

Panel 3: Interim Charge #8

Senate Health and Human Services Committee
February 24, 2010

Presentation by Dawn Richardson
Parents Requesting Open Vaccine Education

<http://vaccineinfo.net>

Charge #8 - Study the state's ability to appropriately respond to the H1N1 influenza pandemic by examining issues related to vaccine distribution and capacity. Consider the benefit of providing the state's independent school districts and various health authorities with standardized protocols for issues including, but not limited to, vaccine administration, absenteeism and the cancellation of school and other school-related events. Assess the state's ability to track and record H1N1 vaccinations through the ImmTrac registry, and review statutes governing ImmTrac to increase the effectiveness and efficiency of immunization information systems.

Issues Related to H1N1 Vaccine Distribution and Capacity

- Delay: Difficulty getting vaccine in the beginning
- Oversupply: Huge waste with unused H1N1 vaccine
 - “In just a couple months, the availability of the H1N1 vaccine has gone from scarce to excess. That prompts another question: what to do with unused vaccine as it reaches its expiration dates?”
 - Texas received almost 693,000 doses from Sanofi Pasteur that have already expired.
 - San Antonio is shipping excess to Haiti

H1N1 Vaccine: From Scarce To Surplus, by Marilyn Moritz, KSAT News, February 12, 2010.
<http://www.ksat.com/health/22551962/detail.html>

Issues Related to H1N1 Vaccine Distribution and Capacity

- Very Low Demand:
Only 2% of Texans received H1N1 Vaccine in 2009
 - 24,326,974 Texans
 - 10,500,000 doses allocated to Texas <http://texasflu.org>
 - Just over 400,000 vaccines administered
(<http://cdc.confex.com/cdc/nic2010/webprogram/Paper22836.html>)
- Some Texas health care workers are forced to resign or are fired for not wanting to take H1N1 vaccine
<http://www.statesman.com/news/local/nurse-fired-over-refusal-to-get-flu-shot-168154.html>
 - Labor code amendment needed to prevent job discrimination on vaccination status

Issues Related to H1N1 Vaccine Distribution and Capacity

- Recommendation: To prevent so much waste and save money, the registry should be adapted to better gauge demand and distribution for state vaccine orders
 - Use data showing registry participants' past vaccine use to better estimate future demand
 - Patients at vaccine administration sites can use the registry to “pre-order” vaccines they want so Texas doesn't end up disposing millions of unwanted and unused shots

From: Kelly Ross

Sent: Tuesday, February 23, 2010 4:42 PM

To: 'Dawn Richardson'

Subject: From Kelly

On November 13th at 10 AM, I received the H1N1 vaccine mandated by my employer. Less than an hour later is when it all began. I was lethargic, uncoordinated, confused, and finally sent home from my job as an operating room nurse. Not only did I sleep the whole weekend, I arrived back to work on Monday with the exact same symptoms and was immediately sent home, only I don't recall even driving home. The next day, I was taken to the emergency room and admitted to ICU with stroke-like symptoms. I was transferred to another facility for more advanced care after an ICU physician told my family that there had been cases of encephalitis reported after getting the H1N1 vaccine. After an exhaustive attempt at several diagnoses (none of which were conclusive) I was sent home 7 days later with residual left sided weakness. The following morning, I had a 15 minute witnessed partial seizure at home with an ensuing 14 hour postictal period. Again, I was sent by ambulance to the hospital for another 3 day stay with the final diagnosis being new onset seizures.

Two Fridays ago, I had a seizure at work after being called in at night. Since then, I was all but accused of being on drugs at work. A drug-test came up negative, yet I was suspended with the threat of termination and notice that this could impact my nursing license. I had no alternative but to resign from the place I worked for 10 years. Ten years, without a single incident, and I was dismissed, just like that. Next week, I'm being re-admitted to the hospital for EEG monitoring and to have a seizure induced. This isn't what I had planned. I didn't really want the vaccine. I wasn't sure it was safe, but it was mandated by my employer who has already fired other employees who have refused to take the vaccine or wear a mask.

Mine is but one story out of thousands. People are getting this vaccine and getting sick, the very thing vaccines are supposed to prevent. I would have rather taken my chances making my OWN healthcare decisions instead of having them made for me with the end result being a health condition that has changed my entire life and turned it upside down. And in the end, I'll be glad to get fired...if I don't have to take one more shot.

