研究要旨

わが国におけるインフルエンザの予防と対策が標準的な手法によって行われることが普及することを目的として、インフルエンザの予防と対策の指針として世界標準である米国疾病管理センター（CDC）の予防接種諮問委員会（ACIP）が毎年行っている勧告の2007年版の内容を翻訳して出版した。

A．研究目的

わが国におけるインフルエンザの予防と対策が標準的な手法によって行われることを普及させる。

B．研究方法

米国疾病管理センター（CDC）の予防接種諮問委員会（ACIP）の勧告（2007年版）[1]を標記の分担研究者、研究協力者、共同研究者によって分担して翻訳し、鷲尾、大藤、小笹が分担して訳文チェックなどを行って共同編集し、鈴木、前田、加瀬が各専門領域について点検し、主任研究者および葛西が監修した。

C．研究結果

（財）日本公衆衛生協会より、2007年版「インフルエンザの予防と対策」として発行予定。

D．考察

インフルエンザの予防と対策の標準的な手法の普及に貢献すると考える。

E．結論

米国疾病管理センター（CDC）の予防接種諮問委員会（ACIP）の勧告を翻訳刊行する。

文献

1) Centers for Disease Control and Prevention (CDC), Department of Health and Human Services: Prevention and Control of Influenza, Recommendations of the Advisory Committee on Immunization Practices (ACIP), Recommendations and Reports. Morbidity and Mortality Weekly Report 56 (RR-6), 1-54, 13 July 2007.

F.健康危険情報

なし

G．研究結果発表

翻訳書

廣田良夫、葛西健（監修）．米国疾病管理センター（CDC）の予防接種諮問委員会（ACIP）勧告、インフルエンザの予防と対策、2007年版．日本公衆衛生協会：東京、

H．知的財産権の出願・登録状況（予定を含む）

1．特許取得

なし

2．実用新案登録

なし

3．その他

なし

厚生労働科学研究費補助金（新興・再興感染症研究事業）
分担研究報告書

インフルエンザワクチンの有効性に関する論文抄訳集の作成

分担研究者

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研究要旨

わが国におけるインフルエンザの予防と対策が標準的な手法によって行われることが普及することを目的として、インフルエンザワクチンの有効性評価に関する最近の論文を抄訳して、抄訳集を作成する。

A．研究目的

インフルエンザワクチンの有効性に関する研究は、ウイルス学、免疫学、臨床医学、疫学など多岐にわたる要素を含んでいるため、それらの理解と普及、並びに、わが国でインフルエンザの予防と対策が標準的な手法に則って行われることの障害となっていると考えられる。そこで、現在までに公表されているインフルエンザワクチンの有効性に関する主要な文献を読解して広く紹介することを目的とし、平成14年度より抄訳集を作成してきた。本年度は引き続き、近年の論文について抄訳集を作成して、各研究内容を紹介することを目的とした。

B．研究方法

抄訳対象としては、できれば日本でのインフルエンザワクチンの有効性評価に役立てられるものとして、下記に沿って各担当者が論文を選択した。

A.インフルエンザワクチンの有効性を評価する論文

1）きちんとした疫学手法に則った研究デザインであること

・対象集団が定義されていること

・観察期間（流行シーズン）が明示されていること

・流行株とワクチン株とその合致度が示されていること（できれば）

・曝露（インフルエンザワクチン接種）の把握方法が明示されていること

診療記録、保険記録、電話、質問票など・・・

・アウトカムの基準およびその把握方法が明示されていること

a.質問票／面接による発熱・呼吸器疾患によるインフルエンザ様疾患（ILI）の定義

b.医療機関診断インフルエンザ（診療録から採録）

c.保険記録などからの採録等・・・

・コホート研究、症例対照研究、横断研究などのデザインが判断できること

2）3価不活化ワクチンの評価

B.インフルエンザワクチンの副作用に関するもの

1)副作用の頻度等、疫学的データを示しているもの

2)従来にない新しい副作用などで、重要と思われるものはケースレポートでも可

C.医療経済学的論文

Cost-effectiveness analysis, cost-benefit analysis　その他

これらの参考として、翻訳担当者が各自でPubMed等を使用して検索し、各1編の論文を選択して抄訳した後、地域別のサブグループ内で相互チェックを行った後、事務局に提出して抄訳集とする。

