

Empirical evidence for participation rates in HIEs adopting Opt-out and Opt-in consent models is limited. However, Opt-out and Opt-in consent policies have been used in other healthcare settings, such as for HIV/AIDS testing and immunization testing, with data on participation rates providing additional insight into how the consent policies might function in an HIE.

### Less Data under Opt-In Model

Anecdotal evidence exists that less data is obtained when consumers are requested to affirmatively consent to the inclusion of their data (“opt-in”), rather than including such data unless the consumer affirmatively objects (“opt-out”). There is currently little empirical data that has been published on the subject. In addition to the issue of data system cost (noted in the study below), other relevant considerations include clinical record completeness and resulting improved patient care and safety, and the extent of use by physicians of clinical data repositories known to be incomplete.

### Evidence for Participation Rates for Immunization Testing:

- Texas Immunization Information System (IIS): “Although originally established as an “opt out” system, where immunization information received for all Texas children was included in the Registry, a revision to the Texas Administrative Code, effective January 1, 1999, resulted in an “opt in” system, requiring parents to consent to have their child’s information included in the Registry. This change resulted in the loss of 675,750 client records, leaving the Registry to rely on voluntary parental consent and medical provider compliance with Texas law requiring ImmTrac participation.”<sup>1</sup>
- A study examining the Texas IIS experience concluded that the cost of collecting opt-in consents was \$2.00-\$2.64 per child v. only \$0.29 per child under an opt-out system.<sup>2</sup> The authors concluded: “*Given national concerns regarding rising healthcare costs, it becomes increasingly important to carefully scrutinize how public and private healthcare dollars are being spent. As IISs continue to mature and prove to be reliable sources of confidential immunization information reconsidering the efficiency and costs associated with consent procedures for populating these systems and other electronic health record systems is essential. Furthermore, the costs associated with consent will be a factor as EMRs become widespread and health information becomes easier to exchange in electronic format with providers. Because the proposed opt-out costs were demonstrated in this study to be substantially less than the actual opt-in model currently utilized, changing to an opt-out IIS could redirect limited healthcare funding to more critical areas such as vaccine purchasing, administration and education.*”

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<sup>1</sup> *ImmTrac History*, Texas Department of State Health Services (Oct. 2010) available at [http://www.dshs.state.tx.us/immunize/immtrac/immtrac\\_overview.shtm](http://www.dshs.state.tx.us/immunize/immtrac/immtrac_overview.shtm)

<sup>2</sup> Boom, “Immunization information system opt-in consent: at what cost?”, *J Public Health Manag Pract.* 2010 Sep-Oct ;16(5):E18-25. <http://www.ncbi.nlm.nih.gov/pubmed/20431419>

Evidence for Participation Rates in HIEs:

*Opt-out*

- In five years, the Delaware HIE (DHIN) has become the information vehicle choice for all acute care hospitals, which post patient information on DHIN. Additionally, 95% of medical providers in Delaware have enrolled and are participating in DHIN. The DHIN database now exceeds 1,400,000 patient records, with more than 9,000,000 clinical results and reports being posted each year on DHIN.<sup>3</sup>
- In the Kansas Health Information Exchange, only four patients completed the required paperwork to Opt-out of the HIE within the first two weeks that it was possible to do so.<sup>4</sup>
- The Nebraska Health Information Initiative (NeHII) reported on February 15, 2012 that it had 2,000,679 patients in the system, with an Opt-out rate of just under 3%.<sup>5</sup>

*Opt-in*

- To aid the State of Connecticut in evaluating an Opt-in consent model, the Connecticut Health Policy Project examined the Opt-in rates of eight different RHIOs and Exchanges in Connecticut and neighboring States:<sup>6</sup>
  - North Adams HIE (MA): 92% of patients chose to Opt-in
  - Newburyport (MA): 88% of patients chose to Opt-in
  - HIXNY (NY): 91.4% of patients chose to Opt-in<sup>7</sup>
  - Southern Tier NY: 91% of patients chose to Opt-in
  - Western NY Health Link: 94% of patients chose to Opt-in
  - Rochester RHIO (NY): 97% of patients chose to Opt-in
  - RIQI (RI): 95% of patients chose to Opt-in
  - Hartford Hospital (CT): > 90% of patients chose to Opt-in

Evidence for Participation Rates for HIV/AIDS Testing:

- Statistics published in the Morbidity and Mortality Weekly Report on November 15, 2002 showed that for the eight states using Opt-in consent, testing rates in

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<sup>3</sup> <http://www.dhin.org/>.

