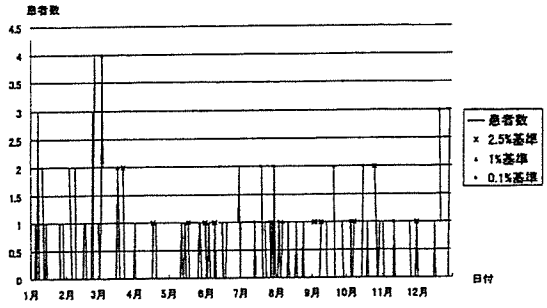

図5　発熱における流行探知

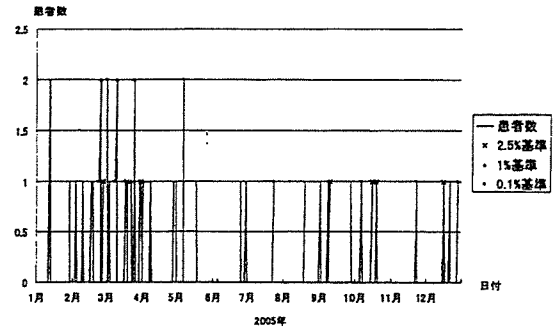

図7　下痢における流行探知

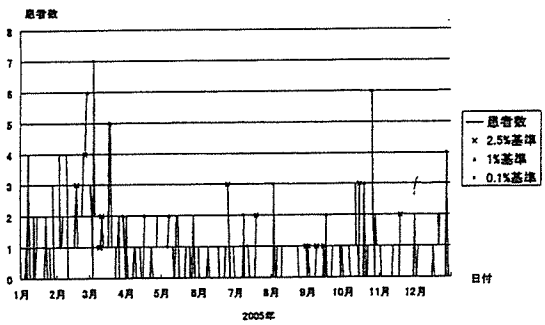

図6　呼吸器症状における流行探知

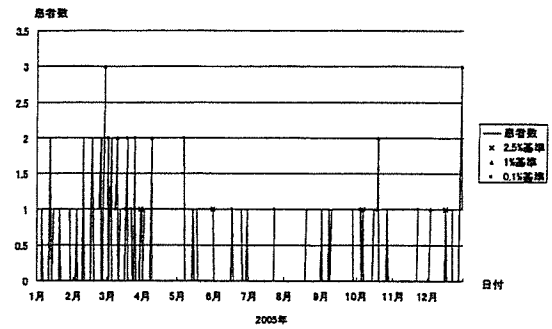

図8　嘔吐における流行探知

れで図9～12に示す。全体的に2.5%基準における特異度は非常に悪い。1人の患者数の増加に対して，それぞれの症状で40，35，65，45%の確率で流行として探知した。これは特異度がそれぞれ60，65，35，55%であることを意味するので，流行探知のおおむね2～3回に1回程度しか正しく流行を探知できない。他方で，4人程度の患者の増加で0.1%基準においても90%以上の確率で流行を探知できる。

D．考察

本研究において，受診者が高齢者中心の内科診療所での症候群サーベイランスの可能性を検討した。その結果，感度は非常に高いものの，特異度が低いため，単独のサーベイランスでは，実用的ではないと考えられた。

その理由として第一に，症状別の患者数が0である日が多く，また最大でも10名を超えないためにその意味で患者数の変化に乏しいことがあげられ，高齢者が中心である医療機関の特徴に起因すると思われる。第2の理由として，この診療所では電子カルテが導入されてまだ2年未満で実験を行っている。そのため，参照すべき過去の情報が十分ではないと思われる。例えば，別の診療所での成績では2年間を過去の情報としてベースラインを推定すると，本研究よりも高い特異度が得られることが知られている[12]。したがって，今後データが蓄積されていくにつれて特異度も増加すると期待される。第3の理由として流行探知アルゴリズムについて，比較的少数の患者数でも精度

