

While legislative initiatives in the United States and Europe have indeed started to change the pediatric drug development landscape, engaging key stakeholders to define challenges and develop solutions will be essential to effectively address unintended consequences that may hamper timely development of new therapeutics for children with cancer.

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Are High Prices a Barrier to Human Papillomavirus Vaccination in the United States? Not in Italy

To the Editor A very recent survey in Italy¹ showed that the main hurdles to human papillomavirus vaccination among adolescent Italian girls are fear of adverse events, scant confidence in new vaccines, and a general lack of information.

In contrast to the interesting review on the barriers to the vaccine in the United States,² the high cost of the vaccine was not considered a hurdle in Italy. This probably reflects the Italian experience of the price of human papillomavirus vaccines since the start of the public campaign in 2008.

Although coverage is still less than the 80% nationally planned target (74.4% for the first dose; 68.5% for the third dose; female cohort, 1999),³ the cost of the vaccine has fallen dramatically over the past years. The ex-factory prices, negotiated by the Italian Medicines Agency in 2007, were €114 (approximately US \$157) per dose for the quadrivalent vaccine and €95 (approximately US \$130.87) per dose for the bivalent vaccine, both assumed to be in line with prices obtained from the 2 manufacturers in other European countries.⁴ To obtain lower prices than those negotiated at a national level, each of the 20 Italian regions, which are financially accountable for health care within the Italian National Health Service, put out tenders to exploit competition between the 2 manufacturers to purchase the vaccines, judged equivalent for cervical cancer prevention. Thanks to competition, prices were reduced by almost half over 2 years, and even decreased to around one-third of the ex-factory prices in the latest tenders in 2013, after 2 regions (Lombardy and Piedmont) awarded the tender to the bivalent vaccine manufacturer (€34.47 [approximately US \$47.49] per dose) and another tender (Veneto) to the quadrivalent one (€32.75 [approximately US \$45.12]).⁵

Although there are broad institutional differences between the American health care system and the Italian National Health Service, we wonder why the Patient Protection and Affordable Care Act in the United States does not con-

sider vaccines a priority, making them sustainable by exploiting price competition to the fullest potential. It seems strange from our point of view that health authorities in the "land of free market" do not exploit their purchasing power whenever possible in the health care field.

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Home Visiting Narrative: Rewrite Is in Progress

To the Editor With great interest we read the recent editorial by Shonkoff¹ and agree wholeheartedly that "a different approach to early childhood investment that catalyzes innovation, seeks far greater impacts, and views best practices as a baseline, not a solution"¹ is needed. The Maternal Infant and Early Childhood (MIECHV) Program, created as part of the Patient Protection and Affordable Care Act, exemplifies this approach. We would like to highlight 3 examples: state evaluations conducted as part of the MIECHV Program, the national evaluation of the MIECHV Program, and the Home Visiting Research Network (HVRN).

To date, the MIECHV Program has awarded a combination of formula, development, and expansion grants to 50 states, Washington, DC, and 5 territories for home visiting programs. These grants build capacity by promoting workforce development, data infrastructure, care coordination, and referral systems. Each state accepting federal funds is required to evaluate its accomplishments in taking evidence-based home visiting to scale.

The MIECHV Program's impact is also being assessed through the Mother and Infant Home Visiting Program Evaluation, which integrates a randomized trial with a rigorous implementation study to identify features of home visiting services that are associated with the greatest effects at a population level. A multilevel, theory-based conceptual framework informs the Mother and Infant Home Visiting Program Evaluation²; 85 programs in 12 states are participating with early findings that will be released in 2015.

The HVRN assembles home visiting stakeholders to set a national research agenda, advance that agenda through innovation research methods, and translate research findings into policy and practice.³ The HVRN identified the top 10 priorities for home visiting research with input from nearly 1800 individuals.⁴ Now, the HVRN is building the Home Visiting Applied Research Collaborative, a national practice-based research network of local home visiting programs to conduct field-initiated studies to address the research agenda's priorities.

We need to learn what works best for which families and under what circumstances and to translate this efficiently to policy and practice. The MIECHV Program's state-level evaluative research, the Mother and Infant Home Visiting Program Evaluation, and the HVRN will substantially "clarify the evidence base"¹ related to home visiting investments to maximize outcomes for children, families, and communities. Stakeholders are key participants in these efforts; they are eager to use results to ensure success in the adoption, adaptation, implementation, and sustainability of home visiting as part of the early childhood system of care and as part of efforts to promote the foundations of health by enhancing the capacity of caregivers and communities.⁵

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Incorrect Classification in Articles About Traumatic Brain Injuries in Children With Minor Blunt Head Trauma

To the Editor We are writing to make readers aware of an analytic error that affected the data reported in 2 of our articles.^{1,2} During recent preparation of another manuscript based on the same data, we discovered an error in construction of the final

analytic database for the entire cohort (an erroneous SQL [Structured Query Language] join statement) that led to the incorrect classification of the mechanism of injury as moderate, rather than severe, for 394 children in our cohort of 42 412 patients. Most of the erroneous classifications were among children aged 2 years or older.

The first article affected by this erroneous classification was titled "Prevalence of Clinically Important Traumatic Brain Injuries in Children With Minor Blunt Head Trauma and Isolated Severe Injury Mechanisms."¹ We have carefully examined the effects of this error on the entire published analysis. As previously noted, the number of children with severe injury mechanism increased by 394, and the number of children with isolated severe injury mechanism increased from 3302 to 3630 as a result. These increased numbers led to numerous modifications to data points in the article. However, the most important data points in the report are only slightly affected. The overall incidence of severe injury mechanism increases by only a single percentage point in this population (from 14% to 15%) and the rates of clinically important traumatic brain injuries associated with isolated severe injury mechanism remain low, decreasing by one-tenth of 1% among older children (from 0.6% to 0.5% for isolated severe mechanism and no other Pediatric Emergency Care Applied Research Network predictors and from 0.3% to 0.2% for isolated severe mechanism and no other predictors in the expanded definition), with no change among younger children from the published report.

The second article affected by the erroneous classification was titled "Cranial Computed Tomography Use Among Children With Minor Blunt Head Trauma: Association With Race/Ethnicity."² Again, an erroneous SQL join statement led to the incorrect classification of the mechanism of injury as moderate, rather than severe, for 394 children in our cohort of 42 412 patients. This led to minor effects on the reported tabular data (Tables 1, 2, and 3), as well as minor differences in reported odds ratios/confidence intervals for association of black non-Hispanic or Hispanic race/ethnicity with cranial computed tomography in the emergency department (these data are reported in the abstract and the Results section of the text).

We regret these errors but also believe unequivocally that the key findings and conclusions of the published papers firmly stand. The articles have been corrected and correction notices published.

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