COMMENTARY

New initiatives to improve HPV vaccination rates

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ARTICLE HISTORY Received 31 December 2015; Accepted 16 January 2016

KEYWORDS Cervical cancer prevention; HPV; HPV vaccine; Human Papilloma Virus vaccine; School entry vaccine requirements; Sex Ed (sexuality education); STDs (sexually transmitted diseases); vaccine hesitancy

In pediatrics, as in all of medicine, prevention of illness is our primary responsibility. Although HPV vaccine is one of the safest and most effective vaccines we have and is one of 2 vaccines that successfully prevent common forms of cancer, the medical and public health communities have had difficulty getting our patients vaccinated against HVP. Although it has been strongly recommended by national and public health organizations for a decade for girls (2006) and 4 years (2011) for boys, we in the US are still protecting fewer than half of our girls and boys. Even when we do, we are often achieving “full protection” well after the individuals have first been exposed to the viruses, so we are failing to protect them.

We all know the challenges. HPV vaccine is not sought after by parents or patients. The illnesses caused by these viruses are not comfortable to discuss and the association between the viruses and cancer is not widely known. Children, parents and even some health personnel don’t understand how important this vaccine is, and thus are not asking for it, nor even expecting it. Though most providers do know, many do not strongly recommend the vaccine, are not effectively educating their patients about it, early, or ever, are not outlining its vaccination schedule, and are not forcefully urging their families to start and then complete the series in time. Other healthcare partners are not pressing for it, e.g. the insurance industry, the quality assurance industry (e.g., HEDIS metrics), the professional societies. No incentives are in place, for anyone. Schools are not insisting that their students all be vaccinated with this vaccine, nor are they helping get those who are behind schedule vaccinated.

We need to engage all players. Leadership by public health professionals and clinicians in medical homes is obviously essential, but parents, teachers, nurses, schools, legislators and regulators all need to do their part. This perspective is about the many ways everyone, particularly schools, can help us get all our children vaccinated on time, and how the successes and failures of Massachusetts, Rhode Island and a handful of other states who have innovative vaccination initiatives can inform all states how to develop best practices for fully protecting their children from cervical and head and neck cancers.

Massachusetts has been a leader in health services for many years. Its first public health lab is said to have been in the basement of the State House. For most of the past hundred years, the State has provided all vaccines free to the children of the state. In part because of this, Massachusetts has often led the

country in vaccination rates. But at this point, Massachusetts is little more effective at achieving full HPV protection than most other states. From 2013 to 2014, our rates for one vaccination for girls rose from 62% to 69%, 3 vaccinations for girls rose from 40% to 50%. Over the same period, our rate for one vaccination for boys rose from 52% to 54%, and for 3 vaccinations for boys rose from 21% to 27%. It takes a huge amount of work, money, organization and motivation on the part of many people to make a vaccination campaign succeed. How can we mobilize all agents and resources to bring HPV immunization rates above 90% from less than 50%?

There seem to be 3 basic approaches to attaining full HPV vaccination rates by 13 years of age: 1) hoping that increased health education of parents and children and increased encouragement by physicians will raise the rates, 2) instituting vaccination requirements for school entry at specific grades, or 3) launching HPV vaccination initiatives in schools and pharmacies as well as offices, with or without school entry requirements.

Rhode Island has been a national leader in vaccinating its children. In 2014, the 3 dose rate for HPV vaccination of girls was 56% and for boys was 43%. The state has a different public health structure from Massachusetts, many fewer (180 as compared to 2160) pediatric practices, and several unique vaccination programs, including “Vaccinate before you Graduate” which is described in another article in this symposium. In July, 2015, Rhode Island passed moderately strict, but not absolute, stepwise school entry vaccination requirements for all boys and girls in seventh, eighth and ninth grades, which Massachusetts has considered but not yet instituted. Medical communities across the country are watching closely to see how effective Rhode Island’s grade entry requirements will be in increasing HPV vaccination rates toward the Healthy People 2020 goal of 80% full vaccination rates.

