REVIEW ARTICLE

Seasonal and pandemic influenza vaccines for the elderly and other risk groups

A review of available data

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KEY WORDS

coverage, influenza, vaccination

ABSTRACT

Human seasonal influenza is a large burden of morbidity and mortality for societies, affecting mainly elderly people and those with underlying chronic medical conditions. Annual vaccination of older adults and other risk groups is the most effective measure for reducing morbidity and mortality associated with infection. A 2008 survey showed 40-fold differences between the vaccination coverage in various European Union countries in individuals aged ≥65 years, ranging from less that 2% to more than 80% in the 2006–2007 season, with Poland belonging to the countries with low influenza vaccination coverage. Annual monitoring of the vaccination coverage is crucial for achieving and maintaining high uptake levels. The need to pay for the vaccine out of pocket is a strong factor discouraging vaccination, and there is evidence that reimbursing costs of influenza vaccination influences vaccination coverage. Although annual influenza immunization of healthcare workers is an important method of preventing the nosocomial transmission of influenza and decreasing the exposure of vulnerable patients, worldwide influenza vaccination rates among healthcare personnel are unacceptably low, rarely exceeding 40%. It is important to keep high vaccination coverage among elderly nursing-home residents. More research is needed to clearly establish the effect of dose sparing strategies of influenza vaccination, e.g., via intradermal immunization, on the immune response in elderly recipients. Finally, due to the emergence of the pandemic influenza A (H1N1) 2009 virus and the development of vaccines directed towards it, the upcoming influenza season 2009–2010 will pose a particular challenge to influenza vaccination programs, and will require careful planning.

Introduction and objectives Human seasonal influenza is a large burden of morbidity and mortality for societies, affecting mainly elderly people and those with underlying chronic medical conditions.[1-3] It is estimated that about 20% of children and 5% of adults develop symptomatic influenza infection each year in Europe[4], leading to a substantial number of hospitalizations and deaths.[5]

Annual vaccination of older adults and other groups at increased risk of severe disease if infected, is the most effective measure for reducing morbidity and mortality associated with infection. The annual VENICE (Vaccine European New Integrated Collaboration Effort, http://venice.cineca.org) and ECDC (European Centre for Disease Prevention and Control) survey of influenza vaccine policies and practice in Europe found that while policies differ in detail, almost all the European Union (EU) member states recommend influenza vaccination to older adults (usually aged ≥65 years) and people with underlying chronic medical conditions.[6]

In 2003, the World Health Assembly recommended that countries where national influenza vaccination policies exist should establish and implement strategies to increase vaccination coverage of all people at high risk, including the elderly and patients with underlying chronic medical conditions, with the goal of attaining vaccination coverage of the elderly population of at least 50% by 2006 and 75% by 2010.[7] By passing that

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resolution all the EU countries committed themselves to those targets.

The present paper describes and discusses the recent data on the coverage of seasonal influenza vaccination in the EU member states. It focuses on special populations where maintaining high vaccination coverage is particularly important, including healthcare workers (HCWs) and nursing-home residents. It also reviews the recent data on possible methods to potentiate the effect of influenza vaccination, e.g., through intradermal vaccination. Finally, the article reviews the data on the pandemic virus A (H1N1) 2009 and its potential contribution to the 2009–2010 influenza season on the Northern Hemisphere.

Overall seasonal influenza vaccination coverage

Seasonal influenza vaccination coverage in the EU differs substantially between the member states. In 2008, the annual survey conducted by ECDC and the VENICE Network showed 40-fold differences between the coverage in various countries. It demonstrated that vaccination coverage in individuals aged ≥65 years ranged from <2% to >80% in the 2006–2007 season.[6] Two countries have already exceeded the 2010 World Health Organization (WHO) target (the Netherlands with the coverage exceeding 80% and the UK with the coverage of 75–80%). Poland belongs to the group of countries with low influenza vaccination coverage. According to the VENICE/ECDC survey, Poland reported coverage in older people to be <10% in the 2006–2007 season. This is broadly confirmed by a household telephone survey of 11 European countries, which found that the coverage of elderly people in Poland in the 2007–2008 season was 13.9%, the lowest of the 11 studied countries.[8] The same survey showed that vaccination coverage in persons with underlying chronic condition was 11.1%, which was again the lowest value of all the examined countries.[8]

Systematic annual monitoring of vaccination coverage also varies between the member states. Only 19 out of 27 countries reported having a mechanism for monitoring annual seasonal vaccination coverage of people aged ≥65 years, and only 7 reported being able to measure coverage in one or more clinical risk groups.[6] Vaccination coverage in the EU member states is measured using different methods, such as reviewing medical records, conducting population surveys (usually telephone surveys), analyzing sales data from pharmaceutical companies, and others. Both administrative methods and surveys are useful and can be applied in the same country for validation purposes or to obtain additional information on the potential reasons for nonvaccination. The ability to annually monitor vaccination coverage is crucial for achieving and maintaining high uptake levels, monitoring and evaluating immunization campaigns, identifying population groups with low coverage, implementing targeted interventions, and facilitating studies to identify barriers to vaccinate.