Kelly, Registered Nurse

Dawn, you have my authorization to use this statement in any way you see fit. I hope it helps, even if it's just a little...even if ONE person drops their mouth open when they hear this.

Vaccine Administration in Schools is Problematic

- Kids vaccinated in schools without and against parental consent
 - Ohio Boy Given H1N1 Vaccine Against Mom's Wishes
<http://www.foxnews.com/story/0,2933,570214,00.html>
 - In Misstep, Schools Vaccinate 2 Without Parental Consent
<http://www.nytimes.com/2009/10/30/nyregion/30swine.html>
- Quality Control Issues
 - Massachusetts teachers sickened due to H1N1 Vaccine mix-up in school vaccine clinic (given insulin by mistake)
<http://www.theswellesleyreport.com/2010/01/schofield-teachers-sickened-due-to-h1n1-vaccine-mixup/>

Vaccine Administration in Schools is Problematic

- Schools aren't kids' doctors – they don't know reaction or allergy history of students
- School clinics can be disruptive to the educational process
- Schools are for educators, not vaccinators
- Liability issues for school and state (failure to recognize a vaccine reaction and provide medical help)

Review of Statutes Governing ImmTrac to Increase Effectiveness and Efficiency

Trust Issues

- “IIS are successful only to the extent that they maintain the trust of participants”

Immunization Registry Strategic Plan 2002-2007, Immunization Registry Support Branch, National Immunization Program, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, p. 15. <http://www.cdc.gov/vaccines/programs/iis/activities/downloads/strat-plan.pdf>

- Data breaches are a huge problem in this country
 - According to Privacy Rights Clearinghouse, since January 2005, the U.S. has experienced 261,441,493 breaches (as of May 4, 2009):
<http://www.privacyrights.org/ar/ChronDataBreaches.htm#CP>
 - 12 percent of data breaches occurred with medical organizations
<http://forhealthfreedom.org/Newsletter/May2009.html#Article1>
 - PROVE has been contacted many times by parents who are harassed by the registry who never gave consent and are against being included
 - Opting out is a euphemism for data breaching

February 23, 2010

To Whom It May Concern:

My name is Kimberly Lloyd and I would like to go on record as being against changing the Texas Immunization Registry from opt in to opt out. As a parent, I know my rights regarding Immtrac. I actually worked as an aide for a state representative years ago when issues with Immtrac were brought out. More recently, I have worked at a pediatric doctor's office where we are required by law to receive written consent from a parent in order to enter their child's immunizations into the registry.

However, knowing my rights and actually declining consent two times were not enough to keep my son out of Immtrac. I found out he was in it by receiving not one but two letters from the Hays County Personal Health Department stating that they did not have all of my son's immunizations in their record and would I please help them resolve this matter. Needless to say, I was more than a little shocked and angry to find out that my child had been put into the registry illegally. Furthermore, nothing on the letter stated anything about it being an opt in program, and nothing stated how I could remove my child if he had been put in the registry by mistake. It actually took really looking through the Immtrac website before I was able to find anything about removing my child.

In conclusion, I believe that parent's rights should be respected and in this case it means following the law as it has been written. Based on my case alone, it is obvious that the Health Department is not doing their job properly. My concern is not only for my own children but for other Texas families, who do not know what their rights are, who are put into Immtrac without their consent. I strongly believe that changing it to an opt out program would only create more chaos and confusion.

Respectfully,

Kimberly Lloyd

Trust Issues

- Incomplete vaccination records cause punitive actions
 - Parents being thrown out of pediatric doctor offices
 - Insurance coverage being denied
 - Kids with legal exemptions still harassed and bullied at school
- PROVE has been contacted parents who got their child H1N1 vaccine who did not want to be in the registry and are angry that they were put in automatically and can't get out for 5 years
- Overarching concerns that efforts to expand registry into a government electronic medical records database will lead to tighter government control of private medicine – the debate consuming Congress right now