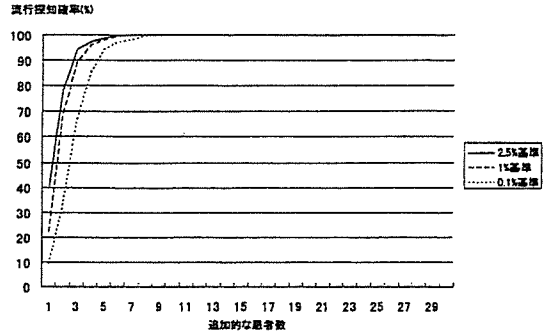

図9　発熱における感度・特異度

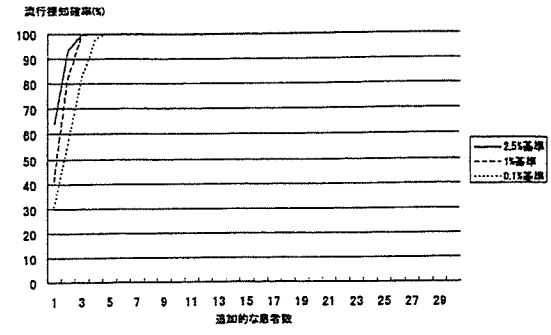

図11　下痢における感度・特異度

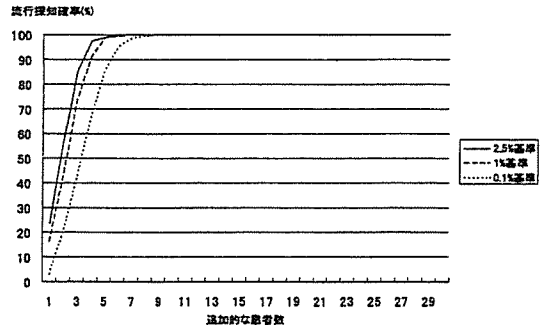

図10　呼吸器症状における感度・特異度

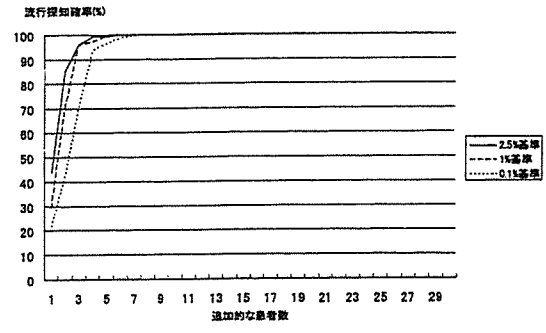

図12　嘔吐における感度・特異度

の高い流行探知アルゴリズムを一層検討する必要があると思われた。

また，感度を下げずに特異度を高める根本的な方策として，同じ地域の他の医療機関における症候群サーベイランス，あるいは同じ地域での救急車搬送や一般用医薬品売り上げ，あるいは欠席，欠勤者情報といった外来受診時以外の情報源に基づく症候群サーベイランスと，その流行探知の結果を相互に交換し，複数の症候群サーベイランスに同時，あるいは数日内で，流行が探知された場合に，はじめて対応をとるという運用が考えられる[12]。幸いこの診療所を含め，同じ行政区域に複数の医療機関において外来受診時の症候群サーベイランスが試行されている。そうした地域での流行探知には，当診療所での症候群サーベイランスもその感度の高さで大きな貢献を担うものと期待される。

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Experimental Surveillance Using Data on Sales of Over-the-Counter Medications — Japan, November 2003–April 2004

Yasushi Ohkusa, M. Shigematsu, K. Taniguchi, N. Okabe
Infectious Disease Surveillance Center, National Institute of Infectious Diseases, Tokyo, Japan

Corresponding author: Yasushi Ohkusa, Infectious Disease Surveillance Center, National Institute of Infectious Diseases, 1-23-1 Toyama, Shinjuku-Ku, Tokyo 162-8640, Japan. Telephone: 81-3-5285-1111; Fax: 81-3-5285-1129; E-mail: ohkusa@nih.go.jp.

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Abstract

Objectives: *This report describes a study to explore the possibility of using data on sales of over-the-counter (OTC) medications as part of a routine syndromic surveillance system aimed at early detection of infections of public health concern. A retrospective evaluation was conducted of sales of OTC medications used to treat the common cold. This report discusses the correlation of these data to influenza activity in Japan during the 2003–04 influenza season and evaluates the potential of using such data to predict influenza epidemics.*

Methods: *Data from approximately 1,100 pharmacies throughout Japan collected during November 2003–April 2004 were analyzed. OTC sales data were compared with influenza incidence data (one weekly and two daily data sets) to determine correlations and predictability. Adjusted R-square was used as an index of goodness-of-fit in the estimation. Data reflecting daily influenza activity were obtained from the National Surveillance of Daily Influenza Outpatients and the Mailing List–Based Influenza Epidemic Database. National sentinel surveillance data for influenza from approximately 5,000 sites nationwide also were analyzed.*

Results: *Although a correlation was demonstrated between sales of OTC medications used to treat the common cold and concurrent influenza activity, analysis of sales data alone was not sufficient to determine influenza activity in advance even when sales promotion effects were excluded from the analysis.*

Conclusion: *Because visiting a health-care provider costs more than purchasing OTC medications, the hypothesis was formed that an ill person will purchase OTC medications first and visit a physician only if the condition does not resolve or worsens. The results of this study do not provide any clear evidence to support this hypothesis. For this reason, OTC sales do not appear to be a good candidate for a national real-time detection system for influenza epidemics in Japan.*

Introduction

In 2000, the first syndromic surveillance prototype in Japan was initiated by the Japanese Ministry of Health, Labour, and Welfare (MHLW) in the Kyushu area during the G-8 summit meeting to assist in the early detection of an act of biologic terrorism or an unusual cluster of tropical diseases imported by travelers from tropical areas (*1*). This limited-scale surveillance involved 17 medical institutes in two prefectures for <1 month. Data for the surveillance system were reported through facsimile transmissions for five syndromic categories (i.e., respiratory, gastrointestinal, neurological, cutaneous-mucous membrane-bleeding, and nonspecific). The second (and the first nationwide) syndromic surveillance system was implemented during May 20–July 14, 2002, in connection with the Japan-Korea 2002 World Cup soccer games. The Internet-based surveillance, which was conducted by MHLW and the Infectious Disease Surveillance Center of the National Institute of Infectious Diseases (NIID), grouped hospitalized patients by symptoms into the same five syndromic categories used in 2000. Both ad hoc syndromic surveillance systems operated during high-profile events and were conducted successfully, and their data were matched with those diseases with the same clinical features that were collected later by routine national surveillance. For example, this second ad hoc syndromic surveillance detected a cluster of viral meningitis and a regional outbreak of measles successfully, thereby illustrating the potential of these data in assisting with early detection of disease. However, further improvements are required to detect pandemic influenza or a possible biologic terrorist attack in time to minimize its consequences.