Factors contributing to low vaccination coverage which may be targeted for interventions

A household survey conducted among 11 European countries showed that the predictors of being vaccinated against influenza in Poland included either old age or a chronic medical condition, or both. The probability of being vaccinated increased with household income but decreased with higher educational level.[8] In a survey conducted in Poland in 2004 and 2005, 34% and 36% of the respondents, respectively, had misconceptions preventing them from having a vaccination (i.e., they believed they were "resistant to influenza"[9]), 6% and 7%, respectively, did not believe they qualified for vaccination, while 24% of the respondents in both years stated that they would not have a vaccination due to financial difficulties.[9] A receipt of a personal invitation from a general practitioner was identified as a strong positive predictor of vaccination. Misconceptions held by risk group patients may be dispelled by educational campaigns. Personal invitations, mail, telephone reminders, and standing orders can be used to increase coverage. The need to pay for the vaccination out of pocket was a strong discouraging factor. There is evidence that reimbursing costs of influenza vaccination increases vaccination coverage.[10]

Vaccination of special populations

Healthcare workers Prevention of influenza transmission in healthcare settings is particularly important, especially among the elderly. These facilities are a frequent site of nosocomial outbreaks.[11,12] Unvaccinated HCWs are a source for nosocomial transmission of influenza.[12] A recent review of influenza outbreaks in neonatal intensive care units found that attack rate sometimes exceeded 40% and case fatality rate was up to 25%.[13] Both symptomatic and asymptomatic infected HCWs spread the infection so that self-isolation of staff may not be effective in preventing nosocomial transmission.[14,15] Healthcare settings are also places with people at high risk for complications of influenza and death from influenza. Infection control can be particularly difficult in acute medical and surgical wards because of the difficulty to identify infected patients when they have other confusing signs and symptoms.[5,16,17] Influenza contracted in healthcare settings is associated with a considerable burden of morbidity, mortality, and costs.[11,12] Apart from the effect on individuals, influenza outbreaks severely disrupt the functioning of healthcare facilities. A recent review of nosocomial outbreaks in the US showed that influenza outbreaks were associated with an almost 40% closure rate of hospital units.[18]

Annual influenza immunization of HCWs is an important method of preventing nosocomial transmission of influenza and decreasing the exposure of high-risk patients. These patients use

healthcare facilities most often, and frequently their vaccination has a more limited protective effect due to, for example, ageing of the immune system or immunosuppressive effect of underlying chronic conditions.[11,12] There are numerous beneficial effects of vaccinating HCWs against influenza. First, there is a direct benefit for HCWs and healthcare units in which they work, because there are fewer episodes of influenza, fewer days of influenza-like illness (ILI) and job absenteeism.[19-21] Indirectly, vaccination of HCWs also considerably benefits patients in long-term care facilities. There is conclusive evidence from a randomized controlled trial that staff vaccination reduces ILI rate, related hospital admissions, and all-cause mortality among residents.[21-23] In a recent French study (another cluster randomized trial on the effect of vaccinating nursing home staff), multivariate adjusted analysis showed 20% lower mortality among nursing home residents in the vaccination arm of the study, and a strong correlation was observed between staff vaccination coverage and all-cause mortality in residents.[24] The rate of ILI in residents in the vaccination arm, and the rate of sick leave among staff were lower by 31% and 42%, respectively.[24]

Despite the evidence of effectiveness and consistent recommendations of public-health authorities to vaccinate HCWs, worldwide influenza vaccination rates among HCWs are unacceptably low, rarely exceeding 40%.[11,12] For example, in 2002, only 36% of the US healthcare workers received influenza vaccination.[25] According to the survey of 11 European countries, vaccination coverage among HCWs in Poland in 2007–2008 season was 6.4%, the lowest of all the studied countries.[8]

Vaccination uptake by HCWs can be increased by targeted interventions. Although few data is available on the potential determinants of being vaccinated among HCWs, a recent Dutch study provided interesting results on the factors associated with influenza vaccination uptake in this population.[26] They included high personal risk for influenza infection, perceived reduction in personal risk and risk to infect patients, knowledge of and agreement with national guidelines, social influence of people close to the respondents, the impact of the media interest in avian influenza, and ethical perspective that all HCWs should get vaccinated. Organizational determinants included receiving information in an information meeting and from a nursing-home physician. Although this information can apply only to a particular study setting, some of the identified characteristics can be used to design activities aimed at increasing the influenza vaccination uptake among HCWs. In hospitals, vaccination availability may be effectively increased for example by organizing vaccination in wards during shift.