C．研究結果

21人の担当者が各1編の論文を選択し、2008年1月11日に行ったワークショップで各自発表、検討した。本報告書作成時点において、各自が抄訳原稿の作成中である。今後、地域別のサブグループ内で相互チェックを行った後、1月31

日を締切として抄訳原稿を事務局に提出して抄訳集とする。

D．考察

わが国において、疫学的根拠に基づくインフルエンザ対策と予防が行われる資料となると考えられる。

E．結論

近年のインフルエンザワクチンの有効性に関する主要な文献を読解して、広く紹介することを目的として抄訳集を作成する。

F.健康危険情報

なし

G．研究結果発表

論文発表・学会発表

なし

H．知的財産権の出願・登録状況（予定を含む）

1．特許取得

なし

2．実用新案登録

なし

3．その他

なし

厚生労働科学研究費補助金（新興・再興感染症研究事業）
分担研究報告書

Recommendations for Using Inactivated Influenza Vaccines.

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Summary

Estimated vaccination coverage remains <50% among certain groups for whom routine annual vaccination is recommended, including young children and adults with risk factors for influenza complications, health-care personnel (HCP), and pregnant women. Strategies to improve vaccination coverage, including use of reminder/recall systems and standing orders programs, should be implemented or expanded. The 2007 recommendations include new and updated information. Principal updates and changes include 1) reemphasizing the importance of administering 2 doses of vaccine to all children aged 6 months-8 years if they have not been vaccinated previously at any time with either live, attenuated influenza vaccine (doses separated by ≥6 weeks) or trivalent inactivated influenza vaccine (doses separated by ≥4 weeks), with single annual doses in subsequent years; 2) recommending that children aged 6 months-8 years who received only 1 dose in their first year of vaccination receive 2 doses the following year, with single annual doses in subsequent years; 3) highlighting a previous recommendation that all persons, including school-aged children, who want to reduce the risk of becoming ill with influenza or of transmitting influenza to others should be vaccinated; 4) emphasizing that immunization providers should offer influenza vaccine and schedule immunization clinics throughout the influenza season; 5) recommending that health-care facilities consider the level of vaccination coverage among HCP to be one measure of a patient safety quality program and implement policies to encourage HCP vaccination (e.g., obtaining signed statements from HCP who decline influenza vaccination); and 6) using the 2007-2008 trivalent vaccine virus strains

A/Solomon Islands/3/2006 (H1N1)-like (new for this season),
A/Wisconsin/67/2005 (H3N2)-like, and B/Malaysia/2506/2004-like antigens.

Introduction

In the United States, annual epidemics of influenza occur typically during the late fall and winter seasons; an annual average of approximately 36,000 deaths during 1990-1999 and 226,000 hospitalizations during 1979-2001 have been associated with influenza epidemics (1,2). Influenza viruses can cause disease among persons in any age group (3-5), but rates of infection are highest among children. Rates of serious illness and death are highest among persons aged ≥65 years, children aged <2 years, and persons of any age who have medical conditions that place them at increased risk for complications from influenza (3,6-8).

Influenza vaccination is the most effective method for preventing influenza virus infection and its potentially severe complications. Influenza immunization efforts are focused primarily on providing vaccination to persons at risk for influenza complications and to contacts of these persons (Box). Influenza vaccine may be administered to any person aged ≥6 months to reduce the likelihood of becoming ill with influenza or of transmitting influenza to others; if vaccine supply is limited, priority for vaccination is typically assigned to persons in specific groups and of specific ages who are, or are contacts of, persons at higher risk for influenza complications. Trivalent inactivated influenza vaccine (TIV) may be used for any person aged ≥6 months, including those with high-risk conditions. Live, attenuated influenza vaccine (LAIV) currently is approved only for use among healthy, nonpregnant persons aged 5-49 years. Because influenza viruses undergo frequent antigenic change (i.e., antigenic drift), persons recommended for vaccination must receive an annual vaccination against the influenza viruses currently in circulation. 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.