The goal of the early detection syndromic surveillance system is to conduct routine (not ad hoc) surveillance that complements existing surveillance systems and to detect increases in the number of patients before they report to hospitals with severe conditions. Data concerning sales of

over-the-counter (OTC) medications, emergency department (ED) visits, ambulance calls, and other factors were assessed as tentative candidates for early detection of disease outbreaks (*2,3*). Because no routine syndromic surveillance for respiratory syndrome had been conducted previously in Japan, the effectiveness of OTC surveillance in early detection was compared with multiple influenza surveillance systems that were already in place. This report presents interim findings from the OTC sales surveillance.

Methods

Data Source

Commercially available data collecting reported daily sales of OTC medications in all forms (e.g., tablets, powder, granules, and syrup) used to treat the common cold from 1,100 pharmacies throughout Japan were obtained. So-called combination or general common-cold medications were chosen for examination because use of such medications has long been accepted in Japanese society as the first and most common treatment for influenza-like illness (ILI). These medications usually consist of a combination of antipyretic analgesics (e.g., acetaminophen or ibuprofen), antitussives (e.g., dihydrocodeine phosphate or noscapine), expectorants (e.g., bromohexine hydrochloride, guaifenesin, or potassium guaiacolsulfonate), exogenous enzyme (e.g., lysozyme chloride), bronchodilator (e.g., dl-methylephedrine hydrochloride), antihistaminics (e.g., carbinoxamine maleate or mequitazine), vitamins (e.g., vitamin B1, B2, or vitamin C), and others (e.g., herbal medicines or caffeine). The category also includes combined herbal medicines that are licensed for common cold treatment.

Data were collected by a private marketing company from randomly chosen pharmacies covering approximately 2.0% of the 50,000 pharmacies in Japan. The influenza season was defined as November–April. Sales data collected during November 2003–April 2004 were subjected to retrospective analysis to examine the suitability of OTC sales surveillance for early detection of unexpected rare events. OTC sales data were compared with reliable sentinel surveillance data for influenza collected during November 2003–April 2004 by the National Epidemiological Surveillance of Infectious Diseases (NESID) and with data on influenza activity collected daily by two other surveillance systems from clinics, hospitals, and health-care providers. In Japan, sentinel reporting of clinical cases of ILI is mandatory, with or without laboratory tests or confirmation. Data (e.g., the number of influenza outpatients, by age and age group) are collected weekly from 5,000 sentinel surveillance sites (including 3,000 pediatricians and 2,000 internal medicine clinics or departments) nationwide covering one tenth of all clinics and hospitals in Japan for all influenza-related visits. Two daily influenza activity information sources are 1) reported numbers of cases of ILI reported by the National Surveillance of Daily Influenza Outpatients (Daily Case Reporting [DCR]), which collects data from 10% of selected sentinel medical institutions and 2) voluntary reporting by clinicians to the Mailing List–Based Influenza Epidemic Database (MLflu). DCR is operated by NIID and began operating in January 2004 for the 2003–04 influenza season; it collects data regarding the number of outpatients who received a diagnosis of ILI either clinically or by diagnostic test from 500 sentinel sites in clinics and hospitals. Date of onset is not included in the reported data, which makes this surveillance vulnerable to the-day-of-the-week effect (i.e., few patient visits reported during the weekend and more on the following Monday). MLflu is operated by volunteer pediatricians and began operating in December 2003 for the 2003–04 influenza season; it collects data from approximately 350 pediatricians regarding outpatients who have received a diagnosis of influenza by rapid test. Cases reported through MLflu are more likely to reflect actual influenza activity. Date of onset is reported, so the surveillance system is free from the-day-of-the-week effect. However, because reporting is voluntary, the number and representativeness of participants varies during the influenza season.

Analysis

A model was created to estimate influenza activity from the OTC sales information during a 6-month period, as follows:

$$\log(\text{influenza activity in period } t) = \alpha + \beta \log(\text{OTC sales in period } t\text{-}j) + \varepsilon$$

OTC sales data were then adjusted for the-day-of-the-week effect and compared with three other different influenza activity surveillance systems (sentinel surveillance, DCR, and MLflu) to examine the number of lead-days by OTC sales. The adjusting procedure consisted of two steps, as follows:

$$\text{Adjusted OTC sales in period } 1 = \text{Replaced OTC sales in period } 1$$

$$\text{Adjusted OTC sales in period } t = \frac{2k}{k(k+1)} \text{Replaced OTC sales in period } t + \sum_{j=1}^{k-1} \frac{2(k-j)}{k(k+1)} \text{Adjusted OTC sales in period } t\text{-}j$$

for $t > 1$ and $t \leq 6$

Adjusted OTC sales in period t
= 7/28 Replaced OTC sales in period t

$$+ \sum_{j=1}^{6} \frac{(7-j)}{28}$$ Adjusted OTC sales in period t-j

for t >6.

