

Consumer Protection Review of CIIS

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Case Presentation

- Consumer protection
- Cost & Benefit analysis
- Evidence-based research
- Privacy & Security
- Legislative history

What is CIIS?

Colorado Immunization Information System (CIIS) is a database that tracks vaccine uptake on individuals. It is promoted as a service to the public health.

Let's compare it to a database that tracks the maintenance on a vehicle. Both vaccines and vehicle safety are public health issues. We have standards for vehicle safety like we have standards for public health. For example, you cannot drive a car with a flat tire or inoperable lights.



Comparing Consumer Protection Across Industries

CIIS: Vaccine Tracking	Auto Maintenance Program
You can opt-out, but not really	You opt-in, leave at any time
State level data	Local dealership of your choice
Funded by state, not doctors	Paid for by private sector & consumers
Sensitive data shared with CORHIO	Data not shared with other car dealerships
Poised to share data federally with CDC	Data not shared with federal agency
Potential to violate FERPA	No violation of federal privacy laws
Does not provide recalls or alerts on hot lots	Provides recall notices & replacement parts
Includes coercive methods for uptake	No coercion: your choice, your timeline
Newborn screening & genetic tests included	No DMV involvement for compliance

Top 10 Consumer Concerns of CIIS

1. Opt-out system
2. Lack of transparency
3. Taxpayer funding
4. CORHIO sharing
5. CDC federal database
6. Circumvents FERPA
7. No recall notifications
8. Coercion Interventions
9. Personal data mining
10. Beyond authority in statute

When asked why CIIS is opt-out,
Rep. Dan Pabon, HB16-1164 responded,



“Because no one would opt-in.”

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

**Patient Privacy and Public Trust: How
Health Surveillance Systems Are
Undermining Both**

Twila Brase, President, Citizens' Council
for Health Freedom, August 2013

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.

FDA is not safety testing & conducting product recalls

Special Report: Powder Keg - FDA bowed to industry for decades as alarms were sounded over talc - Reuters Dec. 3, 2019



“Over the past 50 years, the FDA has relied upon - and often deferred to - industry even as outside experts and consumers repeatedly raised serious health concerns about talc powders and cosmetics, a Reuters investigation found.”

A criminal investigation and \$5 billion in jury verdicts against Johnson & Johnson found carcinogenic asbestos in 11 talc-based products, including Johnson’s Baby Powder, first detected in 1971. J&J recalled 33,000 bottles, voluntarily.

The FDA’s written report stated it has no power to ensure product safety nor can it force companies to recall products when potential hazards are discovered. “We are dependent on manufacturers to take steps to ensure the safety of their products,” the FDA said.

16,000 lawsuits are pending in 2019.

Other countries have vaccine recalls, but not in the US

Big Pharma and Big Profits: The Multibillion Dollar Vaccine Market

New Report says “Vaccine Market”
Worth \$61 Billion by 2020



“Vaccines are the only products in the U.S. that do not have liability. You cannot sue for injuries or death. But that is only in the U.S. Around the world, there are law suits because of serious injuries and deaths from vaccines. In Spain over **Gardasil**. In Japan over **Gardasil**. The **flu shot** was taken off the market for under five in Australia after deaths and injury. **Pfizer’s** vaccination program was kicked out of the country. France just pulled **Rotavirus** off their schedule after infant deaths and injuries.”

Coercion – Home Visits

- Home visitors assess clients' vaccination status, discuss the importance of recommended vaccinations, and either provide vaccinations to clients in their homes or refer them to other services. Home visits may be conducted by vaccination providers (e.g., nurses) or others (e.g., social workers, community health workers).
- Interventions may be directed to everyone in a designated population (e.g., low-income single mothers), or to those who have not responded to other intervention efforts, such as client **reminder and recall systems**.

<https://www.thecommunityguide.org/findings/vaccination-programs-home-visits-increase-vaccination-rates>



CIIS costs

\$1.5 Million/per year

from the Colorado state budget

- + CDC Grant \$720,000 in 2011
 - + CDC Grant \$799,957 in 2012
 - + CU Denver/AHRQ grant \$55,000 annually since 2011
 - + Colorado Health Foundation \$26,000
- (not a complete funding list)

CIIS Data Collection

- Vaccines for all ages
- Insurance source
- Language
- Employment information*
- Medical home information
- School enrollment
- Targeting interventions

<https://teamvaccine.com/2019/07/31/how-does-the-colorado-immunization-information-system-ciis-benefit-colorados-public-health-efforts/>

