deemed so important that various Amendments to protect privacy were added by the Bill of Rights to the Constitution of the United States.

Government agencies, with private data in hand, can build patient profiles, even genetic
profiles. Furthermore, in the future, health officials may use a patient’s private data to restrict certain access to care if medical records indicate a persistent unwillingness to submit to government-endorsed vaccinations, a history of unhealthy behaviors or ongoing engagement in unhealthy lifestyles, such as smoking, drug use, overeating, or a failure to exercise. For example, the Patient Protection and Affordable Care Act of 2010 (“Obamacare”) requires federal officials to gather outcomes data “from employers who provide employees with access to wellness programs.”\textsuperscript{254}

As the public learns about government patient tracking and health surveillance, hospitals and clinics may be seen as intrusive arms of the government’s data collection process rather than caring and trusted institutions. Thus, government health surveillance through state and federal reporting mandates threatens to diminish patient trust and violates the freedom and privacy rights of all Americans.

As government lays hold of the most private of individual data, patients may also lose access to the full realm of private medical choices. Their willingness to engage with the health care system may be limited by their unwillingness to give up their privacy rights. A 1999 study found 15 percent of Americans already engaged in privacy-protecting behaviors that compromise their access to timely and accurate medical care.\textsuperscript{255}

**Summary**

Health surveillance is a significant and ever-expanding activity of state public health agencies, yet few people realize these patient-tracking systems exist. Although this report details four surveillance systems across the country, these systems are just a subset of the vast array of public health surveillance systems now in place and expanding primarily as a result of federal funding.

Using laws, regulations, and electronic access to medical records, government health officials are daily collecting personal data on individuals and families without the knowledge or consent of subjects.

As a result of birth, illness or injury, individuals have become the unwitting subjects of government surveillance. They have no choice and there is little to no public notice of this infringement on their privacy rights. Often, even if the law gives them the right to opt-out, they are:

1) not told they are “in” the system;
2) not told they have a choice to get out of the system; and
3) not told that if they opt-out, the government retains a permanent record of their choice.

Until individuals know about the vast array of health surveillance systems, they cannot protect themselves or take the necessary action to stop government data collection and analysis and sharing. Protective actions could include advancing state legislation to limit the permissive sharing under HIPAA and to require informed written consent. This report uses research, tables of statutes, and a 50-state chart of raw data gathered from official sources to inform the public about the hidden health surveillance systems that currently allow government intrusion into the private lives of individuals in the name of “public health.”

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Appreciation to Sandra Raup, a team of interns from The Heritage Foundation, Patrick Henry College and CCHF who assisted with the original efforts to secure data from state health department personnel or helped with the final organization of the health surveillance charts found at http://bit.ly/HealthSurveillanceReport.

For Endnotes, see next page.
endnotes


2 "Because of the automation of clinical data — inpatient and increasingly outpatient — via the Electronic Health Record Systems (EHRs), public health programs stand at the threshold of change in the way in which they gather programmatic data. … 'Many public health agencies are examining their existing information systems and seeking to improve their ability to support programmatic needs to detect, assess, and respond to a range of threats to the public, including infectious diseases, pandemics, such as avian flu, bioterrorism, and chronic diseases such as obesity, diabetes and asthma.' … Electronic transmission of data from the clinical care settings to public health agencies via EHR systems is essential to (1) support key public health functions and services and (2) supply public health data repositories, e.g., registries, research databases, etc., for aggregated analysis of the health status of populations. Provision of real-time aggregated community-level information back to providers — bi-directional EHR-based data exchanges between public health practitioners and clinicians — will inform clinical decision support, improve care coordination and response capabilities to a public’s health threat event. The integrated Electronic Health Record-Public Health (EHR-PH) systems will become the backbone of a NHIN and regional HIEs.” SOURCE: IHE Task Force, "Building a Roadmap for Health Information Systems Interoperability for Public Health (Public Health Uses of Electronic Health Record Data)," Public Health Data Standards Consortium, 2007. Accessed June 17, 2013. http://www.ihe.net/Technical_Framework/upload/IHE-PHDSIC_Public_Health_White_Paper_2008-07-29.pdf.


