PETER DOSHI

Vaccination Creep and Questions of Democracy: will influenza vaccination remain voluntary?

Introduction

In the United States, official guidelines regarding the prevention of influenza are issued by the Centers for Disease Control and Prevention (CDC). Its recommendations are issued in the annual report entitled *Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP).* As stated in the title of the report, official CDC policy is drawn from a federal advisory group, ACIP. This group is comprised of representatives of the CDC, academia, vaccine manufacturers, and other federal departments (Department of Defense, Food and Drug Administration, etc.).[1]

This paper is presented as a collage of quotations, primarily drawn from the CDC's annual report on influenza. Since 1999, this report has included language that has become increasingly ambitious in its recommendations on influenza vaccination. A few decades ago, only a small minority of Americans took the influenza vaccine. But today, influenza vaccine production and consumption are at all time highs, with more than 130 million doses of vaccine delivered to the U.S. for the 2007-2008 influenza season. This dramatic increase over time has occurred for a variety of reasons. First, by expanding the concept of who is "at risk". Second, by improved strategies by the government and some private groups to ensure that as many people who are in targeted "risk groups" actually get vaccinated. Where this may be leading, the documents indicate, is a future recommendation of universal vaccination (vaccination of the entire population).

Taken together, the documents in this report indicate that policy makers:

1. have taken an approach of "creeping incrementalism", or gradually increasing the vaccination recommendations to more and more groups of people over time;

2. are interested in the possibility of "universal vaccination", or vaccination of the entire U.S. population;

3. consider one important benefit of universal influenza vaccination to be the creation of a "resilient and sustainable platform for delivering vaccines ... for other urgently required public health interventions".

The possibility that the CDC may recommend universal vaccination first appeared in the 2006 ACIP guidelines. It is arguable, however, that government officials have had plans (whether official or not) to slowly expand influenza vaccination coverage towards universal vaccination from as early as 1976, the year of the swine flu fiasco. In the aftermath of this unsuccessful[2] attempt to vaccinate the entire U.S. population, officials at the CDC looked for

1 National Center for Immunization and Respiratory Diseases, "ACIP/Members."

2 Here I use the word "unsuccessful" only to denote that the program did not achieve its original intentions. I am putting aside the question of whether those intentions were appropriate or not.

alternative mechanisms to achieve the goal of universal vaccination. The final element to this collage of quotations, then, recalls the swine flu experience in the form of a quotation of the former director of the Division of Immunization (now the National Immunization Program) at the CDC.

From the perspective of both science and democracy, the evolution of CDC policy raises critical questions. I address these questions in the last section of this paper.

Contents:

1. The Chronology (ACIP reports, 1999-2007)

In 1999, ACIP first announced its interest in expanding the use of influenza vaccine. The report cited three reasons for the potential expansion: first the "impact of influenza might decline" because of newer pharmaceutical interventions; second, healthy children less than 5 years old might be at greater risk of complication from influenza than older children; third, a "substantial cost benefit might result from vaccinating groups such as healthy young adults" (p14).

From ACIP's 1999 report

> "This report updates 1998 recommendations by the Advisory Committee on Immunization Practices (ACIP) ... The principal changes include ... discussion of the potential expanded use of influenza vaccine." (p1)

By 2000, ACIP was calling for a large increase in the potential vaccine recipient pool.

From ACIP's 2000 report

> "Increasing vaccination coverage among persons at high risk aged <65 years now is the highest priority for expanding influenza vaccine use." (p2)

Language in the ACIP report changed little during 2001 and 2002.

From ACIP's 2001 report

> "Increasing vaccination coverage among persons who have high-risk conditions and are aged <65 years, including children at high risk, is the highest priority for expanding influenza vaccine use." (p7)

From ACIP's 2002 report[3], page 6:

> "Increasing vaccination coverage among persons who have high-risk conditions and are aged <65 years, including children at high risk, is the highest priority for expanding influenza vaccine use." (p6)

By 2003, however, the annual ACIP report made clear that ACIP saw its work at both sides of the product delivery chain, in both increasing demand and finding ways to increase supply. (Note: I have highlighted in yellow those passages that I wished to draw the reader's attention.)

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3 Carolyn B Bridges, Keiji Fukuda, Timothy M Uyeki, Nancy J Cox, and James A Singleton, "Prevention and control of influenza. Recommendations of the Advisory Committee on Immunization Practices (ACIP)," *MMWR. Recommendations and reports : Morbidity and mortality weekly report. Recommendations and reports / Centers for Disease Control*, 51 (2002), 1-31.