This article will outline the factors, challenges and potential solutions being considered in Massachusetts, a much larger state than Rhode Island, which has 2160 pediatricians and 500,000 children in middle and high schools. Almost all children in this state have their own personal medical homes. Like Rhode Island, Massachusetts children get their vaccines in their doctors’ offices not in public health clinics. Children and parents have strong longitudinal personal and professional relationships with their doctors, perhaps even more so than

they do with their teachers and schools. Although many schools do not have school based health centers, most do have nurses on site at least some days each week. Some health teaching and health care must take place in schools, but because of unequal local funding streams and administrative oversight, there is no consistency of approach, care, services or even philosophy between schools and school districts. Despite this fragmentation, in the past Massachusetts has been able to engage schools in health care initiatives.

Two decades ago, when we needed to immunize all teenagers with Hepatitis B virus (HBV) vaccine, the state faced a similar problem to the one now posed by HPV vaccine. It was relatively straightforward to immunize the infants 3 times in the first year against HBV since pediatricians already had a schedule of routine visits to achieve that. We had 2 major challenges with HBV: establishing standing orders in every hospital to give every newborn an HBV vaccine within the first 24 hours of life, and catching up the unvaccinated teens. We generally succeeded in convincing hospital services to make newborn vaccination routine, but it was much more difficult to get teenagers caught up. The MCAAP Immunization Initiative, which I had started and lead, together with the MDPH, schools, school nurses, and local health departments orchestrated a several year, primarily school based campaign to get 3 doses of Hepatitis B vaccine into teenagers. It was widely successful. I believe that this kind of program could be replicated to achieve full HPV vaccination.

The basic components of an HPV initiative must include education, standing orders and routine scheduling of vaccine appointments in all medical homes, thorough recording of all administered vaccines no matter where they are given in a central registry, and either or both widespread school-based vaccine administration and grade-specific school-entry requirements.

Education

No one has ever assigned or accepted the responsibility for the education of children (and families) about puberty, sexuality, “raging hormones” and responsible adult interpersonal relationships. In truth, we all share it: families, clinicians, public health professionals and educational professionals. But because of the complexity of the science, the social embarrassment adults feel about talking about sex with “children,” and the difficulty of teaching respectful social relationships, these teaching assignments have never been made. This is exacerbated by the fact that different cultures have strongly held taboos about various steps in this process, even medically established “best practices.” HPV is a new and distasteful disease. Unlike polio, measles, pneumonia and meningitis, which most parents have at least heard of and know enough to fear, HPV is a largely unknown entity.

For the past couple of years, I have been asking my 10 and 11 year old patients if they have ever heard of HPV. Almost none have, unless I have asked them before. Most have heard of HIV / AIDS. Not until they are into their mid teens can they list herpes, chlamydia or gc. Parents do not broach the subject at all. I ask about whether they have gotten “health education” or “sex ed” in school, in gym, by a nurse, a coach or teacher, and, after some hesitation, many say “yes.” However, as far as I

can tell, the students have learned next to nothing from these courses. They are not tested on them nor reminded of them in subsequent years, basic tenets of successful education. HPV is rarely mentioned by name and neither its short-term nor long term affects are described. The fact that these illnesses are sexually transmitted and are preventable by vaccines recommended between 9 and 11 years of age rarely comes up.

Recently, the CDC released a report on sex education in schools (1). The results from the 2013-2014 school year show that fewer than 20% of middle schools, and only half of high schools, are teaching sex ed as recommended by the CDC. North Carolina middle schools reported the highest compliance in covering recommended topics (45%) while Kentucky reported under 4% compliance. The schools are governed and administered locally, and the sex ed curricula, though sometimes designed and recommended statewide, are determined and taught locally, a recipe for disastrous variability.

In medical practice, it is clear that presenting HPV vaccine as an anti-cancer vaccine is much more powerful than saying that it prevents some sexually transmitted infections. This is a lesson clinicians have only recently learned. Because the vaccination of girls was recommended and rolled out years before vaccination of boys, there is still a serious lack of awareness that boys need the vaccine too. The fact that manual and oral sexual activity can transmit the infection is little recognized. Parents cling to 2 misconceptions, that the only risky sex is penile - vaginal intercourse and that their children are not engaged in any sexual exploration in their early teen and pre-teen years.