Antiviral medications are an adjunct to vaccination and are effective when administered as treatment and when used for chemoprophylaxis after an exposure to influenza virus. Oseltamivir and zanamivir are the only antiviral medications currently recommended for use in the United States. Resistance to oseltamivir or zanamivir remains rare. Amantadine or rimantidine should not be used for the treatment or prevention of influenza in the United States until evidence of susceptibility to these antiviral medications has been reestablished among circulating influenza A viruses.

Evaluating Influenza Vaccine Efficacy and Effectiveness Studies

The efficacy (i.e., prevention of illness among vaccinated persons in controlled trials) and effectiveness (i.e., prevention of illness in vaccinated populations) of influenza vaccines depend primarily on the age and immunocompetence of the vaccine recipient, the degree of similarity between the viruses in the vaccine and those in circulation, and the outcome being measured. Influenza vaccine efficacy and effectiveness studies typically have multiple possible outcome measures, including the prevention of medically attended acute respiratory illness (MAARI), prevention of laboratory-confirmed influenza virus illness, prevention of influenza or pneumonia-associated hospitalizations or deaths, seroconversion to vaccine strains, or prevention of seroconversion to circulating influenza virus strains. Efficacy or effectiveness for specific outcomes such as laboratory-confirmed influenza typically will be higher than for less specific outcomes such as MAARI because the causes of MAARI include infections with other pathogens that influenza vaccination would not be expected to prevent (9). Observational studies that compare less-specific outcomes among vaccinated populations to those among unvaccinated populations are subject to biases that are difficult to control for during analyses. For example, an observational study that determines that influenza vaccination reduces overall mortality might be biased if healthier persons in the study are more likely to be vaccinated (10). Randomized controlled trials that measure laboratory-confirmed influenza virus infections as the outcome are the most persuasive evidence of vaccine efficacy, but such trials cannot be conducted ethically among groups recommended to receive vaccine annually.

Immunogenicity, Efficacy, and Effectiveness of TIV Children

Children aged ≥6 months typically have protective levels of anti-influenza antibody against specific influenza virus strains after influenza vaccination (11-18). Children aged 6 months-8 years who have never been vaccinated previously require 2 doses of TIV separated in time by ≥4 weeks to induce an optimal serum antibody response. A study assessing protective antibody responses after 1 and 2 doses of vaccine among children aged 5-8 years who never were vaccinated previously indicated that children who received 2 doses were substantially more likely than those who received 1 dose to have a protective antibody response (19). The proportion that had a protective antibody response against the H1N1 antigen and the H3N2 antigen increased from 67% and 92%, respectively, after the first dose to 93% and 97%, respectively, after the second dose. However, 36% of children who received 2 doses did not have a protective antibody response to the influenza B antigen (19).

When the vaccine antigens do not change from one season to the next, priming young children with a single dose of vaccine in the spring followed by a second dose in the fall engenders similar antibody responses compared with a regimen of 2 doses in the fall (20). In consecutive years, when vaccine antigens do change, young children who received only 1 dose of vaccine in their first

year of vaccination are less likely to have protective antibody responses when administered only a single dose during their second year of vaccination, compared with children who received 2 doses in their first year of vaccination (21,22). An open-label, nonrandomized study compared children aged 6-23 months who received 1 dose of vaccine during the 2003-04 influenza season and a second dose of a different vaccine during the 2004-05 season with children who received 2 doses of the same vaccine during the 2004-05 season. The proportion that had protective antibody levels against the H3N2 antigen (changed in the second year) or the H1N1 antigen (unchanged) was similar. However, 27% of children who had received only 1 dose of influenza vaccine during 2003-2004 had a protective antibody response to a single dose of the 2004-2005 vaccine influenza B virus antigen (changed from the previous year), compared with 86% of children who received 2 doses of the 2004-2005 vaccine in their first year of vaccination (22).

The antibody response among children at high risk for influenza-related complications might be lower than those typically reported among healthy children (23,24). However, antibody responses among children with asthma are similar to those of healthy children and are not substantially altered during asthma exacerbations requiring prednisone treatment (25).