The data set was adjusted by replacing data for weekends, holidays, and the day before and after weekends or holidays with data for the nearest preceding nonholiday weekday. Then the replaced data were smoothed to the past by taking a moving average from the current period to 1 week previous, giving a relatively heavier weight to the nearer days, and gradually reducing the weight for the far past. Although this adjusting procedure did not require future data, the adjustment result might be affected (pulled) from the data used for the replacement and smoothing procedure.

Comparative analysis of OTC sales with one weekly and two daily data sets recording influenza incidence was performed to determine correlations and predictability. Adjusted R-square was used as an index of goodness-of-fit in the estimation.

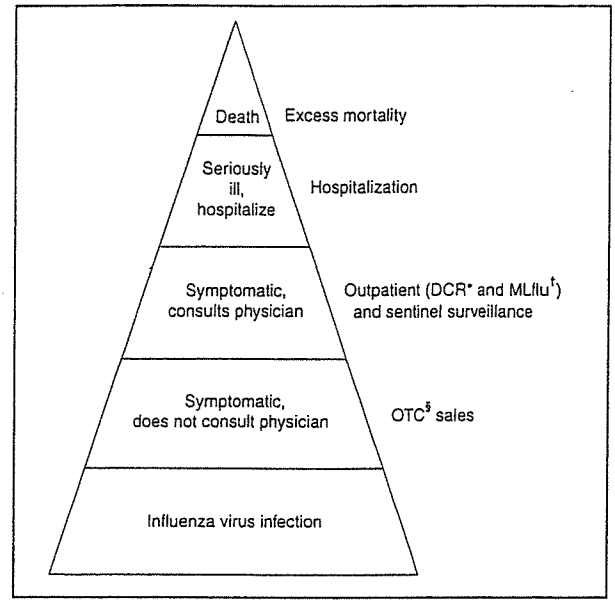
Results

Because national surveillance data do not capture the number of persons who consult a health-care provider for general respiratory symptoms, data regarding consultations for influenza symptoms were used as a substitute to assess lead time of OTC information. Influenza surveillance in Japan was designed to report all potential influenza patients from at least one system for robust detection of influenza activity other than hospitalization (Figure 1). The case definition of influenza used for both outpatient sentinel surveillance and DCR was based on clinical symptoms, which resulted in reporting of patients with ILI.

For this analysis, the hypothesis used was that the majority of persons who were infected by influenza virus and who experienced mild symptoms would choose to self-treat with OTC medications and that those persons whose condition subsequently became more serious would then consult a physician later. Data of sales of OTC medications used to treat the common cold, readily provided as commercial databases, were assumed to reflect the population of preclinical visits by persons with ILI. Data on outpatient visits were represented by sentinel surveillance, DCR, and MLflu. An increase in OTC sales of medications used to treat the common cold was assumed to indicate an initial increase of ILI, and the lead time of the sales to the influenza activity was expected to be observed.

OTC sales per pharmacy were tracked, and the time trend of sales per pharmacy, which was adjusted for the-day-of-the-week

FIGURE 1. Relationship of influenza status and influenza-related surveillance



* Daily case reporting of the National Survey of Daily Influenza Outpatients.
† Mailing List–Based Influenza Epidemic Database.
§ Over-the-counter medications.

effect and then smoothed, was given as a line (Figure 2). Multiple peaks of different size were observed during the 5-month surveillance period, with the consistent underlining trend being that sales were higher in winter and decreased toward spring. Peaks observed were in early and mid-December, early February, and late March. The third peak observed occurred during late January–early February and corresponded with the peak of ILI sentinel reporting generally recorded during influenza seasons; a subsequent period of decline toward spring was also matched. However, the pattern of the early influenza season was fairly discrete between the two data sets (Figure 3).

Adjusted OTC sales data also were compared with adjusted influenza data from DCR to identify a similar pattern during the height of the influenza season (Figure 4). DCR for clinically confirmed ILI is case-based and includes the patient's age and age group, date of visit, performance of rapid test, and result of a rapid diagnostic test as a single thread of information. Because data are reported by clinics and hospitals, numbers were low on Saturdays and Sundays and high on Mondays; consequently, numbers were adjusted for the-day-of-the-week effect. As with sentinel surveillance, DCR also indicated a different pattern early in the influenza season, and the peak coincided with the third peak of OTC sales. Characteristically, no rise in DCR was observed to match the last peak of OTC sales during late March.