11 Oath of Hippocrates.


13 Ibid.


17 Ibid.


Ibid.


73 Ibid.

74 Ibid.


87 Ibid.


105 Ibid.
110 Ibid.
111 Ibid.
119 Ibid.
Patient Privacy and Public Trust: How Health Surveillance Systems Are Undermining Both


168 Ibid.

169 Ibid.

170 Ibid.


176 Ibid. p. 1.


Appendix A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

The Assistant Secretary for Planning and Evaluation
Washington, D.C. 20201

JUL 26 2005

Twila Brase, R.N.
President
Citizens’ Council on Health Care
1954 University Avenue W, Ste. 8
St. Paul, Minnesota 55104

Dear Ms. Brase:

Secretary Leavitt has asked me to thank you for informing us about your latest survey project: Privacy and Public Awareness of State Health Databases. I understand that this type of survey concerning public awareness about State health data bases has never been done before. As such, your survey should provide original and informative State level perspectives as we move forward on the President’s health information technology initiative.

As you know, HHS considers privacy protection as an essential focus in national health information technology deliberations. Consequently, I am pleased to lend our encouragement and support for your State health database awareness survey project and look forward to its results. I am also sharing a copy of this letter with the Centers for Disease Control and Prevention, which regularly communicates with State health officials.

Thank you for taking the time to bring this information to the Secretary’s attention. I look forward to the results of your study as we continue to examine the best ways to protect the privacy interests of patients while bringing information technology into the health care system.

Sincerely,

Michael J. O’Grady, Ph.D.
Assistant Secretary for Planning and Evaluation

cc: Director
Centers for Disease Control and Prevention
Appendix B

CITIZENS’ COUNCIL ON HEALTH CARE
Privacy and Public Awareness of State Health Databases Project

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
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<td>STATE NAME OF DATABASE START YEAR YEAR THE DATABASE BEGAN CURRENT NUMBER OF INDIVIDUALS IN THE DATABASE ARE INDIVIDUAL NAMES COLLECTED? (Y/N) IF SO, ARE INDIVIDUAL NAMES INCLUDED IN THE DATABASE? (Y/N) STATUTORY OR REGULATORY AUTHORITY FOR DATABASE HAS THERE BEEN A BREACH OF PRIVACY IN THE DATABASE? (data sold, hacked, placed online, etc; internal breach or external breach) IF SO, WHEN? ARE YOU REQUIRED TO NOTIFY ALL PERSONS IN THE DATABASE IF THERE IS A BREACH?</td>
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Comments:

Data Completed ____________________________
Name of Person Completing the Survey ____________________________
Title ____________________________
Department ____________________________
Phone Number ____________________________
Email ____________________________

CITIZENS’ COUNCIL ON HEALTH CARE
Privacy and Public Awareness of State Health Databases Project

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CITIZENS' COUNCIL ON HEALTH CARE
Privacy and Public Awareness of State Health Databases Project

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<td>RS 40:1299.1 IAC 48: V. 6303</td>
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Comments:
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Title: Unknown
Department: Newborn Screening
Phone Number 319-441-4413
Email: charlie@dhc.legis
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<td>IS THERE A SPECIFIC GOVERNMENT FORM FOR THE PARENT OR PATIENT TO SIGN? (Y/N)</td>
<td>IS NOTIFICATION OF PATIENTS AND PARENTS REQUIRED? (Y/N) (notified that they, or their data have or will be placed in the database)</td>
<td>IF YES, WHAT IS THE SPECIFIC MECHANISM FOR PARENT/PATIENT NOTIFICATION? (clinic notice, postcard, letter, phone call, etc.)</td>
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<td>no</td>
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**Comments:**

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Title ____________________________
Department ____________________________
Phone Number ____________________________
Email ____________________________