Education needs to start at home, but in most cases, in this country, sex education at home will always be inadequate because of social, ethnic, religious and educational challenges (1). Some of this education should be provided by physicians and nurses in medical homes, but at this point no time is allotted for it and there are few incentives (money, quality measures) or guidelines for this to happen routinely beyond Bright Futures and “HEADS” assessments.

Much basic health education should happen in schools, in elementary, middle and high school grades. It should be age-appropriate, progressive, summative and monitored by testing such that by the ages when any form of petting or intercourse are likely to occur, the children and youth have at least heard the whole range of medical, social and economic consequences of their actions.

In schools, the curriculum can start at age 8 (3rd grade) when children are very concrete in their thinking and interested in physical things and cause and effect. At that stage lessons should include information about the physical and emotional changes that are going to occur during puberty. Then, at about age 9 or so, when many children are whispering about sex, schools, with parent-involved homework, should outline basic types of common illnesses and their consequences. This is when prevention and vaccination can be introduced, and descriptions of how vaccines work and why we give shots when we do can be taught. By 11 or 12 years of age, depending on the child and the environment, we all need to be discussing the means of transmission, not simply penile-vaginal intercourse. As uncomfortable as many feel doing it, 12 to 13 year olds need to know the whole range of ways to prevent such transmission, including, but never limited to

abstinence, barrier contraception (which many people think of primarily as preventing pregnancy), and sexual hygiene. Personal respect and the life-altering outcomes of pregnancy such as birth, parenting, school interruption, termination of pregnancy, etc., must be taught openly.

If the children are well prepared in school, they might understand the importance of vaccination and even teach their parents a thing or two. In the clinician's office, we need to start early, gently, matter of factly and authoritatively. Doctors and nurses have to be absolutely direct and uninflected in their recommendation that both boys and girls must be vaccinated against HPV. It's nationally recommended and an essential part of the vaccination schedule. Doctors' discussions on cervical and head and neck cancers should be a review, not news. It is clear that presenting HPV vaccine as an anti-cancer vaccine is a much more effective argument than is saying that HPV vaccine prevents STDs, "Would you like it today?"

Who are the most effective teachers of the different subjects? Doctors probably are for parents and perhaps also for some teens. Informed parents and trained school teachers are probably most influential for preteens. Older student peers are for teenagers (2). We are only beginning to utilize the small army of willing, interested, motivated and effective high school and college age sex and relationship peer educators. They have to go into schools and discuss, not lecture, about all the essential issues, preferably in small groups. Peer teachers have to provoke, challenge and motivate their students. Much of the time, however, physical education teachers teach sex ed, yet they are almost never the most well-trained or well-respected teachers of these subjects.

Funding

State and local funding of vaccines, vaccination administration, and oversight is a major challenge preventing the vaccination of all children against HPV in many states. For over a hundred years, Massachusetts was a "universal distribution" state, and all recommended vaccines were provided free for all children in the state. Rhode Island now is as well. But when HPV vaccine, and several catch up doses of other vaccines, were approved and recommended nationally a few years ago, the cost of these vaccines overwhelmed the Massachusetts state budget, and we spent the better part of the past decade fixing this funding and distribution crisis. Many states rely on federal VFC and 317 funding and variable reimbursement from insurance companies and health plans. Those states that refuse federal Medicaid funds face even greater challenges to healthcare for lower income families' children.

Recently, Massachusetts made 2 essential breakthroughs. 1) Last year, we instituted a public-private system involving a statewide trust fund into which all federal, state and insurance funding for vaccinations is held. This enabled us once more to provide universal distribution of HPV and all other ACIP and AAP recommended vaccines. Our DPH manages the distribution of all vaccines. 2) Over the past couple of years, Massachusetts has also been rolling out a very high quality Statewide Immunization Registry which will enable us to track and manage all these vaccines for all children.