FIGURE 2. Time-trend of adjusted over-the-counter (OTC) sales per pharmacy, by date — Japan, November 2003–April 2004

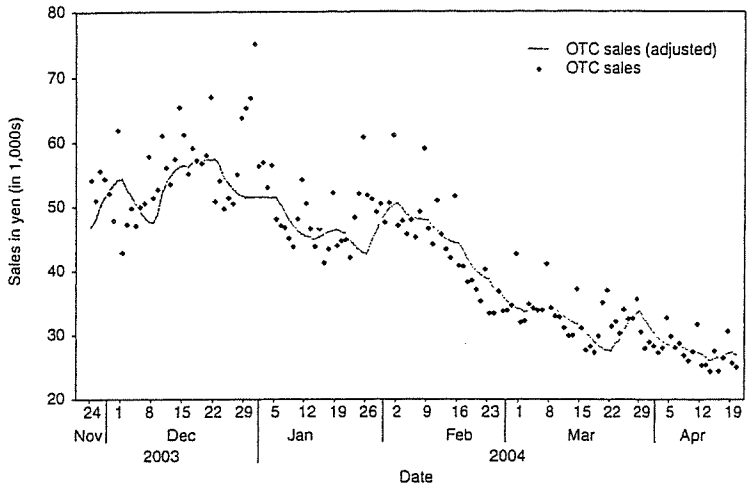
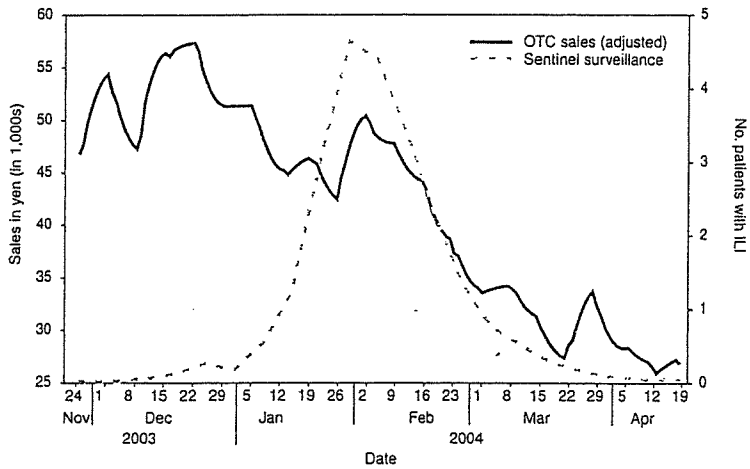


FIGURE 3. Comparison of over-the-counter (OTC) sales per pharmacy (adjusted) with number of patients with influenza-like illness (ILI) reported per sentinel point by national sentinel surveillance, by date — Japan, November 2003–April 2004



MLflu data were reported voluntarily by physicians interested in influenza preparedness. Information collected through the case-based reporting system included the patient's age, date of illness onset, date of visit, type of rapid diagnostic test used, type of influenza virus (A or B) diagnosed, and name of antivirals or other common cold medications prescribed. The date of onset was available for MLflu, which made it free from the-day-of-the-week effect. Additionally, this system was able to provide the number of laboratory-confirmed cases of influenza (i.e., those diagnosed by rapid diagnosis tests). A limitation of this system was that the number of participants varied during the season (low at the beginning and the end of the season). Interest of the clinicians participating in MLflu was high when ILI was rapidly increasing but decreased after the peak period ended (Figure 5). The effect of this variance in the reporting rate should be considered when interpreting the results. As with the other two influenza surveillance systems, MLflu indicated a different pattern from the OTC medicine surveillance at the beginning of the influenza season (Figure 5). However, for the third peak, the rise in sales of OTC medications did not coincide with the peak of MLflu reporting. Instead, the peak observed by MLflu preceded sales by 1–2 weeks (Figure 5). No matched peak was observed for the one during March.

OTC sales data were compared with other influenza activity surveillance data to determine lead time (i.e., the number of days that OTC sales elevation preceded an increase in the number of influenza patients) (Figure 6). Fitness among DCR declined as lead time became longer. The highest adjusted R-square was obtained when OTC data led by 1 day. Conversely, fitness among sentinel surveillance or MLflu rose when lead time was longer. In the case of sentinel surveillance or MLflu, OTC sales appeared to lag behind influenza activity. A peak in OTC sales observed at the end of 2003 was suspected to reflect influenza activity.

Discussion

Syndromic surveillance in Japan has been conducted on an ad hoc basis during high-profile events (*1*). A short-term, labor-intensive analysis system was used that was expensive and resource-intensive to run on a daily basis. To date, several routine influenza surveillance systems have been implemented in Japan. However, each system by itself is unable to provide sufficient information to prepare for the potential emergence of pandemic influenza or related diseases. None of three currently existing influenza surveillance systems might be able to detect the early stage of a pandemic because all systems detect patients only at the point of consultation. In addition, each surveillance system has certain limitations. For example, the national sentinel surveillance provides reliable mandatory reporting but captures only the number

of patients who visit sentinel clinics and hospitals without collecting sufficient qualitative information. These data are reported weekly, with a 1-week delay during which data are compiled. DCR captures additional qualitative information but reports include only the date of visit. MLflu reports the number of patients who receive a diagnosis for influenza with rapid testing. In each surveillance system, timeliness, accuracy, and representativeness have been traded off for other advantages. The rationale for using readily available data of OTC sales for monitoring is to establish routine early detection surveillance for pandemics and other unexpected events to complement those surveillance systems.