Trust Issues

- Health Department causes repeated breeches of public trust
 - Caught initiating registry years prior to legislative authority given in 1997
 - Caught Populating Registry with non-consented records against law (HB 3054) (we even found a record for my child)
 - Caught warehousing unconsented baby DNA from Newborn Screen and Sued Parents Sue Texas Health Dept. and Texas A&M over Infant Blood Databank
<http://www.texascivilrightsproject.org/?p=1096>
 - Texas Tribune catches Health Department sending unconsented baby DNA to Military
<http://www.texastribune.org/stories/2010/feb/22/dna-deception/>

Recommendation

- Tighter legislative controls are needed on agency behavior regarding consent, privacy and use of health records

Registry Consent

- Even CDC and NVAC Committee Say Parents Should Choose Participation
 - “It is essential that once a parent or guardian has been notified of the existence of the registry, he or she has the ability to choose whether or not to participate in the registry. NVAC specifically recommends that parents must be given the option to decide whether or not their children will participate in a registry.”

Centers for Disease Control Community Immunization Registries Manual, Chapter 2: Confidentiality, Section 4: Choice, p. 17, February 2000.
<http://www.cdc.gov/vaccines/programs/iis/pubs/downloads/cir-manual/cirman2.pdf>

Methods Used for Obtaining Registry Consent

- From registry inception 1997 until 2005 (HB 3054):
 - on the vaccine information statement at the vaccine provider
 - on the birth certificate application form
- From 2005 until present (HB 1921):
 - Birth certificate application process
 - Only for a new person who never gave registry consent at birth, the vaccine provider would be contacted by the health department to figure out if the person wants in
 - Parent can send in consent

Consent Guidelines for Providers



CONSENT GUIDELINES for PROVIDERS

WHEN to Obtain Parental Consent for ImmTrac Participation

Providers need **ONLY** obtain written parental consent for Registry participation IF the child is not already enrolled in ImmTrac. *Performing a "Smart Search" in ImmTrac will help determine if the child is currently participating in ImmTrac.*

- Parental consent for Registry participation is required only one time and is valid until the child reaches 18 years of age or consent is withdrawn by the parent, legal guardian or managing conservator.

NOTE:

A majority of Texas newborns are enrolled in ImmTrac during the birth registration process.


http://www.dshs.state.tx.us/immunize/docs/consent_guidelines.pdf

Highlights: Health department secures consent from majority of newborns at birth so providers only check consent on new vaccinations if the health department can't find a child already in ImmTrac, and consent only has to be gotten once!

How Records and Consent Flow

- Consent collected at birth and registry file opened on child
- Registry education is in the paperwork

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
IMMUNIZATION REGISTRY (ImmTrac)
NEWBORN REGISTRATION FORM



(Please print clearly)

Child's Last Name

Child's First Name

Child's Date of Birth / / *Newborn only

Mother's First Name

Mother's Street Address

City

For Clinic/Office Use

Child's Middle Name

Child's Gender: Male Female

Mother's Maiden Name

Apartment # Telephone

State Zip Code County

ImmTrac, the Texas immunization registry, is a free service of the Texas Department of State Health Services (DSHS). The immunization registry is a secure and confidential service that consolidates and stores your child's (under 18 years of age) immunization records. With your consent, your child's immunization information will be included in ImmTrac. Doctors, public health departments, schools and other authorized professionals can access your child's immunization history to ensure that important vaccines are not missed.

The Texas Department of State Health Services encourages your voluntary participation in the Texas immunization registry.

Consent for Registration of Child and Release of Immunization Records to Authorized Entities

I understand that, by granting the consent below, I am authorizing release of the child's immunization information to DSHS and I further understand that DSHS will include this information in the state's central immunization registry ("ImmTrac"). Once in ImmTrac, the child's immunization information may by law be accessed by:

- a public health district or local health department, for public health purposes within their areas of jurisdiction;
- a physician, or other health care provider legally authorized to administer vaccines, for treating the child as a patient;
- a state agency having legal custody of the child;
- a Texas school or child care facility in which the child is enrolled;
- a payor, currently authorized by the Texas Department of Insurance to operate in Texas, regarding coverage for the child.

I understand that I may withdraw this consent to include information on my child in the ImmTrac Registry and my consent to release information from the Registry at any time by written communication to the Texas Department of State Health Services, ImmTrac Group – MC 1946, P.O. Box 149347, Austin, Texas 78714-9347.

Please mark the appropriate box to indicate your choice.

I **GRANT** consent for registration. I wish to **INCLUDE** my child's information in the Texas immunization registry.