This past year, both Massachusetts and Rhode Island received federal grants to improve our HPV vaccination rates

more rapidly. We pulled together a coalition of health care and education professionals, distributed brochures, aired public service announcements, and gave dozens of Grand Rounds. It may be too early to tell, but we have not yet moved the needle, so to speak, more than a few inches. Massachusetts rates for one vaccine for girls is 69% and for 3 vaccines for girls is about 50%. The rate for one vaccine for boys is approximately 54% and for 3 vaccines is still in the 27% range. Rhode Island's rates for girls were higher than Massachusetts' to start with, about 56%, but have not risen. Its three dose rates for boys rose from 17% to 43% between 2012 and 2014.

This effort, in Massachusetts at least, demonstrates that our focus has been far too limited. All attention so far has concentrated on broad public education (PSAs and professional presentations) and increasing the administration of the HPV vaccines in our children's medical homes. That seemed a logical place to start because the public health advice tends to be dispensed as inexpensively as possible, parents are known to get very questionable medical advice off popular social media and internet sources, and families are used to getting vaccinations in doctors' offices. Added to that, initiatives involving multiple educational and medical sites are not coordinated. Communication systems, hospital, practice and pharmacy EHRs are rarely interoperable, and our schools, health departments and pharmacies rarely speak the same language.

Vaccination exemptions on religious and philosophical bases

As mentioned above, opposition to vaccinations in general is still widespread, for a number of reasons. States have responded to this push back from parents by defining when it is allowable, in the context of both personal and public health benefits, to refuse the administration of vaccines to their children. Statistics show that clear and consistent state requirements and vaccination sufficiency enforcement are key factors in achieving high vaccination rates. For those states that allow philosophical exemptions, achieving consistently high vaccination rates is very difficult. State health departments and schools have a hugely challenging job because any family can refuse vaccines. They try, but it is very difficult, to keep meticulous track of specific vaccination rates, exemption statements for every child, and individual school rates for each immunization. It is all of our responsibility to closely follow outcomes, and protect high risk children such as those with compromised immunity. Adequate HPV infection and cancer prevention will be almost impossible to maintain in communities allowing personal and philosophical exemptions because of the promiscuity of teenagers.

Those states that do not allow philosophical exemptions but do allow religious exemptions must keep equally good records and state and local statistics. Their job is only slightly easier because, without clear definitions of "personal religion" (of which there are none) and precise state guidelines for valid reasons and "emancipation of minors", adherence to vaccination schedules is almost impossible. States need to decide how to word exemptions, how often to renew exemption documentation, where to store the signed forms, and how and how often to publicize the rates in each school regardless of size, funding or level. Yearly recertification is good and rigorous, especially if accompanied by

repeated education about how important vaccination is and how timely HPV vaccination is critical to protection, but it requires extensive time and personnel.

School entry vaccination requirements

Massachusetts decided not to press for school entry requirements when HPV was first recommended because, a decade ago, we felt such action was premature. We needed time to calm people's fears about the new vaccine, demonstrate the safety and efficacy of the vaccine, and show that teen sexual activity would not rise once children had been vaccinated. These issues have now been largely resolved.

Many states like ours are now discussing the wisdom of requiring initial or even full vaccination against HPV for high school and even middle school entry. Rhode Island was the first state, this year, to pass a requirement for graduated HPV vaccination for both boys and girls entering 7th, 8th and 9th grades (4). Massachusetts decided not to introduce similar legislation this season because attention was being paid to opposing efforts to introduce philosophical exemptions in the State. Massachusetts will watch with the rest of the country the effectiveness of Rhode Island's school entry requirements. We hope it will be rapidly effective, and if so, Massachusetts may well follow suit.

Administration of HPV vaccine in schools

The third alternative approach outlined above is for Massachusetts to start not with school entrance requirements but with school-based vaccination campaigns. Parallel statewide experiments could be very informative, though what works in one state could be quite different from what works in another. In both cases, public knowledge will rise dramatically, base vaccination rates will certainly go up, which is our common goal, and other states will benefit from our experience.

A coordinated, statewide school and medical home vaccination campaign could bring the state HPV immunization rate up to 90% quickly. This would be a major undertaking involving many partners, including the State's DPH, all schools, and all primary care offices, but we have made similar efforts successfully before.