The lead time for OTC sales was compared with influenza surveillance to evaluate the timeliness of sales data for detecting seasonal influenza epidemics. An estimated 72% of Americans with cough, cold, influenza, or sore throat often purchase OTC medications early in the course of their illnesses (*4*). Increases in OTC sales were expected to precede an increase in patient visits to hospitals, assuming that consumer behavior in Japan is similar to that in other developed countries (i.e., persons purchase OTC medications when they first feel ill and then visit clinics or EDs if their illness becomes more serious). Although OTC sales correlated well with contemporary influenza activity (*2,3*), a clear lead time was lacking, and analysis of OTC sales data indicated no evidence of advance detection of influenza activity. Additionally, difficulties were encountered in interpreting sales increases in late December from influenza surveillance alone. The increase appeared to reflect preparation for a long holiday season accelerated by year-end discount promotions but not an actual increase in influenza activity. However, further analysis excluding this sales promotion effect was also not able to determine any influenza activity in advance.

These results indicate that sales data on OTC medications used to treat common colds have a low potential for predicting increased influenza activity in Japan. Multiple factors might account for this outcome. Because the analysis was performed only on a national level, the study did not take into account regional varia-

FIGURE 4. Comparison of over-the-counter (OTC) sales per pharmacy (adjusted) with number of patients with influenza-like illness (ILI) per hospital or clinic recorded through daily case reporting (DCR) of the National Survey of Daily Influenza Outpatients (adjusted), by date — Japan, January–April 2004

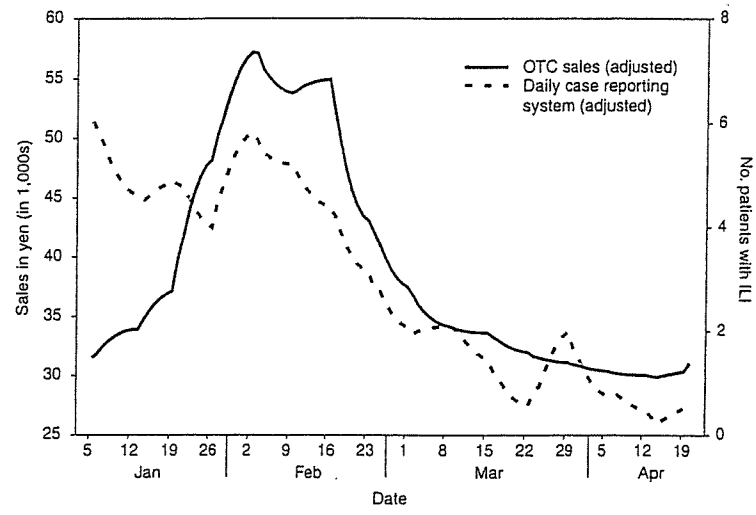
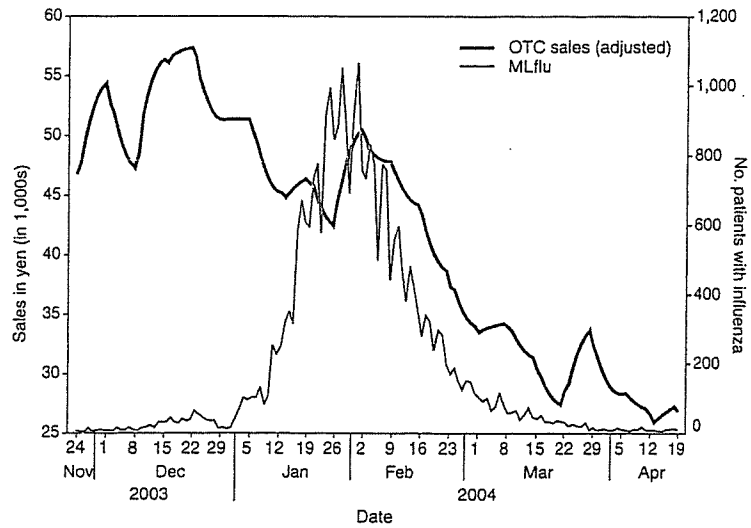
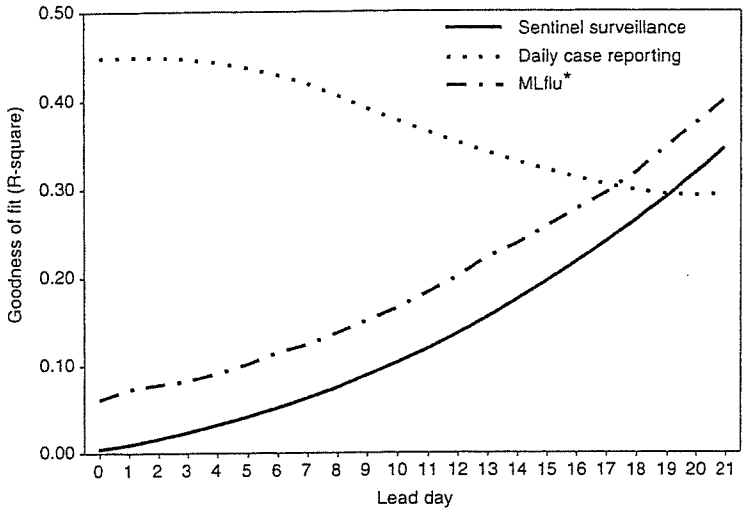