I **DENY** consent for registration. I wish to **EXCLUDE** my child's information from the Texas immunization registry.

Parent, legal guardian or managing conservator: _____


Printed Name

Date _____ Signature _____

PRIVACY NOTICE: With few exceptions, you have the right to request and be informed about information that the State of Texas collects about you. You are entitled to receive and review the information upon request. You also have the right to ask the state agency to correct any information that is determined to be incorrect. See <http://www.dshs.state.tx.us> for more information on Privacy Notification. (Reference: Government Code, Section 552.021, 552.023, 559.003 and 559.004)

Questions? (800) 252-9152 • (512) 458-7284 • www.ImmTrac.com ImmTrac NB-2 Stock No. P11-11936

Texas Department of State Health Services • ImmTrac Group – MC 1946 • P.O. Box 149347 • Austin, TX 78714-9347 Revised 07/22/08



BIRTH REGISTRARS – Please enter newborn client information in Texas Electronic Registrar and **affirm** that consent has been granted. **DO NOT** fax to DSHS. Retain this form in the client's birth record.

Identifying Consent Preferences at Birth Very Successful

ImmTrac Newborn Consent Process Analysis

2009 Performance Analysis Nov 2008-Aug 2009
Birth Centers ≥ 12 Birth per Quarter (avg)
Sorted by County

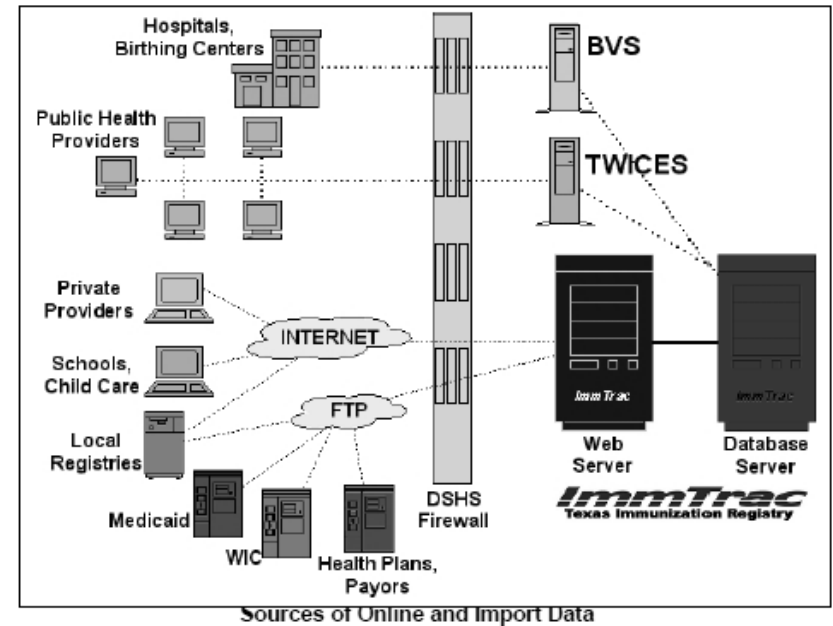
						LEGEND	0% TO <25%	25% to <50%	50% to <75%	75% to <95%	95% to 100%
TER Facility Name	Facility City	Birth County	TER Hospital Code	SFY 2009 Perform Rate	SFY 2009 Total Births						
PALESTINE REGIONAL MEDICAL CENTER	PALESTINE	ANDERSON	0362	99.8%	635						
PERMIAN REGIONAL MEDICAL CENTER	ANDREWS	ANDREWS	0116	99.5%	216						
MEMORIAL MEDICAL CENTER OF EAST TEXAS	LUFKIN	ANGELINA	0081	99.8%	534						
WOODLAND HEIGHTS MEDICAL CENTER	LUFKIN	ANGELINA	0305	99.4%	505						
SOUTH TEXAS REGIONAL MEDICAL CENTER	JOURDANTON	ATASCOSA	0194	99.6%	227						
SEYMOUR HOSPITAL	SEYMOUR	BAYLOR	0336	100.0%	48						
CHRISTUS SPOHN HOSPITAL BEEVILLE	BEEVILLE	BEE	0265	98.2%	330						
DARNALL ARMY COMMUNITY HOSPITAL	FORT HOOD	BELL	0476	98.6%	1891						
KING'S DAUGHTERS HOSPITAL	TEMPLE	BELL	0115	97.1%	631						
METROPLEX HOSPITAL	KILLEEN	BELL	0236	100.0%	812						
SCOTT AND WHITE MEMORIAL HOSPITAL	TEMPLE	BELL	0335	96.8%	2068						
BAPTIST MEDICAL CENTER	SAN ANTONIO	BEXAR	0071	99.2%	1513						
CHRISTUS SANTA ROSA HOSPITAL	SAN ANTONIO	BEXAR	0200	98.6%	1725						
CHRISTUS SANTA ROSA HOSPITAL - WESTOVER HILLS	SAN ANTONIO	BEXAR	0673	100.0%	77						
METHODIST HOSPITAL	SAN ANTONIO	BEXAR	0100	99.4%	4456						
METHODIST STONE OAK	SAN ANTONIO	BEXAR	0672	100.0%	191						
METROPOLITAN METHODIST HOSPITAL	SAN ANTONIO	BEXAR	0098	99.3%	2711						
NIX HEALTH CARE SYSTEM	SAN ANTONIO	BEXAR	0234	100.0%	137						
NORTH CENTRAL BAPTIST HOSPITAL	SAN ANTONIO	BEXAR	0379	99.4%	2300						
NORTHEAST BAPTIST HOSPITAL	SAN ANTONIO	BEXAR	0084	97.5%	1573						
SOUTHEAST BAPTIST HOSPITAL	SAN ANTONIO	BEXAR	0053	100.0%	176						
SOUTHWEST GENERAL HOSPITAL	SAN ANTONIO	BEXAR	0139	99.5%	1552						
ST LUKE'S BAPTIST HOSPITAL	SAN ANTONIO	BEXAR	0318	83.4%	2255						
UNIVERSITY HOSPITAL	SAN ANTONIO	BEXAR	0103	99.8%	2157						
WILFORD HALL MEDICAL CENTER	LACKLAND AIR FORCE BASE	BEXAR	0491	98.3%	1429						
GOODALL-WITCHER HEALTHCARE FOUNDATION	CLIFTON	BOSQUE	0045	100.0%	76						
CHRISTUS ST. MICHAEL HEALTH SYSTEM	TEXARKANA	BOWIE	0391	96.6%	1047						
WADLEY REGIONAL MEDICAL CENTER	TEXARKANA	BOWIE	0093	99.6%	924						

