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Effectiveness of primary care–public health collaborations in the delivery of influenza vaccine: a cluster-randomized pragmatic trial ☆

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ABSTRACT

Objective. To assess effectiveness and feasibility of public–private collaboration in delivering influenza immunization to children.

Methods. Four pediatric and four family medicine (FM) practices in Colorado with a common public health department (PHD) were randomized at the beginning of baseline year (10/2009) to Intervention (joint community clinics and PHD nurses aiding in delivery at practices); or control involving usual care without PHD. Generalized estimating equations compared changes in rates over baseline between intervention and control practices at end of 2nd intervention year (Y2 = 5/2011). Barriers to collaboration were examined using qualitative methods.

Results. Overall, rates increased from baseline to Y2 by 9.2% in intervention and 3.2% in control ($p < .0001$), with significant increases in both pediatric and FM practices. The largest increases were seen among school-aged and adolescent children ($p < .0001$ for both), with differences for 6-month-old to 5-year-old children and for children with high-risk conditions not reaching significance. Barriers to collaboration included uncertainty regarding the delivery of vaccine supplies, concerns about using up all purchased vaccine by practices, and concerns about documentation of vaccination if collaboration occurred.

Conclusions. In spite of barriers, public–private collaboration resulted in significantly higher influenza immunization rates, particularly for older, healthy children who visit providers less frequently.

Introduction

A recent report by the Institute of Medicine stressed the importance of integration of primary care and public health efforts in order to achieve lasting improvements in population health, especially in prevention (IOM (Institute of Medicine), 2012). The yearly effort to deliver influenza immunizations to all children is a perfect example of the need for collaboration between primary care and public health. Because of the significant morbidity associated with influenza infection in some children and the key role children play in the propagation of influenza outbreaks (Fox et al., 1982; Glezen and Couch, 1978; Heikkinen et al., 2004; Monto and Sullivan, 1993; Neuzil et al., 2000, 2002; Poland and Hall, 1999; Weycker et al., 2005), the Advisory Committee on Immunization Practices (ACIP) has recommended universal yearly influenza vaccination for all children 6 months and older since 2008 (Centers for Disease Control, Prevention, 2008). It has been estimated that accomplishing universal coverage for children could mean 42 to 49 million additional visits if all vaccinations were to be given in the medical home Rand et al., 2008 in the relatively narrow time frame during which the vaccine is optimally recommended (Fiore et al., 2010). The enormity of this task, and the additional number of visits that it might require, have led many to believe that universal vaccination can best be accomplished in a collaborative manner with other community vaccinators, including schools and public health departments (Fiore et al., 2012).

Few truly collaborative vaccination interventions involving health care providers and community settings have been described for adults or children prior to 2009 (Shenson et al., 2008; Bechtol, 2008; Barker et al., 1999; Bennett et al., 1994). However, the 2009 pandemic

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influenza A (H1N1) outbreak fostered some cooperation in the U.S. between private practices and public health departments (National Influenza Vaccine Summit June, 2009, 2010; Regional influenza A (H1N1), 2010), and may have created a framework on which future collaborations could grow in subsequent seasons. Such collaborations could take a variety of forms, including coordinating the distribution of vaccine to providers (as occurred in the H1N1 epidemic), setting up joint vaccination clinics between practices and other community vaccinators, collaborative delivery between practices and public schools, and coordinated referral of patients from practices to community vaccinators. Ideally, such efforts would be designed collaboratively, in order to optimize providers' preferences about who would be vaccinated outside of the practice and to ensure appropriate transfer of vaccination records.

Although there has been one previous study examining physician attitudes toward collaborations between public health and private practices (Kempe et al., 2012), to our knowledge, there have been no previous trials specifically examining the effectiveness of such collaborations in the delivery of influenza immunizations to children. In order to address this gap, we conducted a pragmatic trial comparing changes in rates of influenza vaccination between practices randomized to an intervention involving active collaboration in the delivery of influenza immunizations and those randomized to a control group, involving delivery at the primary care site. Our a priori hypotheses were: (1) intervention practices would increase childhood influenza immunization rates more than control practices when compared to the baseline year (2009); (2) increases in rates would be higher among older children compared with children five years or less or those with chronic conditions; and (3) intervention practices would have a lower rate of missed opportunities for influenza vaccine compared with their baseline year (2009) than would control practices. We employed a mixed methods design, engaging qualitative methods to enrich our understanding and interpretation of the quantitative results of the trial.

Methods

The study was approved by the Colorado Multiple Institutional Review Board (COMIRB) as an expedited protocol not requiring patient consent.

