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Cluster randomized trial of a toolkit and early vaccine delivery to improve childhood influenza vaccination rates in primary care

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ABSTRACT

Purpose: To increase childhood influenza vaccination rates using a toolkit and early vaccine delivery in a randomized cluster trial.

Methods: Twenty primary care practices treating children (range for $n = 536–8183$) were randomly assigned to Intervention and Control arms to test the effectiveness of an evidence-based practice improvement toolkit (4 Pillars Toolkit) and early vaccine supplies for use among disadvantaged children on influenza vaccination rates among children 6 months–18 years. Follow-up staff meetings and surveys were used to assess use and acceptability of the intervention strategies in the Intervention arm. Rates for the 2010–2011 and 2011–2012 influenza seasons were compared. Two-level generalized linear mixed modeling was used to evaluate outcomes.

Results: Overall increases in influenza vaccination rates were significantly greater in the Intervention arm (7.9 percentage points) compared with the Control arm (4.4 percentage points; $P < 0.034$). These rate changes represent 4522 additional doses in the Intervention arm vs. 1390 additional doses in the Control arm. This effect of the intervention was observed despite the fact that rates increased significantly in both arms – 8/10 Intervention (all $P < 0.001$) and 7/10 Control sites (P-values = 0.04 to <0.001). Rates in two Intervention sites with pre-intervention vaccination rates >58% did not significantly increase. In regression analyses, a child's likelihood of being vaccinated was significantly higher with: younger age, white race (Odds ratio [OR] = 1.29; 95% confidence interval [CI] = 1.23–1.34), having commercial insurance (OR = 1.30; 95%CI = 1.25–1.35), higher pre-intervention practice vaccination rate (OR = 1.25; 95%CI = 1.16–1.34), and being in the Intervention arm (OR = 1.23; 95%CI = 1.01–1.50). Early delivery of influenza vaccine was rated by Intervention practices as an effective strategy for raising rates.

Conclusions: Implementation of a multi-strategy toolkit and early vaccine supplies can significantly improve influenza vaccination rates among children in primary care practices but the effect may be less pronounced in practices with moderate to high existing vaccination rates.

Clinical trial registry name/number: From Innovation to Solutions: Childhood Influenza/NCT01664793.

1. Introduction

Despite the 2008 Advisory Committee on Immunization Practices recommendation that all children over the age of 6 months receive an annual influenza vaccine [1], national vaccination uptake in the United States remains substantially below desired levels of 70% [2], averaging 51.5% [3]. An array of evidence-based interventions to improve childhood influenza vaccine uptake exists [4–7]. While significant gains have been reported, no

Abbreviations: 95%CI, 95% confidence interval; Task Force, Community Preventive Services task force; EMR, Electronic medical record; OR, Odds ratio; SOPs, standing order programs; VFC, Vaccines for Children; VIF, variance inflation factor.

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single intervention has raised rates sufficiently; rather, the evidence suggests the need for a combination of strategies. The Community Preventive Services Task Force (Task Force) [8] recommended using two or more of three strategic approaches in preference to using several techniques within a single strategic approach. They are: (1) enhancing access to vaccination services; (2) increasing demand among patients; and (3) provider- and system-based interventions such as reminders, modified office flow, standing order programs (SOPs) and electronic immunization tracking.

Based on Task Force recommendations [8] and previous research in adult primary care practices [9], we modified an adult immunization toolkit to create the 4 Pillars Toolkit for Increasing Childhood Influenza Immunization (4 Pillars Toolkit) in primary care practices serving children. A practice-based, cluster randomized trial was conducted using the 4 Pillars Toolkit and early delivery of vaccine supplies for Vaccines for Children (VFC)-eligible children. This report describes: (1) the intervention that included the 4 Pillars Toolkit; (2) resultant changes in influenza vaccination rates; (3) the individual and practice level characteristics that affected influenza vaccination from two-level generalized linear mixed modeling; and (4) recommendations for policy and practice.

2. Methods

This trial took place during the 2011–2012 influenza season and was approved by the University of Pittsburgh Institutional Review Board.