http://www.dshs.state.tx.us/immunize/docs/newborn_consent_2009.pdf

<http://vaccineinfo.net>

How Records and Consent Flow

- Consent collected at birth and registry file opened on child
- Providers and Payers just dump all records regardless of consent
- Health department keeps consented records and only tries to get provider to verify consent if there is no previous record in ImmTrac



http://www.dshs.state.tx.us/immunize/docs/Payers/ImmTrac_QA.pdf

Which Way is it Dr. Boom?

You Asked For These Changes in HB 1921

WITNESS LIST

HB 1921
HOUSE COMMITTEE REPORT
Public Health Committee

March 26, 2003 - 8:00A

For: Boom MD, Julie (Self and Texas Children's Hospitals
Texas Pediatric Society)
Fergie, Jaime (TMA)
Milley, Frankie Lynn (Self)
Pollard, Mike (Texas Association of Life & Health
Insurers)

Against: Hill, Allison (Self)
King, James (Self)
Richardson, Dawn (PROVE)
Wilson, Jim (Self)

On: Stanley MD, Sharilyn (TDH)

<http://www.legis.state.tx.us/tlodocs/78R/witlistbill/html/HB01921H.htm>

Now You Don't Like Them?

The Cost of Consent: Can we afford it? Policy considerations based on the cost analysis of an "opt-in" consent system for Immunization Information System (IIS) participation

Anna C. Dragsbaek¹, **Leila C. Sahni**¹, **Luisa Franzini**², and **Julie A. Boom**³. (1) Immunization Project, Texas Children's Hospital, 6621 Fannin FC240, Houston, TX, USA, (2) Management, Policy, and Community Health, The University of Texas School of Public Health, 1200 Herman Pressler, Houston, TX, USA, (3) Academic General Pediatrics, Baylor College of Medicine, 1 Baylor Plaza, Houston, TX, USA

Background:

Currently, Texas law requires consent from parents for children to participate in the statewide IIS, ImmTrac. In addition, a law passed in 2005 now requires the State to verify and maintain proof of consent. Texas Children's Hospital, supported by other statewide stakeholders, led an effort to quantify the cost of consent to the public and private sectors in Texas.