Some authors go a step further and argue that when the uptake of vaccination as part of a voluntary program for HCWs decreases, a short mandatory program may be justified in institutions caring for vulnerable elder people, similarly to obligatory immunization of medical staff against hepatitis B. Yet, this suggestion has been challenged on the grounds of personal freedom.[27]

Nursing-home residents As people age they become more vulnerable to complications of influenza.[5,28] Conditions at nursing homes encourage the spread of influenza, and disease outbreaks frequently occur in such settings.[29,30] Nursing-home residents are usually elderly, often with one or more underlying chronic medical conditions, and thus they are at an increased risk of severe complications and death from influenza.[31] Influenza outbreaks in nursing-home settings may be associated with high mortality.[5,28,30,32]

There is substantial evidence for the effectiveness of seasonal influenza vaccination of the elderly. An almost unique placebo-controlled trial of an inactivated vaccine during the 1991–1992 influenza season in the Netherlands among predominately healthy persons aged ≥60 years led to an estimated efficacy of 58% (95% CI 26–77%) against serologically confirmed influenza illness, and 47% (95% CI 27–61%) against clinically diagnosed influenza.[33] Other studies on the effectiveness of influenza vaccine in the elderly have had to be observational, both because it would be considered unethical to withhold the vaccine from any older person, and because severe outbreaks of influenza are too uncommon to be studied in any manageable trial. The results of meta-analyses of such studies on community-dwelling elderly people and nursing-home residents[34,35] showed significant reductions in hospitalization and death rates in vaccinated individuals.

Recently, the results of such observational studies have been challenged on the grounds that residual bias resulting from unmeasured confounding might have overestimated the effectiveness of influenza vaccine in the elderly.[36] As a result of a discussion on the potentially limited effect of influenza vaccine in the elderly, it was proposed to prioritize vaccination to indirectly protect this population.[37] However, various methods to minimize such residual confounding have been applied in various observational studies leaving little scope for unmeasured confounders, including for example the use of laboratory confirmed influenza as outcome, restriction of the analyzed population, multivariable regression to adjust for confounders, propensity scores, and others.[38] It has to be emphasized that even after taking such unmeasured confounding into account, influenza vaccination is still associated with substantial reduction in mortality risk.[39]

Intradermal use of influenza vaccines There is an ongoing discussion among experts whether intradermal (ID) influenza vaccine delivery potentiates immune response. In healthy adults, ID administration can be dose-sparing, i.e., a lower antigen dose can cause similar immune response to that of intramuscular (IM) administration.[40-42] The aim of this strategy is to increase vaccine

supply in case of vaccine shortage, e.g., using a 0.1 ml injection would increase the supply five times. The immune system in the skin has been recognized as a good target for dose-sparing vaccination attempts because it is rich in antigen-presenting, dendritic cells.[43] Antigen delivered via the IM route has to be brought first to the draining lymph node, while ID injection delivers an antigen directly into the skin, with its abundance of antigen presenting cells. However, studies investigating immune response after ID administration in the elderly provide confusing results. Various studies on the elderly have found that ID delivery may be associated with a diminished[44,45] or enhanced immune response.[45]

Pandemic influenza A (H1N1) 2009 **Implications**

In April 2009, a new strain of human influenza A (H1N1) causing human disease was identified and characterized.[46,47] Due to the evidence of community transmission of the new strain from person to person in more than one of its regions, the WHO declared a pandemic on June 11, 2009.[48] The signs and symptoms of this novel influenza A (H1N1) 2009 virus infection are similar to those of seasonal influenza.[49] Definitive diagnosis of novel influenza A (H1N1) 2009 virus infection requires specific testing for H1N1 viruses including real-time reverse transcriptase-polymerase chain reaction or viral culture.[50] It is not yet clear whether the mortality associated with this virus will be greater than that associated with circulating seasonal influenza A virus infections because many elderly patients seem to be immune.[51] The overall severity of this pandemic A (H1N1) 2009 influenza is judged by the WHO to be moderate. The criteria for such evaluation are not entirely clear, but it is supposed to mean that while most people recover from infection without a need for hospitalisation or medical care, serious cases and deaths also occur, becoming a particular burden for hospitals and intensive care units.[51] Pandemic strains have on at least one occasion (1918–1919) become more pathogenic and/or more transmissible in the course of a pandemic. Also after a pandemic, the new virus invigorates the circulating seasonal strains resulting in higher morbidity and mortality in the annual epidemics. However, over time and after repeated waves of infection and disease, the pandemic virus generally adapts and becomes less pathogenic, although usually maintaining a higher level of pathogenicity than the preceding seasonal influenza A viruses. So far most deaths and cases of severe disease in the US and elsewhere have occurred in people with chronic underlying conditions, but also in pregnant women and very young children.[51,52] The comparison of age distribution of the cases reported in the US shows a striking difference from seasonal influenza. As of July 31, 2009, the median age of persons with laboratory-confirmed infections in the US was 12 years, and the median age of hospitalized persons with laboratory-confirmed novel influenza A (H1N1) 2009 virus infection was 20 years.[53] Paradoxically, older people, with or without underlying conditions, are less likely to be infected, but those who get infected are more likely to suffer a more severe form of the disease than a younger person. Current seasonal influenza vaccines do not protect against the pandemic influenza A (H1N1) 2009 virus.[54] Specific vaccines against the novel virus have been developed, and in Europe they are now awaiting licensure before they are manufactured. Based on early epidemiological findings, groups that are at increased risk of developing severe clinical conditions when infected (and thus considered priority groups for vaccination) include: 1) people aged ≤65 years with chronic underlying conditions (chronic respiratory diseases, chronic cardiovascular diseases, chronic metabolic disorders, such as diabetes, chronic renal and hepatic diseases, persons with congenital or acquired immune deficiency, chronic neurological or neuromuscular conditions, or any other condition that impairs a person's immunity or respiratory function); 2) young children (especially aged <2 years, at present no clinical data are available for children <6 months of age, so other preventive measures have to be used in this group); 3) pregnant women. More information on pandemic vaccines is available in the ECDC interim guidance on the use of specific pandemic influenza vaccines during the H1N1 2009 pandemic.[55]