When Polio vaccine was first introduced in the US in 1955, there were huge school-based vaccine initiatives. When Rubella vaccine was introduced in 1969, there were similar roll-outs in elementary schools. When Hepatitis B vaccine was introduced a decade ago, Massachusetts pulled together all the pediatricians, birth hospitals, junior high and high schools, and local health departments and managed to vaccinate most children and teens before they escaped into adulthood, through a combination of education, coordination, outreach and data management.

Over the next 3 years Massachusetts, and other states highly motivated to prevent HPV-related illnesses, could build unified programs to administer all HPV vaccinations in the State's elementary schools, or in PCP's offices, depending on the choice of the parents. If successful, we could then decide whether or not we also needed to legislate statewide school entry guidelines.

These initiatives will not be cheap, but the cost of the logistics, nursing time, etc., will be much smaller than the cost of treatment of HPV-related cancers down the line. In Massachusetts, the cost of the vaccines would be covered through our

State Vaccine Trust Fund. The personnel, planning, data entry and other logistical requirements of the effort could be funded by the same public-private coalition of the private health insurers, VFC and 317 programs that exists for our Vaccine Trust Fund, since they would otherwise have to foot the bill of cancer treatment in subsequent decades. Changes, including the payment of school nurses, the financing of logistical infrastructure and increased school physician time would have to be made.

A rotating schedule could be set up whereby once a year, for several days or a week, school and public health nurses, armed with simple phone or school-based apps, could administer that year's vaccines to every 9, 10, and 11 year old who was not up to date in that school. Those children who were absent might have to report to their medical home, or local pharmacy, within a set period of time. The apps would report the administration to the school and the State Vaccine Registry, and a system of reporting the vaccinations would be set up to notify the children's medical homes that that year's vaccine had been given.

Because Massachusetts is a "universal distribution state" the cost of all vaccines would be covered for all children. There would be a standing cost to the State Public Health system of paying the nurses and maintaining their supplies. Most schools have nurses' offices or gyms where the vaccines could be given, as has been done before, and the cost of running this program could be analyzed and compared to cost to the projected insurance and Medicaid programs' expenses to diagnose and treat cervical cancer in Massachusetts women and head and neck cancers in Massachusetts men.

From parents' point of view, there would be several advantages. Parents would not have to take time off work to get each child to the physician's office for 3 vaccinations in a year as is now recommended. Permission slips could be signed once and kept in the school and on line. (These permissions should be "opt out," meaning that every child in an age or grade cohort would routinely get the vaccine unless there was a form signed by the parent in the system.)

Obviously, parents and PCP's could choose to receive these vaccines in their medical homes. Massachusetts does not allow "philosophical" exemptions, so, since there is no "religion" that prohibits HPV vaccination while allowing all the others, if the family had not filed an "exemption" for all the other school-required vaccines, there would not be an option to file a singular exemption for HPV vaccination.

In summary, improving HPV vaccination rates can and must be done, rapidly. Such an effort will require agreement between our medical, educational and public health communities that this initiative is a high priority. Each sector will have major challenges gearing up to do this and each needs the other's cooperation and commitment. Physicians and nurses need to agree that prevention of cervical and head and neck cancers is so important that they will all educate and convince parents and teens that vaccinations must be taken before the children become teens and commence *any* form of sexual experimentation. Parents, along with teachers and schools, need to be convinced that education about life and death are as important as the humanities, math and science, and that they own a significant portion of the responsibility to teach their children and teens real, gritty health lessons before they put themselves at risk. The CDC and many medical and public health organizations have made this recommendation and provided us with

templates and guidelines. The public health and legislative sectors must pull together to fund this HPV vaccination initiative the same way they did the smallpox, polio, Hepatitis B and other mass immunization initiatives because elimination of these important forms of cancers is both possible, cost effective, and the right thing to do for their communities.

Comparison of the costs, difficulties and effectiveness of two approaches like the ones Rhode Island has taken and Massachusetts might take could be extremely informative. Both depend on determination, perseverance and hard work on the part of many partners, but the stakes are high for many young people, and the sooner we begin, the better. The past decade has shown us that provider and public education has resulted in an unacceptably slow rate of rise in complete immunization and thus adequate protection, so more effective approaches, greater effort, and new initiatives seem warranted.

Disclosure of potential conflicts of interest

No potential conflicts of interest were disclosed.

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