Results/Lessons Learned:

Obtaining and verifying consent on 96% of the population is expensive and leads to a less robust database. State law and administrative procedures should be amended to eliminate the consent process and institute a voluntary exclusion system.



<http://cdc.confex.com/cdc/nic2008/webprogram/Paper15746.html>

Contrary to Assertion by TCH, Opt-In Promotes Registry Participation and Texas Beats US Averages

- Many of states have opt-out registries yet Texas is a leader in our country at honoring consent and still significantly outperforms the national participation statistics in vaccine tracking registries in all age groups under 18
- When people know about a system and opt-into it, they are more likely to continue to participate than if they are duped into it and have to opt-out

	US - 2000	US - 2007	TX - 2007
Participation of U.S. children < 6 years in an IIS with 2 or more immunizations.	21%	71% (16.5 million children < 6 years)	92% (1.5 million children < 6 years)
Participation of U.S. children 19-35 months in an IIS with 2 or more immunizations.	-	66% (4.0 million children 19-35 months)	71% (321, 757 children 19-35 months)
Participation of U.S. adolescents 11-18 years in an IIS with 2 or more immunizations.	-	64% (21.5 million adolescents 11-18 years)	80% (1.7 million adolescents 11-18 years)
Participation of U.S. adults >19 years in an IIS with 1 or more immunizations.	-	20% (45.5 million adults >19 years)	-

Source: 2007 Immunization Information System Annual Report

 SAFER · HEALTHIER · PEOPLE
DEPARTMENT OF HEALTH AND HUMAN SERVICES 

http://www.slideshare.net/immunizehouston/friday-330-pm-gary-urquhart-national-overview-registries-phase-ii-presentation?from=share_email

Why Opt-Out is Wrong

- The current opt-in process requires tracking only of those who ask and want to be tracked
- Changing to an opt-out process requires tracking of everyone including those who don't want to be tracked
 - In order for registry records to be deleted, the health department has to keep an alternative database of registry “non-consenters” so they know whose vaccination records to delete

Why Opt-Out is Wrong

“In the state of Texas, we have a longstanding history of honoring parental rights. We support homeschooling, we support parents being in control of the medical decisions of their children, and we support medical privacy. The legislature has debated opt-in consent with this registry for over a decade and has decided over and over again that in order to have trust in the system, asking permission before the state takes a child’s private medical information is worth it and the right thing to do.

If Texas can’t afford to take the time or the money for a single checkbox at birth to make sure someone wants their child in the system, then this is a system we should abolish and not use. When we look at the time, money and resources Texas has already put into 2% of Texans getting an H1N1 vaccine and couple that with the fact that we are willing to spend well over \$1000 to fully vaccinate a school age child, it is a complete waste of the legislature’s time to be squabbling over a few dollars per child to do the right thing with consent. “ – Dawn Richardson

Simplest and Most Efficient Consent is at Provider Level

- The simplest method for obtaining consent would be to have to vaccine provider ask when the first shot they ever give to the child if the family would like to participate
- The provider flags affirmative consent in the record, and software sorts and only sends vaccine records for a consented child
- Health department assumes if a record comes in, it is consented - Payers do nothing
- Done – Two steps, nothing else needed

Registry Necessity Under Question

- Limited health care dollars
- Questionable effect on childhood vaccination rates
- Inappropriate function of state government to be a watchdog over providers and patients
- State honors vaccine choice, registry doesn't (all or nothing system)
- Time and money should be spent on access and education, and not reporting
- Ethical issues

Recommendations for Increased Adult Support of ImmTrac

- Maintain opt-in informed consent
- Legislative protections needed where vaccination status or lack of registry participation is not used punitively against
 - Insurance coverage
 - Employment
 - Vocational training eligibility etc.
- Emergency powers language in the Health and Safety code needs to be amended to include conscientious and medical exemptions in times of emergency (Health and Safety Code Sec 81.009)