CIIS Data as of Feb. 2019

- 6.1 million people
- 91% of Coloradans
- 1468 practices

CDPHE Brief: Immunizations, exemptions, and vaccine hesitancy



Recent Use of Data

Primary use

- Data at the county level
(% of immunization rates)

Targeting

- Hep A
- Pregnant women*
- Medicaid populations
- Recall: ages 9-12 months, ages 19-35 months, HPV vaccine

<https://teamvaccine.com/2019/07/31/how-does-the-colorado-immunization-information-system-ciis-benefit-colorados-public-health-efforts/>

	"Safety and effectiveness of FLUVIRIN® have not been established in pregnant women, nursing mothers "
	"There are insufficient data on FLULAVAL QUADRIVALENT in pregnant women to inform vaccine associated risks"
	"Available data on Flublok Quadrivalent and Flublok (trivalent formulation) administered to pregnant women are insufficient to inform vaccine-associated risks in pregnant women."
	"Safety and effectiveness of FLUARIX have not been established in pregnant women or nursing mothers."
	"There are insufficient data for FLUCELVAX QUADRIVALENT in pregnant women to inform vaccine-associated risks in pregnancy."
	"Available data with Fluzone Quadrivalent use in pregnant women are insufficient to inform vaccine-associated risk of adverse developmental outcomes"
	There are insufficient human data o establish whether there is a vaccine-associated risk with use of FLUAD in pregnancy
	"There are limited data for AFLURIA QUADRIVALENT administered to pregnant women, and available data for AFLURIA (trivalent formulation) administered to pregnant women are insufficient to inform vaccine associated risks in pregnancy."

<https://thehighwire.com/flu-shot-pushed-on-pregnant-women-despite-unanswered-safety-risks/>

Sharing of CIIS Data

- Medicaid
- HCPF
- WIC
- School-based health centers
- Refugee Health
- Child Fatality Prevention System
- Vaccines for Children

HIPAA notice: A permission slip for the government to disclose medical information without transparency

<https://teamvaccine.com/2019/07/31/how-does-the-colorado-immunization-information-system-ciis-benefit-colorados-public-health-efforts/>

No “Confidentiality” between doctor and patient

- The individual or parent/guardian of the individual
- The individual’s healthcare provider
- A school, childcare center or university where the individual is enrolled
- A managed care organization or health insurer where the individual is enrolled
- Hospitals
- Persons or entities who have an agreement or research contract with the state for immunizations
- The Colorado Department of Health Care Policy and Financing for individuals eligible for Medicaid
- Medical and epidemiological information can be released in a manner so that no individual person can be identified
- To the extent necessary for the treatment, control, investigation, and prevention of vaccine preventable diseases in the minimum amount necessary

Incentives and Recruitment to use CIIS

- Colorado AAP¹
- Colorado AAFP¹
- Schools and child care centers¹
- Meaningful Use: \$1.5 Billion EHR Incentive Program renamed “Promoting Interoperability”²

Objectives	Measures	Points
e-Prescribing	e-Prescribing***	10 points
	Query of PDMP	5 points (bonus)
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information****	20 points
	Support Electronic Referral Loops by Receiving and Incorporating Health Information****	20 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Report to two different public health agencies or clinical data registries for any of the following: Immunization Registries Reporting** Electronic Case Reporting** Public Health Registry Reporting** Clinical Data Registry Reporting** Syndromic Surveillance Reporting**	10 points

1. <https://teamvaccine.com/2019/07/31/how-does-the-colorado-immunization-information-system-ciis-benefit-colorados-public-health-efforts/>
2. <https://www.cdc.gov/vaccines/programs/iis/meaningful-use/index.html>



Accuracy

- Duplicate and Fragmented records
- No process to inactivate people who have moved on gone elsewhere (MOGE)
- Schools & daycares are required to report more accurate infectious disease with currently enrolled students <https://www.sos.state.co.us/CCR/GenerateRulePdf.do?ruleVersionId=8099&fileName=6%20CCR%201009-1>
- County level data is not accurate <https://www.colorado.gov/pacific/cdphe/ciiscountylevel>

Immunization Coverage Rates

Immunization coverage rates are calculated based on the data reported to CIIS. As participation in CIIS is voluntary, rate calculations may be based on incomplete data. If there are significant numbers of patients and/or immunizations missing in CIIS, it will impact the results. The immunization rates calculated may not accurately reflect the true rates in your county. According to national guidelines, a minimum of 85% of providers in the county must submit data to the registry, and 85% of patients living in the county must have records in the registry, in order to use registry data to accurately estimate county-level immunization rates. Most counties do not have all providers reporting to CIIS, so it is likely that the immunization rates generated out of CIIS underestimate the actual county rates.