Multiple studies have demonstrated vaccine efficacy among children aged ≥6 months, although efficacy estimates have varied. In a randomized trial conducted during five influenza seasons (1985-1990) in the United States among children aged 1-15 years, annual vaccination reduced laboratory-confirmed influenza A substantially (77%-91%) (26). A limited 1-year placebo-controlled study reported vaccine efficacy of 56% among healthy children aged 3-9 years and 100% among healthy children and adolescents aged 10-18 years (27). A retrospective study conducted among approximately 30,000 children aged 6 months-8 years during an influenza season (2003-04) with a suboptimal vaccine match indicated vaccine effectiveness of 51% against medically attended, clinically diagnosed pneumonia or influenza (i.e., no laboratory confirmation of influenza) among fully vaccinated children, and 49% among approximately 5,000 children aged 6-23 months (28). Another retrospective study of similar size conducted during the same influenza season in Denver but limited to healthy children aged 6-21 months estimated clinical effectiveness of 2 TIV doses to be 87% against pneumonia or influenza-related office visits (29). Among children, TIV efficacy might increase with age (26,30).

In a nonrandomized controlled trial among children aged 2-6 years and 7-14 years who had asthma, vaccine efficacy was 54% and 78% against laboratory-confirmed influenza type A infection and 22% and 60% against laboratory-confirmed influenza type B infection, respectively. Vaccinated children aged 2-6 years with asthma did not have substantially fewer type B influenza virus infections compared with the control group in this study (31). Vaccination also might provide protection against asthma exacerbations (32); however, other studies of

children with asthma have not demonstrated decreased exacerbations (33). Because of the recognized influenza-related disease burden among children with other chronic diseases or immunosuppression and the long-standing recommendation for vaccination of these children, randomized placebo-controlled studies to study efficacy in these children have not been conducted because of ethical considerations.

TIV has been demonstrated to reduce acute otitis media. Two studies have reported that TIV decreases influenza-associated otitis media approximately 30% among children with mean ages of 20 and 27 months, respectively (34,35). However, a large study conducted among children with a mean age of 14 months did not provide evidence of TIV efficacy against acute otitis media (36), although efficacy was 66% against culture-confirmed influenza illness. Influenza vaccine efficacy against acute otitis media, which is caused by a variety of pathogens and is not typically diagnosed using influenza virus culture, would be expected to be relatively low because of the nonspecificity of the clinical outcome.

Vaccine Effectiveness for Children Aged 6 Months-8 Years Receiving Influenza Vaccine for the First Time

Among children aged <8 years who have never received influenza vaccine previously and who received only 1 dose of influenza vaccine in their first year of vaccination, vaccine effectiveness is lower compared with children who receive 2 doses in their first year of being vaccinated. Two recent, large retrospective studies of young children who had received only 1 dose of TIV in their first year of being vaccinated determined that no decrease was observed in ILI-related office visits compared with unvaccinated children (28,29). Similar results were reported in a case-control study of children aged 6-59 months (37).

When the vaccine antigens do not change from one season to the next, priming with a single dose of vaccine in the spring followed by a dose in the fall provides a degree of protection against ILI but with substantially lower efficacy compared with a regimen that provides 2 doses in the fall. One study conducted over two consecutive seasons in which the vaccine antigens did not change estimated 62% effectiveness against ILI for healthy children who had received 1 dose in the spring and a second the following fall, compared with 82% for those who received 2 doses separated by ≥4 weeks, both in the fall (29).

Adults Aged <65 Years

TIV is highly immunogenic in healthy adults aged <65 years. Limited or no increase in antibody response is reported among adults when a second dose is administered during the same season (38-42). When the vaccine and circulating viruses are antigenically similar, TIV prevents laboratory-confirmed influenza illness among approximately 70%-90% of healthy adults aged <65 years in randomized controlled trials (42-45). Vaccination of healthy adults also has resulted in decreased work absenteeism and decreased use of health-care resources, including use of antibiotics, when the vaccine and circulating viruses are

well-matched (42-44,46-48). Efficacy against laboratory-confirmed influenza illness was 50%-77% in studies conducted during different influenza seasons when the vaccine strains were antigenically dissimilar to the majority of circulating strains (42,44,48-50). However, protection among healthy adults against influenza-related hospitalization, measured in the most recent of these studies, was 90% (50).

