



Frontiers in Public Health Services and Systems Research

Volume 3 | Number 2

Article 7

April 2014

The Effects of the Changes in Section 317 Rules for Administration of Federally Purchased Vaccines

Margaret A. Knight

University of Tennessee, maknight@king.edu

Anne D. Kershenbaum

University of Tennessee, Knoxville, akershen@utk.edu

Martha Buchanan

Knox County Health Department, martha.buchanan@knoxcounty.org

Janet Ridley

East Tennessee Region, Tennessee Department of Health, Janet.Ridley@tn.gov

Paul C. Erwin

perwin@utk.edu

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Recommended Citation

Knight MA, Kershenbaum AD, Buchanan M, Ridley J, Erwin PC. The Effects of the Changes in Section 317 Rules for Administration of Federally Purchased Vaccines. *Front Public Health Serv Syst Res* 2014; 3(2). DOI: 10.13023/FPHSSR.0302.07

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The Effects of the Changes in Section 317 Rules for Administration of Federally Purchased Vaccines

Abstract

Section 317 of the Public Health Services Act is a federal program that provides funds for the purchase of vaccines. These annual Congressional allocations fluctuate from year to year as Congress responds to changes in national needs for immunizations. The Affordable Care Act requires first dollar coverage of immunizations and other preventive care, allowing a reduction in federal funding for vaccine purchase and a reallocation of funds to other uses such as infrastructure development. In fiscal year 2013, Section 317 rules redefined the population eligible for immunization with Section 317 purchased vaccines. In Tennessee, the response was a policy change that redefined the population who would receive immunizations at health departments.

Keywords

Section 317, Vaccination Program, Affordable Care Act, Preventive Care

Cover Page Footnote

I would like to acknowledge the help of all of the people at Knox County Health Department and the East Tennessee Region of the Tennessee Department of Health who helped with data collection, advise, and providing important assistance during this project.

The Centers for Disease Control and Prevention (CDC)-administered Section 317 program is a federal grant program that provides funding for the purchase of immunizations for children who are not eligible for Vaccines for Children (VFC) immunizations¹. Addressing epidemics during the 20th century, this program traditionally filled the gaps in access to needed vaccinations and supported infrastructure established for immunization efforts³. Funding for Section 317 remains dependent upon fluctuating annual Congressional allocations. Research shows that such budgeting variance significantly impacts access to and uptake of vaccinations². With the requirement of first dollar coverage of preventive care since September of 2011 by the Patient Protection and Affordable Care Act (PPACA), the number of children and adults without immunization coverage will decrease drastically. Only the uninsured and people insured under grandfathered plans in existence prior to the PPACA that exclude first dollar preventive care coverage will remain eligible for Section 317-purchased vaccines. With this requirement in effect and fewer grandfathered health plans each year, the federal government reallocated Section 317 funds to the continued support of infrastructure for the national vaccination program, leading to the promulgation of new rules regarding the use of Section 317 funds starting with fiscal year (FY) 2013. The new rules state that no one with health insurance coverage for vaccinations may receive vaccines purchased with Section 317 funds except under specific circumstances. Both Knox County Health Department and the East Tennessee Region (ETR) of the Tennessee Department of Health successfully implemented the changes needed to comply with the new rule. KCHD elected to put in place a process for billing insurance and administrative fees for immunizations given to insured people. ETR elected to redirect patients to other providers if they were insured. Both KCHD and the 15 counties¹ under ETR used staff education to ensure application of the new rule. The purpose of this study is to determine if this new rule has had a significant impact on vaccination uptake in East Tennessee.

METHODS

The East Tennessee Practice Based Research Network (PBRN), consisting of researchers from ETR, KCHD, and the University of Tennessee, Department of Public Health, collected immunization data from the Patient, Tracking, Billing, and Management Information System (PTBMIS) used by Tennessee health departments to maintain information on their service provision activities. Monthly immunization counts provided the basis for monthly medians for two age groups: birth to five years and six years to eighteen years from both KCHD and ETR from 2007 through 2013. The US Census reports the catchment population for 1,190,412 persons in the 16 counties area⁴. Analysis for statistically significant change using the Mann-Whitney is based on differences in monthly median immunizations by type between fiscal year (FY) 2012 to FY 2013. Results of this analysis data showed that there was very little decrease in median monthly vaccines.