2.1. Sample size and sites

Optimal Design software (University of Michigan, Version 1.77, 2006) was used to calculate sample size, for a randomized trial seeking a 10–15% absolute increase in vaccination rate, and a minimum practice size of 100–200 pediatric patients. A sample size of 20 clusters (10 Intervention and 10 Control practices) was determined necessary to achieve 80% power with an alpha of 0.05. Primary care pediatric and family medicine practices from two practice-based research networks (http://www.familymedicine.pitt.edu/content.asp?id=2353; http://www.pedspittnet.pitt.edu/) and one clinical network in Southwestern Pennsylvania were solicited for participation. When 20 sites agreed to participate, solicitation ceased. All sites were part of the UPMC Health System and used a common electronic medical record (EMR), EpicCare, with the exception of one practice with two offices that used Allscripts Professional EMR.

2.2. Cluster randomization

Cluster randomization allocates clinical practices rather than individuals to the intervention arms [10]; hence, each practice or office was considered as a cluster. To be eligible, the office must have had a patient population of at least 200 children ages 6 months through 18 years, access to vaccination data via an EMR and willingness to make office changes to increase influenza vaccination rates. Participating practices were stratified by location – inner city (urban practices with primarily disadvantaged children), urban, suburban and rural and by discipline (pediatrics vs. family medicine). The practices were then randomized into the

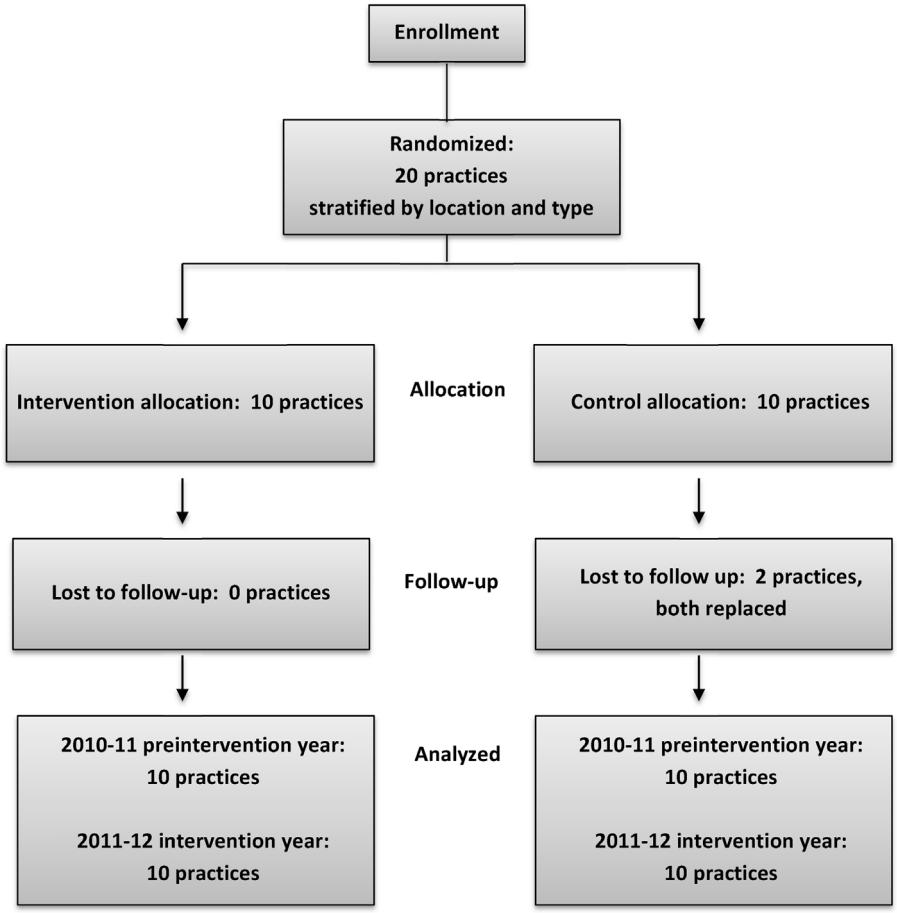

Fig. 1. Randomization scheme.

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