In certain studies, persons with certain chronic diseases have lower serum antibody responses after vaccination compared with healthy young adults and thus can remain susceptible to influenza virus infection and influenza-related upper respiratory tract illness (51-53). Vaccine efficacy among adults aged <65 years who are at risk for influenza complications is typically lower than that reported for healthy adults. In a case-control study conducted during 2003-2004, when the vaccine was a suboptimal antigenic match to many circulating virus strains, effectiveness for prevention of laboratory-confirmed influenza illness among adults aged 50-64 years with high risk conditions was 48%, compared with 60% for healthy adults (50). Effectiveness against hospitalization among adults aged 50-64 years with high-risk conditions was 36%, compared with 90% efficacy among healthy adults in that age range (50).

Studies using less specific outcomes, without laboratory confirmation of influenza virus infection, typically have demonstrated substantial reductions in hospitalizations or deaths among adults with risk factors for influenza complications. In a case-control study conducted in Denmark during 1999-2000, vaccination reduced deaths attributable to any cause 78% and reduced hospitalizations attributable to respiratory infections or cardiopulmonary diseases 87% (54). Benefit was reported after the first vaccination and increased with subsequent vaccinations in subsequent years (55). Among patients with diabetes mellitus, vaccination was associated with a 56% reduction in any complication, a 54% reduction in hospitalizations, and a 58% reduction in deaths (56). Certain experts have noted that the substantial effects on morbidity and mortality among those who received influenza vaccination in these observational studies should be interpreted with caution because of the difficulties in ensuring that those who received vaccination had similar baseline health status as those who did not (10). One meta-analysis of published studies did not determine sufficient evidence to conclude that persons with asthma benefit from vaccination (57). However, a meta-analysis that examined efficacy among persons with chronic obstructive pulmonary disease identified evidence of benefit from vaccination (58).

TIV produces adequate antibody concentrations against influenza among vaccinated HIV-infected persons who have minimal AIDS-related symptoms and high CD4+ T-lymphocyte cell counts (59-61). Among persons who have advanced HIV disease and low CD4+ T-lymphocyte cell counts, TIV might not induce protective antibody titers (61,62); a second dose of vaccine does not improve the immune response in these persons (62,63). A randomized, placebo-controlled trial

determined that TIV was highly effective in preventing symptomatic, laboratory-confirmed influenza virus infection among HIV-infected persons with a mean of 400 CD4+ T-lymphocyte cells/mm^3; however, only a limited number of persons with CD4+ T-lymphocyte cell counts of <200 were included in that study (63). A nonrandomized study of HIV-infected persons determined that influenza vaccination was most effective among persons with >100 CD4+ cells and among those with <30,000 viral copies of HIV type-1/mL (64).

Pregnant women have protective concentrations of anti-influenza antibodies after vaccination (65,66). Passive transfer of anti-influenza antibodies that might provide protection from vaccinated women to neonates has been reported (65,67-69). A retrospective, clinic-based study conducted during 1998-2003 reported a nonsignificant trend towards fewer episodes of MAARI during one influenza season among vaccinated women compared with unvaccinated women and substantially fewer episodes of MAARI during the peak influenza season (66). However, a retrospective study conducted during 1997-2002 that used clinical records data did not observe a reduction in ILI among vaccinated pregnant women or their infants (70). In another study conducted during 1995-2001, medical visits for respiratory illness among the infants were not substantially reduced (71). However, studies of influenza vaccine efficacy among pregnant women have not included specific outcomes such as laboratory-confirmed influenza.