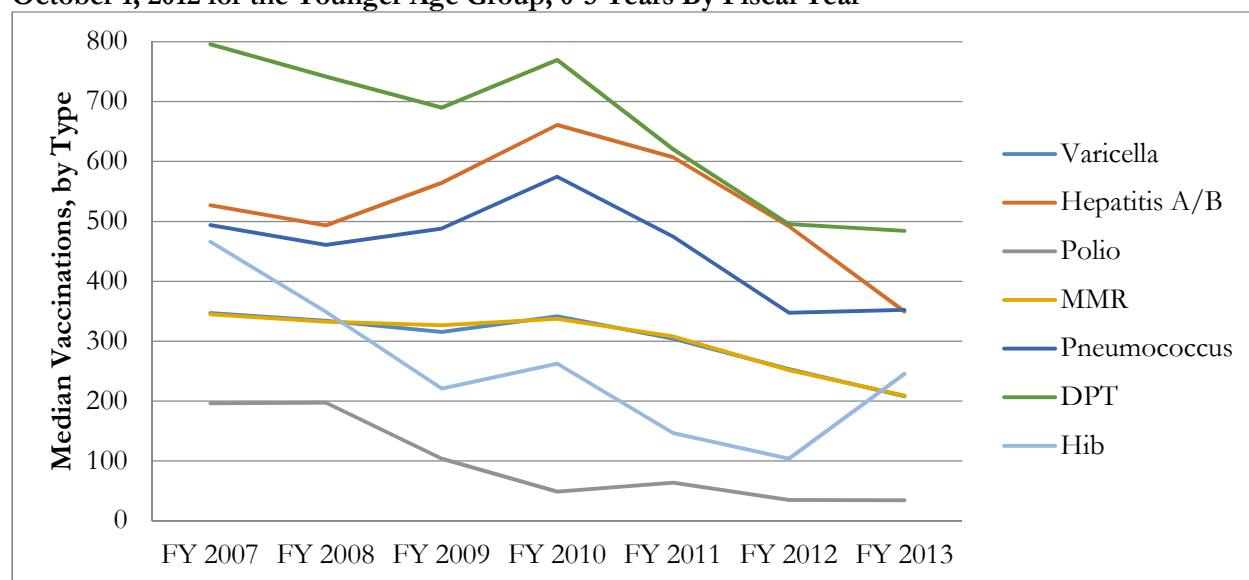
¹ The East Tennessee Region includes the following counties: Anderson, Blount, Campbell, Claiborne, Cocke, Grainger, Hamblen, Jefferson, Knox, Loudon, Monroe, Morgan, Roane, Scott, Sevier, and Union Counties. Knox County Health Department serves Know County as a Metro Health Department.

Vaccinations required by the State of Tennessee for admission to school are the immunizations of interest.² Hepatitis A was included along with Hepatitis B because that is the predominant method of immunization. Immunization data were categorized into immunization types: combination immunizations were categorized into one immunization type only. Statistical analysis was performed in SPSS version 20. The Mann-Whitney test was used to determine the significance of the difference in numbers of immunizations administered year to year, producing p-values for each age group and each immunization at a level of significance for statistical tests set at $p < 0.05$.

RESULTS

Graph 1 shows a general decline in the median immunizations by type provided at local health departments (LHD) over the years 2007 through 2013 in the younger age group. A decline started in 2007 for most immunization types with an increase for all immunizations except polio starting between fiscal years (FY) 2008 and 2009 with peaking on FY 2010. At that point, the decline in monthly median immunizations at LHDs reestablished itself well prior to the implementation of this policy change. The only exception is the sharp increase in the *H. influenza* immunization in FY 2012-2013. Graph 2, illustrating the results for the older age group, shows a decline over the period FY 2007 through 2013 in the Hepatitis A/B vaccine type, with no obvious trends in the other vaccine types.

Graph 1: Median Immunization Uptake in East Tennessee Before and After Policy Change of October 1, 2012 for the Younger Age Group, 0-5 Years By Fiscal Year



² The State of Tennessee requires the following immunizations for admission to school or daycare: Diphtheria-pertussis-tetanus (DPT); Polio; Measles-mumps-rubella (MMR); *H. Influenza* type B (Hib); Hepatitis B; Pneumococcus, and Varicella⁵.

Graph 2: Median Immunization Uptake in East Tennessee Before and After Policy Change of October 1, 2012 for the Older Age Group, 6-18 Years By Fiscal Year