From ACIP's 2003 report[4]

> "Increasing vaccination coverage among persons who have high-risk conditions and are aged <65 years, including children at high risk, is the highest priority for expanding influenza vaccine use." (p7)
>
> "Influenza vaccine delivery delays or vaccine shortages remain possible in part because of the inherent critical time constraints in manufacturing the vaccine given the annual updating of the influenza vaccine strains. Steps being taken to address possible future delays or vaccine shortages include identification and implementation of ways to expand the influenza vaccine supply, improvement of targeted delivery of vaccine to groups at high risk when delays or shortages are expected, and encouragement of the continued administration of vaccine beyond November and throughout the influenza season (December–March) every year (see Timing of Annual Vaccination with Inactivated Influenza Vaccine)." (p16)

In 2004, a section of the ACIP report named "Future Directions" appeared.

From ACIP's 2004 report[5]

> "Increasing vaccination coverage among persons who have high-risk conditions and are aged <65 years, including children at high risk, is the highest priority for expanding influenza vaccine use." (p8)
>
> "Influenza vaccine delivery delays or vaccine shortages remain possible in part because of the inherent critical time constraints in manufacturing the vaccine given the annual updating of the influenza vaccine strains. Steps being taken to address possible future delays or vaccine shortages include identification and implementation of ways to expand the influenza vaccine supply and improvement of targeted delivery of vaccine to groups at high risk when delays or shortages are expected." (p21)
>
> "**Future Directions**
> ACIP plans to review new vaccination strategies for improving prevention and control of influenza, including the possibility of expanding recommendations for use of influenza vaccines. In addition, strategies for regularly monitoring vaccine effectiveness will be reviewed." (p21)

Little changes occurred in the published 2005 ACIP report, but language emphasizing the intention of expanding influenza vaccine use remained. ACIP's concern for vaccinating healthcare workers is also apparent: despite recommendations for healthcare workers, the majority remain unvaccinated.

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4 Carolyn B Bridges, Scott A Harper, Keiji Fukuda, Timothy M Uyeki, Nancy J Cox, and James A Singleton, "Prevention and control of influenza. Recommendations of the Advisory Committee on Immunization Practices (ACIP)," *MMWR. Recommendations and reports : Morbidity and mortality weekly report. Recommendations and reports / Centers for Disease Control*, 52 (2003), 1-34; quiz CE1-4.

5 Scott A Harper, Keiji Fukuda, Timothy M Uyeki, Nancy J Cox, and Carolyn B Bridges, "Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP)," *MMWR. Recommendations and reports : Morbidity and mortality weekly report. Recommendations and reports / Centers for Disease Control*, 53 (2004), 1-40.

From ACIP's 2005 report[6]

> "Increasing vaccination coverage among persons who have high-risk conditions and are aged <65 years, including children at high risk, is the highest priority for expanding influenza vaccine use." (p9)
>
> "Annual vaccination is recommended for health-care workers. Nonetheless, NHIS reported vaccination coverage of only 40% among health-care workers in the 2003 survey (CDC, National Immunization Program, unpublished data, 2005). Vaccination of health-care workers has been associated with reduced work absenteeism (9) and fewer deaths among nursing home patients (125,126) and is a high priority for reducing the impact of influenza in health-care settings and for expanding influenza vaccine use (127,128)." (p9)
>
> Steps being taken to accommodate possible future delays or vaccine shortages include identification and implementation of ways to expand the influenza vaccine supply and improvement of targeted delivery of vaccine to groups at high risk when delays or shortages are expected. (p22)
>
> "**Future Directions for Influenza Vaccine Recommendations**
> ACIP plans to review new vaccination strategies for improving prevention and control of influenza, including the possibility of expanding recommendations for use of influenza vaccines. In addition, strategies for regularly monitoring vaccine effectiveness will be reviewed." (p22)

The year 2006 marked a major change in the published ACIP report. For the first time, the ACIP document discussed the possibility of working towards establishing universal vaccination policies. In addition, the ACIP report highlighted the CDC's role in improving vaccine financing.