Study design and cohorts

This was a cluster-randomized pragmatic trial involving pediatric and family medicine private practices with a single common public health department in three urban counties in the Denver Metropolitan area (see Consort Diagram http://dx.doi.org/10.1016/j.ypmed.2014.08.019). Practices randomized to the control arm delivered influenza vaccines in their usual way without involvement of the public health department and their rates were monitored at the end of each season without feedback until after the study ended. Practices randomized to the collaborative intervention participated with the collaborating public health department in designing the intervention during the baseline year (2009). Four pediatric and 4 family medicine practices were enrolled and randomized in October of 2009 (beginning of the baseline year) and participated for three subsequent years. Randomization was stratified by specialty and a random number generator was used to allocate practices to intervention or control. Practices were chosen to be roughly similar in size, percentage of children with high-risk conditions, and percentage of children eligible for the Vaccines for Children (VFC) program. One of the enrolled pediatric intervention practices had three sites and, at the time of randomization, it was thought that the patients and medical records from these sites were distinct. During the development year, it became apparent that there was significant overlap in patient populations and that records could not clearly be attributed to individual sites. Therefore, the three sites from this practice were included as a single practice and data from the three practices sites were averaged for purposes of describing practice sites. The three sites were treated as a single practice for all subsequent analyses. All three sites participated in the same intervention activities within this practice. Therefore, the study included a total of 4 intervention practices (with 7 sites) and 4 control practices balanced by specialty. The study was powered to detect a 7% difference with 85% power in family medicine practices and a 2% difference with 97% power in pediatric practices.

Intervention design

Using a developmental qualitative approach (Landsverk et al., 2012), interview data from the intervention practices and the public health department were used during the baseline year (2009) to collaboratively develop the intervention that was implemented during implementation years 1 and 2. This approach involved individual meetings and qualitative data collection with the study team, the public health department, and each practice. Subsequently, there were two group meetings with all intervention practices and the public health department to discuss the results of the data collection and possible implementation plans. Finally, the study team met with each practice again individually to clarify their specific decisions about implementation. Meetings with practices involved a physician champion and an office manager. All practices had to agree to common decisions about the form collaboration would take but individual practices could decide about the intensity of their involvement in collaborations. The two interventions agreed upon were: (1) community clinics involving practices and the public health department and (2) public health department nurses coming to practice sites to aid in delivery. Autodialer and mailed postcards were used to inform families about the collaborative efforts.

Study populations and data sources

Three cross-sectional cohorts of eligible patients were defined each August (pre-season) during 2009–2011 at each intervention and control practice. Eligible patients included children seen at least once during the past two years and who were ≥6 months of age on August 1 of each study year. Influenza immunization rates were assessed for these cohorts at the end of each study year (July 2010–2012) using a combination of practice administrative data and data from the Colorado Immunization Information System (CIIS) within both the intervention and control arms.

Qualitative data were collected during and after the intervention from the 4 intervention practices and the public health department. In May 2011, after the first intervention year, a focus group was conducted with representatives of each of the 4 practices and the public health department in order to assess the effectiveness of the collaborative interventions and discuss how to improve the interventions for the subsequent year. In August–September 2012, following the second intervention year, individual interviews were conducted with representatives of each of the 4 practices and of the public health department to assess the effectiveness of the collaborative interventions and discuss sustainability. Self-identified practice "leads" included 2 physicians, 1 physician's assistant, and 1 practice administrator; the public health department representative was a nurse manager. The interviews were conducted over the phone and lasted approximately 45 minutes; interviewees received a $20 gift card as compensation for their time.

Outcomes

The major study outcome was the receipt (yes/no) of at least one influenza vaccination at the end of each study year for each eligible child. The primary comparison was the end of year 2 (2011–2012 influenza season), when the intervention was considered to be mature, to the baseline year (2009–2010 influenza season). In order to assess whether inclusion of the practice with three sites were skewing the results, we conducted additional sensitivity analyses for our primary outcomes among the pediatric practices. Patients from the practice with three sites were randomly assigned to a designated site using a random number generator. Then, three additional analyses were conducted, each including a single site from this practice. Secondary outcomes included receipt of at least one vaccine within (1) different age groups (6 months to 5 years, 6–12 years, and 13–18 years) and in (2) children with a high-risk medical condition for each eligible child for each study year. High-risk conditions were defined based on ICD-9 codes in the practices' administrative databases as previously described by our group (Daley et al., 2004). Another secondary outcome compared the missed opportunities (yes/no) for each eligible child during the second intervention year between intervention and control practices. Missed opportunities were defined as any visit that occurred from the first day that the practice had a record of flu vaccine administration according to billing data through March 31 of each study year in which a child who needed an influenza vaccine did not receive it. The end date of March 31 was based on recommendations from the CDC as well as previous publications of influenza trials (Stockwell et al., 2012; Fiks et al., 2009; Verani et al., 2007).