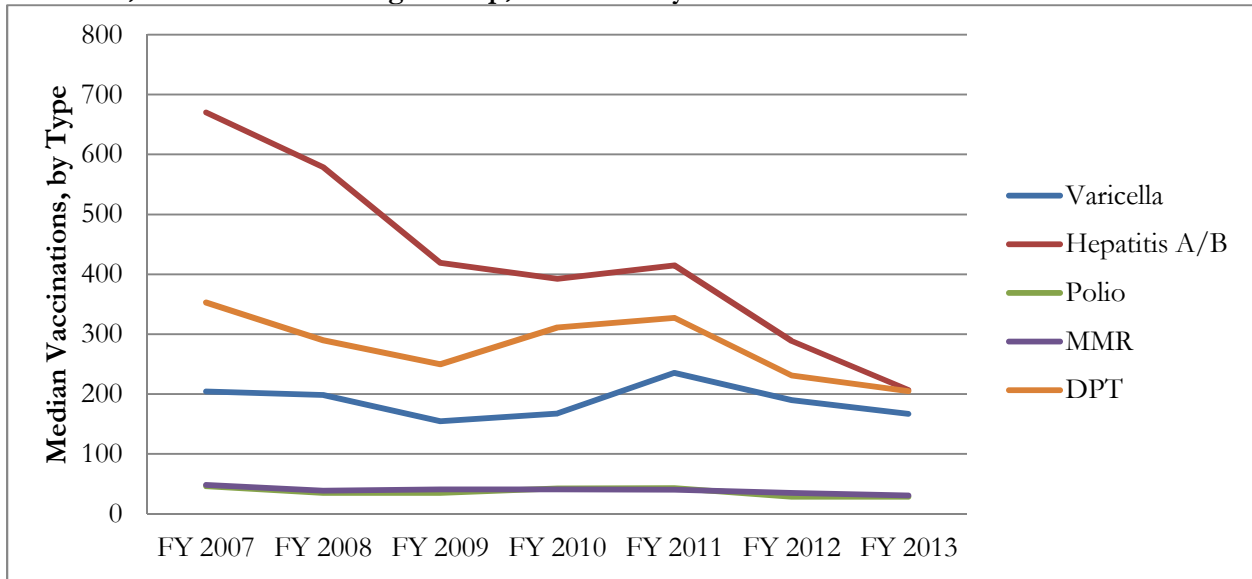


Table 1: Summary of the monthly median of the monthly vaccination uptake in FY 2012 and 2013 by age group (p-values calculated using Mann-Whitney Test)

| Age Group | Vaccine(s) | FY2012 | FY2013 | FY 2012 to FY 2013 p-values |
|--------------------------|---------------------------|---|--------|-----------------------------|
| Birth through five years | Varicella | 254 | 208 | 0.453 |
| | Hepatitis A & B | 492 | 350 | 0.004 |
| | Polio | 35 | 34 | 0.977 |
| | MMR | 252 | 209 | 0.564 |
| | Pneumococcus | 348 | 353 | 0.84 |
| | DPT | 496 | 484 | 0.707 |
| | <i>H. Influenza</i> (Hib) | 104 | 246 | 0.000 |
| | Total | 1991 | 1874 | 0.817 |
| Six through 18 years | Varicella | 190 | 167 | 0.371 |
| | Hepatitis A & B | 289 | 207 | 0.225 |
| | Polio | 29 | 29 | 0.885 |
| | MMR | 35 | 31 | 0.773 |
| | Pneumococcus | Numbers too low for statistical assessment. | | |
| | DPT | 231 | 205 | 0.419 |
| | <i>H. Influenza</i> (Hib) | Numbers too low for statistical assessment. | | |
| | Total | 712 | 636 | 0.341 |

The decline and the periodic upturns in some immunizations suggests that other forces were at work from 2009 onward that affected LHD-provided immunizations, at least in the younger age group. The proliferation of other, convenient sites for immunizations such as pharmacies may have pulled some people away from LHDs. The increase in preventive care coverage under the ACA with ETR LHDs redirecting covered people to other providers and KCHD’s policy of requiring an

administrative fee for immunizing covered people may have had a similar effect. Even so, a policy change designed to restrict access of Section 317-funded immunizations to insured patients would reasonably be expected to further the ongoing decline already in evidence. However, as can be seen in Table 1, only the younger group showed a significant decrease in FY 2013 compared to 2012, and only in one vaccine-type, Hepatitis A & B. The other statistically significant change was an increase in *H. Influenza* uptake in the younger group in FY 2013 compared to 2012. These findings suggest the Section 317 rule change for the use of immunizations purchased under this program did not have as great an effect as policymakers hoped in the State of Tennessee.

IMPLICATIONS

Policymakers designed the change in the Section 317 policy to facilitate reallocation of Section 317 funds to the needs of Americans who continue to be uninsured and underinsured and for the support and development of vaccination program infrastructure nationally³. In East Tennessee, there was very little significant change directly attributable to the Section 317 policy. There are likely a number of other forces in effect that have sustained a downward trend in vaccinations in this area for several years. Further study several months into mandatory health coverage under the ACA would provide more information on the effects of this broad health policy change and would document its effects on the provision of public health services.

There are several limitations to this study. First, we were unable to include influenza, which is frequently used as a benchmark for vaccination programs, due to issues with data collection. Second, in a parallel study we are conducting on the effects of state-level immunization policy changes, data from 2007-2012 indicate that there was already a downward trend in vaccination uptake prior to the implementation of the Section 317 policy change, thus we cannot fully attribute the continued trend to this particular policy change. Third, other causal factors such as the Tennessee State Department of Health FY 2012 policy redefining immunization administration rules could also explain the trend in vaccination uptake in addition to the impact of the FY 2012 policy change implemented by the Tennessee Department of Health on vaccination administration.

SUMMARY BOX:

What is Already Known about This Topic? Section 317 funding is dependent on annual Congressional budget allocations which change from year to year. Funding changes which result in rules about whom may receive immunizations purchased with Section 317 funds can create barriers to accessing vaccinations.

What is Added by this Report? Policymakers intended the Section 317 policy change to free funding previously used for vaccine purchase for use in other areas such as infrastructure development and maintenance. However, the policy change does not appear to have had the effect of reducing the number of vaccinations significantly.

What are the Implications for Public Health Practice, Policy, and Research? Public health practice professionals have to remain agile in their response to fluctuations in funding, but not all policies have a significant impact on service provision. Policymakers need to plan policy change that will have the impact needed to sustain programs.

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