From ACIP's 2006 report[7]

> "Increasing vaccination coverage among persons who have high-risk conditions and are aged <65 years, including children at high risk, is the highest priority for expanding influenza vaccine use." (p10)
>
> "Vaccination of health-care workers has been associated with reduced work absenteeism (9) and fewer deaths among nursing home patients (144,145) and is a high priority for reducing the effect of influenza in health-care settings and for expanding influenza vaccine use (146,147)." (p10)
>
> "However, influenza vaccine distribution delays or vaccine shortages

6 Scott A Harper, Keiji Fukuda, Timothy M Uyeki, Nancy J Cox, and Carolyn B Bridges, "Prevention and control of influenza. Recommendations of the Advisory Committee on Immunization Practices (ACIP)," *MMWR. Recommendations and reports : Morbidity and mortality weekly report. Recommendations and reports / Centers for Disease Control*, 54 (2005), 1-40.

7 Nicole M Smith, Joseph S Bresee, David K Shay, Timothy M Uyeki, Nancy J Cox, and Raymond A Strikas, "Prevention and Control of Influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP)," *MMWR. Recommendations and reports : Morbidity and mortality weekly report. Recommendations and reports / Centers for Disease Control*, 55 (2006), 1-42.

remain possible in part because of the inherent critical time constraints in manufacturing the vaccine given the annual updating of the influenza vaccine strains. To ensure optimal use of available doses of influenza vaccine, health-care providers, those planning organized campaigns, and state and local public health agencies should 1) develop plans for expanding outreach and infrastructure to vaccinate more persons than last year and 2) develop contingency plans for the timing and prioritization of administering influenza vaccine, if the supply of vaccine is delayed and/or reduced." (p21)

"ACIP continues to review new vaccination strategies to protect against influenza, including the possibility of expanding routine influenza vaccination recommendations toward universal vaccination or other approaches that will help greatly reduce or prevent the transmission of influenza (279–282). In addition, as noted by the National Vaccine Advisory Committee, strengthening the U.S. influenza vaccination system will require improving vaccine financing, increasing demand, and implementing systems to help better understand the burden of influenza in the United States (283). Strategies to evaluate the effect of vaccination recommendations remain critical." (p24)

The 2007 ACIP report on influenza builds on the interest in achieving universal vaccination seen in the 2006 report. Expanding vaccine use towards universal vaccination may soon include recommendations to vaccinate older children. In addition, the 2007 report identifies ways in which universal influenza vaccination may be useful beyond the prevention and control of influenza: they may "*potentially serve as a resilient and sustainable platform for delivering vaccines ... for other urgently required public health interventions*" (emphasis mine).

From ACIP's 2007 report[8]

"*Updates or supplements to these recommendations (e.g., expanded age or risk group indications for currently licensed vaccines) might be required.*" (p1)

"Although vaccination coverage has increased in recent years for many groups recommended for routine vaccination, coverage remains unacceptably low, and strategies to improve vaccination coverage, including use of reminder/recall systems and standing orders programs, should be implemented or expanded." (p2)

"Increasing vaccination coverage among persons who have high-risk conditions and are aged <65 years, including children at high risk, is the highest priority for expanding influenza vaccine use." (p20)

"Although annual vaccination is recommended for HCP and is a high priority for reducing morbidity associated with influenza in health-care settings and for expanding influenza vaccine use (307–309), national survey data demonstrated a vaccination coverage level of only 42% among HCP (CDC, unpublished data, 2006)." (p22)

8 Anthony E Fiore, David K Shay, Penina Haber, John K Iskander, Timothy M Uyeki, Gina Mootrey, Joseph S Bresee, and Nancy J Cox, "Prevention and control of influenza. Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2007," *MMWR. Recommendations and reports : Morbidity and mortality weekly report. Recommendations and reports / Centers for Disease Control*, 56 (2007), 1-54.

“Expanded age and risk group indications for currently licensed vaccines are likely over the next several years, and immunization providers should be alert to these changes.” (p27)

“ACIP continues to review new vaccination strategies to protect against influenza, including the possibility of expanding routine influenza vaccination recommendations toward universal vaccination or other approaches that will help reduce or prevent the transmission of influenza and reduce the burden of severe disease (349–354). For example, expanding annual vaccination recommendations to include older children requires additional information on the potential communitywide protective effects and cost, additional planning to improve surveillance systems capable of monitoring effectiveness and safety, and further development of implementation strategies. In addition, as noted by the National Vaccine Advisory Committee, strengthening the U.S. Influenza vaccination system will require improving vaccine financing and demand and implementing systems to help better understand the burden of influenza in the United States (355). Immunization programs capable of delivering annual influenza vaccination to a broad range of the population could potentially serve as a resilient and sustainable platform for delivering vaccines and monitoring outcomes for other urgently required public health interventions (e.g., vaccines for pandemic influenza or medications to prevent or treat illnesses caused by acts of terrorism).” (pp31–32)