FIGURE 5. Comparison of over-the-counter (OTC) sales per pharmacy (adjusted) with number of patients with influenza reported through the Mailing List–Based Influenza Epidemic Database (MLflu), by date — Japan, November 2003–April 2004*



* MLflu reporting system was activated in November 2003 and officially launched in December 2003 for the 2003–04 influenza season.

FIGURE 6. Goodness of fit (adjusted R-square) between over-the-counter (OTC) sales and other influenza activity surveillances at different OTC lead times for 2003–04 influenza season — Japan, November 2003–April 2004



* Mailing List–Based Influenza Epidemic Database.

tions in influenza activity and variations in when the influenza season began. Variation of lead time of OTC sales to the actual disease incidence by locality has been suggested previously (*5*); therefore, to assess the real situation, smaller geographic areas must be analyzed. The next step to confirm correlations will be to break down the analysis at the prefecture level for 47 prefectures, with and without the effects of sales promotions. However, commuters cross prefecture borders frequently every day, and spatial correspondences or noncorrespondences of OTC sales and physician visits might remain biased in certain instances as a result of inexact geographic data.

The choice of OTC medications selected for this study might have contributed to the outcome. The study was limited to medications used to treat the common cold, which were already grouped in the commercialized sales reporting database. However, in certain cases of early stages of influenza, persons might purchase more symptom-oriented medications (e.g., antipyretic analgesic, antitussive, and antihistaminic medications). To include the entire sales rise attributable to ILI in the analysis, medications in those categories should be examined to formulate a suitable product group to use as precursor for detecting increased ILI as soon as data become available (*5*).

As the copayment proportion of payment for medical care by consumers continues to rise, a gradual move toward self-medication is under way in Japan. Consequently, the potential value of using OTC medication sales data as an indicator of disease outbreaks should continue to rise. However, Japanese consumers are still relatively reluctant to take an active role in decision making regarding their own health care. In addition, the majority of Japanese have easy access to medical care, and the national health insurance system provides a high degree of coverage. As a result, persons who are ill are more likely to visit a clinic at an early stage of illness. The introduction of antiviral agents (e.g., oseltamivir) that require a physician's prescription also has promoted medical assistance–seeking behavior during the influenza season. All of these factors combined might have influenced the study results.

Conclusion

The results presented in this report are tentative. Thorough data cleaning and additional analysis are required before a final decision is made concerning the use of OTC medication sales data as part of a national real-time syndromic surveillance system. Further studies are planned, including a geographic breakdown analysis, analysis with exclusion and inclusion of sales promotion effects (other than the year-end discount promotion), choice of methods for statistical analysis, and analysis taking into account bargain sales and associated promotion types and trial surveillance concerning respiratory symptoms in a limited area.

Acknowledgments

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電子カルテを用いた自動的な感染症サーベイランスのためのシステム開発

菅原民枝[1]、飯島信夫[2]、杉浦弘明[3]、大日康史[1]

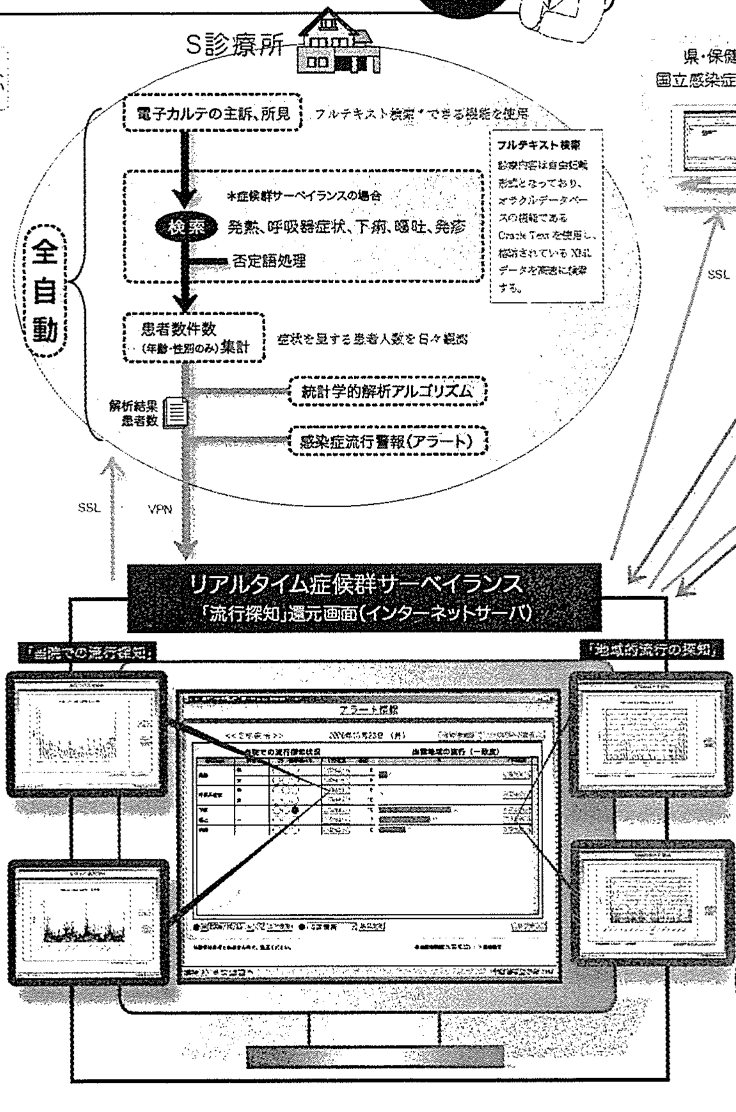
1）国立感染症研究所　2）株式会社 テクノプロジェクト　3）医療法人医純会すぎうら医院