Older Adults

Lower postvaccination anti-influenza antibody concentrations have been reported among certain older persons compared with younger adults (52,53). A randomized trial among noninstitutionalized persons aged ≥60 years reported a vaccine efficacy of 58% against influenza respiratory illness but indicated that efficacy might be lower among those aged ≥70 years (72). Among elderly persons not living in nursing homes or similar chronic-care facilities, influenza vaccine is 30%-70% effective in preventing hospitalization for pneumonia and influenza (73,74). Influenza vaccination reduces the frequency of secondary complications and reduces the risk for influenza-related hospitalization and death among adults aged ≥65 years with and without high-risk medical conditions (e.g., heart disease and diabetes) (74-79). Influenza vaccine effectiveness in preventing MAARI among the elderly in nursing homes has been estimated at 20%-40%, but vaccination can be as much as 80% effective in preventing influenza-related death (79-82).

Elderly persons typically have a diminished immune response to influenza vaccination compared with young healthy adults, suggesting that immunity might be of shorter duration and less likely to extend to a second season (83). Infections among the vaccinated elderly might be related to an age-related reduction in ability to respond to vaccination rather than reduced duration of immunity.

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BOX. Persons for whom annual vaccination is recommended

Annual vaccination against influenza is recommended for

- all persons, including school-aged children, who want to reduce the risk of becoming ill with influenza or of transmitting influenza to others
- all children aged 6–59 months (i.e., 6 months–4 years);
- all persons aged ≥50 years;
- children and adolescents (aged 6 months–18 years) receiving long-term aspirin therapy who therefore might be at risk for experiencing Reye syndrome after influenza virus infection;
- women who will be pregnant during the influenza season;
- adults and children who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological or metabolic disorders (including diabetes mellitus);
- adults and children who have immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus;
- adults and children who have any condition (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, or other neuromuscular disorders) that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk for aspiration;
- residents of nursing homes and other chronic-care facilities;
- health-care personnel;
- healthy household contacts (including children) and caregivers of children aged <5 years and adults aged ≥50 years, with particular emphasis on vaccinating contacts of children aged <6 months; and
- healthy household contacts (including children) and caregivers of persons with medical conditions that put them at higher risk for severe complications from influenza.

適応評価分野（第３分野）

厚生労働科学研究費補助金（新興・再興感染症研究事業）
分担研究報告書

高齢者への肺炎球菌ワクチン接種の公費助成などに関する調査分析

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研究要旨

高齢者に対する肺炎球菌ワクチンの公費助成接種を実施する自治体が近年徐々に増加している。しかし、自治体独自の事業であったため、予防接種の対象者、公費助成額、自己負担額などは自治体が主体的に設定してきた。そのため、これらをまとめ、比較したデータはない。

本研究は，高齢者に対する肺炎球菌ワクチン接種の効率性を明らかにするための費用効果分析の先行調査として、公費予防接種の経験を持つ自治体に対して調査を行い、実施年度、対象者、費用の設定方式および1接種当たりの公費助成額・自己負担額を明らかにすることを目的とした。

A．研究目的

65 歳以上高齢者の肺炎球菌性肺炎の罹患に対する肺炎球菌ワクチン（以下 PPV とする）の防御効果に関してはまだ一致した結果が得られていないが、侵襲性肺炎球菌性疾患（以下 IPD とする）の発症予防には有効で有ると報告されている[1,2]。アメリカでは 1998 年で 65 歳以上の高齢者の接種率が約 46%に達し、「Healthy People 2010」では接種率を 90%まで引き上げることを目標としている[3]。カナダの 13 ある州・準州のうちの 11 州では、2000 年時点で高齢者に対する公費助成接種プログラムを実施していた[4]。イギリスは、2003 年に 80 歳以上、2004 年に 75 歳以上、2005 年に 65 歳以上、と接種対象年齢を引き下げてきた[5]。オーストラリア・ドイツ、アイルランド、チェコなども上記の国々と同様に、高齢者に対する公費助成接種プログラムを実施している[6,7]。高齢者に対する PPV 接種実施国の増加に伴い、接種プログラムに対する経済評価も多く見られるようになった。ワクチン効果を IPD の発症予防に限定し、西ヨーロッパ 10 ヶ国（ベルギー、デンマーク、イングランド&ウェールズ、フランス、ドイツ、イタリア、オランダ、スコットランド、スペイン、スウェーデン）の国別データを用いて各国の 65 歳以上高齢者に対する PPV 接種の費用対効果を分析した研究は、すべての国において接種群は接種しない群に比べ、生存期間は長くなったものの費用も上回った。接種により 1 QALY（質調整生存年）を獲得するに要する費用は 139 万円（デンマーク）～355 万円（スウェーデン）（1 ユーロ＝150 円）と報告している[8]。