<sup>4</sup> Phil Cauthon, "Fewer than Projected Patients Opting Out of Health Information Exchange," KHI News Service, June 14, 2012, available at: <http://www.khi.org/news/2012/jun/14/far-fewer-patients-opt-ing-out-exchange-officials/>

<sup>5</sup> NeHII Current Status Webinar, "Community Betterment Through HIE 'Engaging Community Stakeholders to Create a Sustainable, Large-Scale HIE,'" February 15, 2012.

<sup>6</sup> Connecticut Health Privacy Project, "CT Health Information Exchange, Why We Need an Opt-In Privacy Policy," (April 2011) available at:

[http://www.cthealthpolicy.org/privacy/20110420\\_hitect\\_privacy\\_memo.pdf](http://www.cthealthpolicy.org/privacy/20110420_hitect_privacy_memo.pdf)

<sup>7</sup> HIXNY Report to Members, December 2011, available at: <http://www.hixny.org/News/hixny-publishes-2010-annual-report>

Re: Amount of Data Obtained Under Opt-In and Opt-Out Participation Models

1998-1999 ranged from 25%-69%. Conversely, in Tennessee, the testing rate with Opt-out consent was 85%.<sup>8</sup>

- An evaluation of a prenatal clinic in Alabama showed that HIV testing increased from 75% to 88% after Opt-out testing was implemented in 1999.<sup>9</sup>
- At the Denver Health Medical Center in Colorado, the testing rate with Opt-out consent for pregnant women who delivered was 98.2% in 1998-2001.<sup>10</sup>

The Centers for Disease Control and Prevention (CDC) issued revised recommendations in September 2006 for HIV testing of adults, adolescents, and pregnant women in healthcare settings. The CDC recommended that HIV testing be a routine part of care in such settings, with an Opt-out model that does not require any separate written consent.<sup>11</sup>

- Rates of HIV testing are consistently higher in settings that provide prenatal and STD services using Opt-out consent compared to those using Opt-in consent, which requires pre-test counseling and explicit written consent. Pregnant women express less anxiety with Opt-out consent for HIV testing and do not find it difficult to decline a test.<sup>12</sup>
- In 2006, approximately 65% of U.S. adults surveyed concurred that HIV testing should be treated the same as testing for any other disease, without the need for special procedures such as written permission from the patient.<sup>13</sup>
- In 2009, the HIV/AIDS Section of the Illinois Department of Public Health began an Opt-out testing initiative with eight clinics throughout Illinois. As of September 2010, the clinics had conducted approximately 7,000 rapid HIV tests with the level of HIV test acceptance being 75-85%. Matt Charles, acting Chief, said, "It is expected that levels will vary slightly according to population served and implementation strategy. It is certainly arguable that there are distinct differences between the individuals who accept an HIV test versus those that deny one. It is our experience in "opt in" settings that individuals engaged in higher risk behaviors are less willing to accept HIV testing. I would expect the same in an "opt out" setting as well."<sup>14</sup>

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<sup>8</sup> "Reducing HIV Transmission from Mother-to-Child: An Opt-Out Approach to HIV Screening," cdc.gov, available at: <http://www.cdc.gov/hiv/topics/perinatal/resources/factsheets/pdf/opt-out.pdf>.

<sup>9</sup> Id.

<sup>10</sup> Id.

<sup>11</sup> Catherine Hanssens, "Legal and Ethical Implications of Opt-Out HIV Testing," pp. 1 (2006).

<sup>12</sup> "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings," cdc.gov, available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm>.

<sup>13</sup> Id.

<sup>14</sup> Email to Mark Chudzinski, General Counsel OHIT, Sept. 21, 2010, from E. Matt Charles, Acting Chief, HIV/AIDS Section, Illinois Department of Public Health, 525 W. Jefferson Street, Springfield, IL 62761.