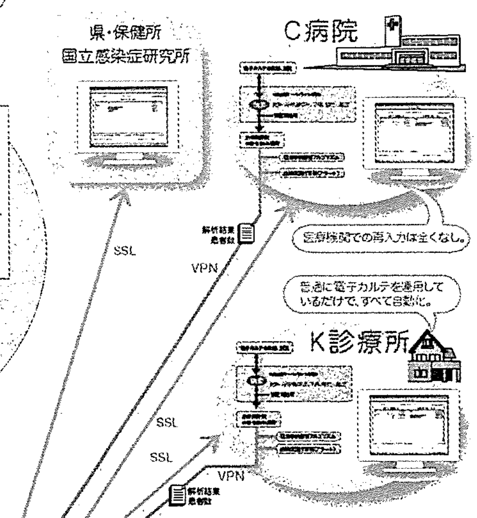
はじめに

- 本研究は、電子カルテを用いて「症状」の検索機能システムを試験的に構築し、自動的に「症候群サーベイランス」と「インフルエンザサーベイランス」に報告することを目的とする。
- このシステムは、電子カルテの主訴・所見欄（診療録の２号紙に該当する）のデータを活用したサーベイランスである。

倫理的配慮

- 国立感染症研究所ヒトを対象とする医学研究倫理審査委員会の承認を得ている。（平成17年12月21日付受付番号77「電子カルテ情報検索システムを用いた症候群及び疾患別リアルタイム・サーベイランス・システム構築のための基礎的研究」）。
- 個人情報保護に配慮して収集されるデータは患者個人が特定できないよう性別、年齢のみとして個人情報は収集しない。検索対象期間の範囲で、同一患者のカルテ情報が存在した場合は、システムで検索される度に動的生成した番号とした。

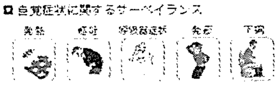




「症候群サーベイランス」とは

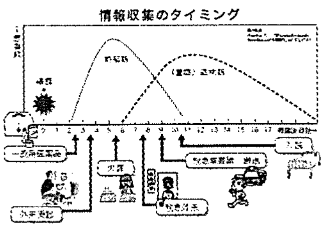
新興・再興感染症の流行、特に未知あるいは稀な感染症に対する探知を迅速に行うためのサーベイランスである。

- 診断の前に流行を探知する。
- 自覚症状に関するサーベイランス



- 外来受診時の症候群サーベイランス：
  医療機関に初診時での主訴の情報を診療録情報から収集し、流行を探知する。

情報収集のタイミング



新型インフルエンザ対策として　　バイオテロ対策として

より早期に探知する。
公衆衛生的な対応を一刻も早く行い、被害の拡大を防ぐことができる。

「インフルエンザサーベイランス」

- 現在の感染症発生動向調査では、全国約5,000のインフルエンザ定点医療機関に受診した患者数が報告されている。
- 迅速に流行状況を把握するための手段として、医師が自主的に参加している「MLインフルエンザ流行前線情報データベース」が1999年以降に運用されている。

考察・結論

- 電子カルテを用いた感染症サーベイランスを運用するために、診療録情報による症状の検索機能システムを構築した。必要なデータを検索し自動的に報告する機能の開発ができた。
- 日本における最初の本格的な症候群サーベイランスはFIFAワールドカップの際に行われたが、入院時にWEB入力形式で、その入力負担の大きさから開催期間前後の2週間のみの運用にとどまった。
- MLインフルエンザ流行前線情報DBも、WEB入力方式のため、流行期になると入力の負担がかかる問題がある。
- 本研究ではその解決策として、電子カルテを用いて、診療録からのキーワード検索を行い、自動的にサーベイランスを報告するシステムを開発した。
- 入力負担の大幅軽減、入力の迅速性、データの正確性は向上した。