一方、わが国では、65 歳以上高齢者の PPV 接種に対する公費助成の実施は各地方自治体の判断にゆだねられている。2001 年度に旧瀬棚町（現せたな町）が 65 歳以上高齢者に対し実施し

た例が注目され、その後、高齢者に対する公費助成接種を実施する自治体が徐々に増加し、PPV を販売している企業によると 2007 年度までで公費助成実施経験を有する自治体は 63 市町村となった。しかし、自治体独自の事業であったため、予防接種の対象者、公費助成額、自己負担額などは自治体が主体的に設定してきた。そのため、それらをまとめ、比較したデータはない。

医療資源は限られているため、効率的な予防接種の実施は大切である。本研究は，高齢者に対する PPV 接種の効率性を明らかにするための費用効果分析の先行調査として、公費助成接種の経験を有する自治体に対して調査を行い、以下の項目を明らかにすることを目的とした。

- 実施年度
- 対象者
- 費用の設定方式
- 1 接種当たりの公費助成額・自己負担額

これらの結果は、公費助成の実施を検討している自治体にも参考になるであろう。

B. 研究方法

2007 年までに高齢者に対する PPV 接種費用を公費で助成した経験を持つ自治体について、万有製薬株式会社が把握している 63 自治体のリストを入手した。2007 年 11 月上旬に、これら 63 の自治体に調査依頼文と調査票(図 1、図 2) を郵送し、11 月末日までの回答を依頼した。未回答自治体に対し、12 月上旬に電話による再依頼を行った。さらに 2008 年 1 月 15 日、未回答の 5 自治体に対し、実施年度、対象者、公費助成額、自己負担額の 4 項目について電話によるインタビューを行い後、当該 4 項目について集計を行った。

C. 結果

1. 公費助成 PPV 接種実施状況

助成を実施した自治体の数は 2002 年度－2007 年度の年度順で、1、17、17、23、42、56（当該年度の純計）であった。期間限定のモデル事業や、市町村合併その他の理由によって助成事業を中止したケースもあるが、実施経験を有する自治体は 2007 年で 63 市町村となった。その多くが町村であった。市および特別区での実施は、2003 年度と 2004 年度の 1 自治体から 2005 年度の 3、2006 年度の 9、2007 年度の 16 と増加傾向であった（表 1）。63 自治体の 2002 年度－2007 年度の 6 年間延べ実施年（1 つの自治体で 3 年実施した場合は 3 実施年と数える）は 156 年であった。

2. 対象者

対象者は、1）年齢（Age-base)、2）リスク状態（Risk-base)、3）年齢とリスク状態の両者、4）国保被保険者、を条件とする 4 種類の設定方式が見られた（表 2)。人数制限を設けた自治体もあった。そのほか、「65 歳以上の者全員、および 60－64 歳で基礎疾患を有するか、または医師の判断による」や「70 歳以上の者全員、および 65－69 歳で基礎疾患を有するか、または医師の判断による」、「75 歳以上全員、および 65－74 歳で基礎疾患を有するか、または医師の判断による」等の設定方式もあったが、その数は少ない。

年齢に関する設定は「65 歳以上」、「70 歳」、「70 歳以上」、「80 歳」などがあり、「65 歳以上」が最も多かった。2007 年度を例として見ると、「65 歳以上」を採用した自治体は全 56 自治体の 42.9% (24/56) を占めていた。しかし、2006 年度、2007 年度の両年度に新規実施した 37 の自治体では、11 自治体が「65 歳以上」、14 自治体が「70 歳以上」、12 自治体が「75 歳以上」を採用した。表 2 から「70 歳以上」や「75 歳以上」を採用する自治体が多くなっていることが分かる。