Conclusions Despite national and international recommendations seasonal influenza vaccination coverage in the EU differs substantially between the member states and is still very low in several countries, including Poland. Vaccination coverage in special populations reviewed in this paper, i.e., among HCWs and nursing-home residents is also low in almost all settings and geographical areas studied, including Poland. Increasing vaccination coverage among HCWs is especially important as an indirect measure to reduce the risk of infection among their patients, who are often at higher risk of severe complications than the general population. More effort is needed to increase vaccination coverage among nursing-home residents to protect this vulnerable population against influenza infection and its complications. More research is needed to clearly establish the effect of dose-sparing strategies of influenza vaccination, for example via intradermal immunization, on immune response in the elderly recipients. Due to the advent of the pandemic influenza A (H1N1) 2009 virus and the development of vaccines directed towards it, the upcoming influenza season 2009–2010 will pose a particular challenge to influenza vaccination program and will require careful planning.

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ARTYKUŁ POGLĄDOWY

Szczepienie przeciwko grypie osób w wieku podeszłym i innych grup ryzyka – sezonowe i w czasie pandemii

Przegląd dostępnych danych

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SŁOWA KLUCZOWE

grypa, szczepienie, zasięg

STRESZCZENIE

Chorobowość i umieralność związane z ludzką grypą sezonową, szczególnie wśród osób w wieku podeszłym i ze współistniejącymi chorobami przewlekłymi, stanowi duże obciążenie dla społeczeństw. Coroczne szczepienie osób starszych i innych grup dużego ryzyka choroby jest najskuteczniejszym środkiem zmniejszania chorobowości i umieralności związanej z tym zakażeniem. W badaniu z 2008 roku wykazano 40-krotne różnice częstości szczepień w różnych krajach Unii Europejskiej w sezonie 2006–2007 u osób w wieku ≥65 lat, sięgającej od <2% do >80%; Polska należy do krajów o małej częstości szczepień przeciwko grypie. Podstawowe znaczenie dla osiągnięcia i utrzymania dużej częstości stosowania szczepień ma możliwość corocznego monitorowania ich zasięgu. Konieczność samodzielnego opłacenia szczepionki jest silnym czynnikiem zniechęcającym do szczepienia, a istnieją dowody, że refundacja kosztów szczepienia przeciwko grypie wpływa na częstość szczepień. Chociaż coroczna immunizacja pracowników opieki zdrowotnej jest ważną metodą zapobiegania wewnątrzszpitalnemu szerzeniu się zakażenia wirusem grypy i zmniejszania ekspozycji pacjentów podatnych na powikłania, to częstość szczepienia personelu medycznego jest na całym świecie niedopuszczalnie mała i rzadko przekracza 40%. Ważne jest utrzymanie dużej częstości szczepień u mieszkańców domów opieki w podeszłym wieku. Potrzeba więcej badań, aby w sposób jednoznaczny ustalić wpływ metod zmniejszania dawki szczepionki, np. przez immunizację śródskórną, na odpowiedź immunologiczną pacjentów w wieku podeszłym. Z powodu pojawienia się pandemicznego wirusa grypy A (H1N1) 2009 i opracowywania skierowanych przeciwko niemu szczepionek, nadchodzący sezon grypowy 2009–2010 będzie szczególnym wyzwaniem dla programów szczepień przeciwko grypie i będzie wymagał starannego planowania.

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