Per Colorado's 2012 Immunization Information System Annual Report to the CDC:

- 66 percent of enrolled public provider sites reported data to CIIS from July 1 – December 31, 2012
- 41 percent of enrolled private provider sites reported data to CIIS from July 1 – December 31, 2012
- 76 percent of enrolled VFC provider sites (regardless of private/public designation) reported data to CIIS from July 1 – December 31, 2012

*Data in the vaccination registry
only agreed with data in
the child's medical record in
59 percent
of cases examined.*

Is CIIS Evidence Based?

The state is required to implement evidence-based programs. **Research does NOT support that CIIS improves public health.**

- A 2015 Economic Review of IIS (Patel et al) found no actual benefit to public health measured by reduced morbidity and mortality, at the cost of \$2.4 million to \$7 million dollars over five years to the state. A cross-sectional study conducted in the United States, evaluated the association between practice use of an IIS and likelihood of children being up-to-date. ¹
- A 2015 Systematic Review of IIS (Groom et al) found that IIS had no performance measures or deliverables for public health, and **practices using IIS did not have significantly higher vaccination rates than those practices not using an IIS.**²

1. https://journals.lww.com/jphmp/Fulltext/2015/05000/Economic_Review_of_Immunization_Information.4.aspx

2. <https://www.thecommunityguide.org/sites/default/files/publications/vpd-jphpm-evrev-IIS.pdf>

Privacy Concerns

- Electronic Health Records have better HIPAA privacy than CIIS
(Remember the long list of agencies CIIS shares data with?)
- HIPAA applies to CIIS, but allows sharing without knowledge or consent.
- No true opt out.
 - “All information about an opted out individual is purged from the CIIS database except: first name, last name, gender, date of birth, city, county, state and zip code.” – Lynn Trefren, CDPHE
- Personally Identifying Information (PII)
- FERPA privacy protections only apply to publically funded schools

***“Utilization of the
functionality is hindered by
the burdensome
requirement of having to
enroll students one at a time
within the system.”***

-Heather Roth
Deputy Immunization Branch
Chief at CDPHE

Security Concerns

The Governor's Office of Information Technology (OIT) hosts and manages CDPHE's three information systems that were under review during a 2017 audit.

The findings:

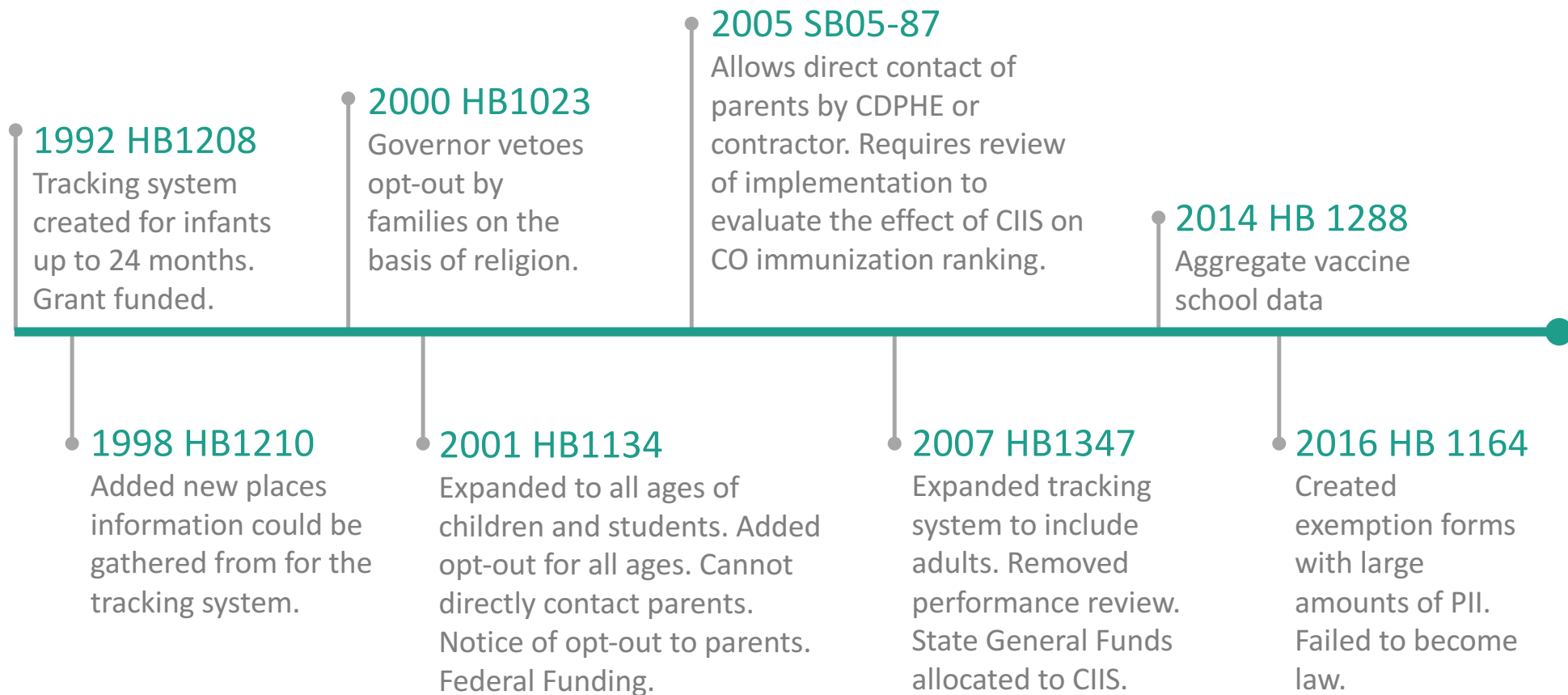
1. The three information systems did not comply with multiple Colorado Information Security Policy (CISP) and OIT Cyber Policy requirements, and did not comply with several best practice recommendations.
2. Security controls implemented for these three systems did not comply with all State policy requirements and need to be remediated to ensure the protection of the confidentiality, integrity, and availability of these systems and the data they maintain.
3. Data protection: We identified control weaknesses indicating OIT was not fully compliant with some requirements related to data protection.
4. CDPHE IT policies are out of date. Twenty-two of the sample of 24 CDPHE agency-wide IT policies we examined had not been reviewed or updated by CDPHE management in over one year, and did not include, explicitly or by reference, current CISP and OIT Cyber Policy requirements.
5. Information System Security Software: We identified control weaknesses indicating OIT was not fully compliant with some requirements related to system security plans.
6. HB 1288 required 25-4-910. (1) THE DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT, IN CONSULTATION WITH OTHER STATE DEPARTMENTS, SHALL ESTABLISH A JOINT POLICY ON IMMUNIZATION DATA COLLECTION AND SHARING. **However that never happened.**

Security Concerns – Why Did These Problems Occur?

1. OIT management stated that it does not have sufficient resources to fully manage all CDPHE applications.
2. OIT management represented that OIT does not have sufficient program level knowledge to manage all its functions.
3. OIT lacks formalized processes to implement CISPS and HIPAA requirements.
4. CDPHE management stated that it was not aware that agency-wide policy and procedures must adhere to current CISP.
5. CDPHE policies and procedures are not periodically reviewed.

The auditor agrees, as noted within the body of this report, **that CDPHE maintains it is not required to adhere to HIPAA, but reiterates that the agency endeavors to maintain HIPAA compliance** in practice given the sensitive nature of the data entrusted to the agency. Therefore, the sensitive data in CDPHE systems are at an increased risk to exposure that violates HIPAA requirements if formalized processes do not include HIPAA requirements. Additionally, it should be noted that the Governor's Office of Information Technology agreed to the recommendation to make technical database changes to meet HIPAA requirements as noted in the response for recommendation 7a of the confidential report.

Legislative Timeline



Surveillance or Coercion?

“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;
- The use of such scores to financially penalize doctors; and the potential refusal of health plans to cover an unvaccinated or under-vaccinated individual.”

SWOT Analysis

Strength

CIIS serves vaccine providers with highly individualized data for targeted sales, inventory, reordering.

“CIIS enjoys strong support among Colorado vaccine providers.” *CIIS Environmental Scan, 2013, page 6*

Weakness

CIIS has no consumer protection functions.

CIIS costs millions of dollars for redundant data collected in aggregate at schools with better accuracy & privacy.

Opportunities

IIS has underutilized functions (section 12) to identify patients & providers who received a recalled vaccine, and functions (section 13) for training, access, and support for investigating reactions within the Vaccine Adverse Reactions System (VAERS). It is likely the Incentives function (section 18) is in direct conflict with reporting reactions.

Threats

CIIS is a security threat to sensitive data & has coercive interventions for targeting people.

“Confidentially” claims are used in a misleading way, and most people would not opt in.

Patient Privacy and Public Trust: How Health Surveillance Systems Are Undermining Both, 2013

Thank you.