2. “Lessons” from Swine Flu (1976)

The following words are of Dr. Alan Hinman, former director of the Division of Immunization (now the National Immunization Program) at CDC. This quote has been transcribed from a CDC video produced in the year 2000. In this section of the video, Hinman recalls the lessons learned from the “swine flu fiasco” of 1976, when the government attempted to vaccinate the entire population against swine flu, a type of influenza virus. The program was aborted prematurely after a link was detected between receipt of the vaccine and the development of a severe neurological disorder (Guillain-Barré Syndrome).

> “We learned many lessons from the swine influenza experience of 1976. Among these lessons was a realization that expansion to pandemic level vaccination of the entire population would be much easier if there was an effective, stable, ongoing vaccination program for those at high risk of complication or death from influenza. Improving our ongoing influenza vaccination program would have a significant overall impact on health by reducing inter-pandemic morbidity and mortality as well as ensuring an ongoing programmatic platform from which a major expansion could occur.”
> Dr. Alan Hinman, MD, MPH
> Former Director, Division of Immunization (now NIP), CDC
>
> *from the CDC produced video*
> "Update: Preparing for the Next Influenza Pandemic, July 13, 2000"[9]
> http://www.phppo.cdc.gov/phtn/pandemic/pan-cybrinfo.asp
> http://video.cdc.gov/ramgen/phppo/PublicAccess/NIP/influenza/influenza_pandemic.rm

9 Note that both webpage and video are no longer online. For an archived version of the webpage, see <http://web.archive.org/web/20011230115052/http://www.phppo.cdc.gov/phtn/pandemic/pan-cybrinfo.asp> and “Satellite Broadcast on Preparing for the Next Influenza Pandemic” [Internet]. JAMA. 2000 Jun 28;[cited 2008 Feb 17] Available from: http://jama.ama-assn.org/cgi/content/full/283/24/3195

3. Feb 27, 2008 update: ACIP expands recommendations to all children

In the two weeks since this collage was first put together, ACIP has officially expanded its influenza vaccination recommendations. On February 27, 2008, the panel met and unanimously voted in favor of recommending all children 6 months to 18 years old be annually administered influenza vaccine.[10] Previously, healthy children above 5 years of age were not recommended to get the shot. But if heeded, the new recommendations will create an additional 30 million young customers.

As should come as no surprise, some members of the panel were in favor of voting for a recommendation of universal vaccination. One member, Dr. Gregory Poland, described the new recommendations as "creeping incrementalism."[11]

This particular expansion—to older children—was predictable, as it had discussed in ACIP's 2007 report. However, at the time, ACIP cautioned that:

> expanding annual vaccination recommendations to include older children requires additional information on the potential communitywide protective effects and cost, additional planning to improve surveillance systems capable of monitoring effectiveness and safety, and further development of implementation strategies.

Whether all of those requirements were met prior to the recommending the expansion is unclear. When ACIP's 2008 recommendations are issued, it will be possible to determine whether the CDC offers any evidence that they were.

Media reportage of ACIP's new recommendation was widespread. Yet few newspapers put the new recommendations in context of the CDC's less-than-optimistic announcement around two weeks earlier suggesting that this season's vaccine was not well matched to the influenza viruses in circulation.[12] Most newspapers simply reported that the expansion will help protect more children and the elderly from contracting influenza.

The Houston Chronicle, however, offered an additional perspective:

> One driving force behind the expanded recommendation is increased availability of the vaccine, said Carol J. Baker, a pediatric infectious disease specialist at Texas Children's Hospital who serves on the advisory panel.

Recommendation? Reporting on the announcement, several newspapers highlighted that the new guidelines are no more than "recommendations," drawing attention to the voluntary nature of influenza vaccination.[13] Here, for example, is Lawrence K. Altman of *The New York Times*:

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10 Lawrence Altman, "Panel Advises Flu Shots For Children Up to Age 18," *The New York Times*, 28 February 2008, p. 18.

11 Mike Stobbe, "All children need flu vaccine, panel says - The Boston Globe." February 28, 2008.

12 "CDC News Conference on Influenza - Transcript." February 8, 2008.

13 Winston-Salem Journal, N.C, "EDITORIAL: Flu Shots," *Winston-Salem Journal (MCT)*, 2 March 2008; "Panel urges wider use of children's flu vaccine," *The Seattle Times*, 28 February 2008, p. A4.

> The recommendation, which is voluntary, was made by the Advisory Committee on Immunization Practice, which advises the Centers for Disease Control and Prevention in Atlanta.[14]

But such sentiment fails to acknowledge the weight and implications of the "recommendations" of this federal advisory panel. Consider the response of Dr. Alfred DeMaria, director of communicable disease control for the Massachusetts Department of Public Health, to the new recommendations:

> "Will this be so fantastically successful that it will warrant making it mandatory for schools?" DeMaria said. "We're going to have to wait and see."[15]

When public health officials speak this way, the gap between recommendations and mandates becomes increasingly tenuous.

14 Lawrence Altman, "Panel Advises Flu Shots For Children Up to Age 18," *The New York Times*, 28 February 2008, p. 18.

15 Mike Stobbe, "All children need flu vaccine, panel says - The Boston Globe." February 28, 2008.

4. Questions of Science and Democracy

- What is the evidence of benefit from influenza vaccines, especially among the general population? Previous reviews[16] have found the evidence to support a policy of universal vaccination, especially among healthy adults, to be lacking. The government's expansion of recommendations is occurring at a time when the evidence in favor of influenza vaccination is being shown to be especially weak.[17]

- Influenza vaccination has traditionally been recommended for those people said to be in a "high risk" group—or those with elevated risk of severe complications of the disease. If so, what evidence is there to support the increasing range of risk groups from year to year? For example, if a healthy 3-year-old was not considered to be "high risk" in 2001, what basis is there for the recommendation that a healthy 3-year-old be vaccinated in 2007?

- If universal influenza vaccination becomes an officially recommended policy of the U.S. government, will there be a legal push at the national, state, or local level to make vaccination mandatory? New Jersey has already mandated influenza vaccination for preschoolers, despite heavy opposition by citizens.[18] Other states are considering similar moves.[19] The CDC has given no indication that they have considered the public acceptability of such a potential program: are they considering this factor?

- There is also an important question of honesty and transparency raised by the multiple goals of universal influenza vaccination. The 2007 ACIP report suggests that universal vaccination will help create "a resilient and sustainable platform for delivering vaccines ... for other urgently required public health interventions" (underlining mine). While this "platform" is being constructed, what reasons will the public be given for the benefit of universal influenza vaccinations? As "health marketing" becomes increasingly utilized as a means of communicating with the public, how will officials convince the public that vaccination is the right choice? Will the threat of influenza be emphasized, as was called for by the CDC's "Seven-Step 'Recipe' for Generating Interest in, and Demand for, Flu (or any other) Vaccination"?[20] Or will officials stress the importance of receiving influenza vaccines in order to help build platforms capable of delivering any other vaccines public health officials deem necessary?

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16 V Demicheli, D Rivetti, J J Deeks, and T O Jefferson, "Vaccines for preventing influenza in healthy adults," *Cochrane database of systematic reviews (Online)* (2004), CD001269.

17 Tom Jefferson, "Influenza vaccination: policy versus evidence," *BMJ*, 333 (2006), 912-915; Tom Jefferson and Carlo Di Pietrantonj, "Inactivated influenza vaccines in the elderly--are you sure?," *Lancet*, 370 (2007), 1199-200; Lone Simonsen, Robert J Taylor, Cecile Viboud, Mark A Miller, and Lisa A Jackson, "Mortality benefits of influenza vaccination in elderly people: an ongoing controversy," *The Lancet infectious diseases*, 7 (2007), 658-66.

18 Associated Press, "New Jersey Mandates Flu Shots for Preschoolers," *The New York Times*, 15 December 2007, p. 5; Bloomberg News, "Day-care kids must get flu shots in New Jersey," *Deseret Morning News*, 15 December 2007, p. A16.

19 Fran Silverman, "More Families Are Shunning Inoculations," *The New York Times*, 2 March 2008, p. 3; Mike Stobbe, "All children need flu vaccine, panel says - The Boston Globe." February 28, 2008.

20 Glen Nowak, "Planning for the 2004-05 Influenza Vaccination Season: A Communication Situation Analysis." April 15, 2004, (p. 24)

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www.dipmat.unipg.it/~mamone/sci-dem