を実施することで、感染症の発生をより早期に探知し、まん延防止のための対策につなげることが可能となる。

現状において避難所サーベイランスはIndicator-based(指標に基づく)とEvent-based(事例に基づく)で構成され、異常が探知された場合には評価され、評価に基づき、調査対応が迅速に行われている。しかし、調査対応後の評価は必ずしもなされておらず、アウトブレイク終息後の対策強化、その後のサーベイランス強化や対応強化につなげるためのサイクルにはなっていない。このようなサイクルを確立し、避難所サーベイランスを質の高いものにしていくことが必要である。避難所において感染症サーベイランスの重要性は認識されており、還元情報も積極的に利用されていた。避難所にとどまらず、支援に入っている医療チームもサーベイランス情報を活用し、感染予防への介入を実施していくことが重要であると思われた。

サーベイランス自体の評価とは離れるが、サーベイランス実施により、避難所リーダーの感染症に関する意識の向上が図られるなど副次的な効果を生み出している。また、単純で分かりやすく誰もが理解可能な症候群によるサーベイランスを構築することが重要である。その他、感染症が大規模に発生した場合は、介入策や評価などの支援を国立感染症研究所や東京都に依頼したいという要望があり、体系的に支援できる仕組みづくりが必要である。

E. 結論

石巻保健所管内での避難所サーベイランスは避難所と保健所において、安定的に運用されていた。避難所では、感染症サーベイランスの重要性は認識されており、還元情報も積極的に利用されていた。保健所では、サーベイランスにおいて異常が探知された場合には評価され、評価に基づき、調査対応が迅速に行われていた。

運用上の課題として、保健所での集計作業の負荷、入力時のアクセス集中による Web システム動作低下、避難所リーダーが収集するデータの妥当性、避難所が減少していく中での対象集団の非同一性、毎週1回のデータ報告という迅速性の低さ、サーベイランス評価サイクルの欠落が挙げられた。基本的には、誰もが理解可能な症候群によるサーベイランスを構築することが求められる。

その他、サーベイランス実施により、避難所リーダーの感染症に関する意識の向上が図られるなど副次的な効果が認められた。避難所にとどまらず、今後は、支援に入っている医療チームにもサーベイランス情報を活用してもうことが必要である。アウトブレイク時に介入策や評価などの支援を体系的に行っていけるような仕組みづくりが今後必要である。

参考文献

1) German RR, Lee LM, Horan JM, Milstein RL, Pertowski CA, Waller MN; Guidelines Working Group Centers for Disease Control and Prevention (CDC). Updated guidelines for evaluating public health surveillance systems: recommendations from the Guidelines Working Group. MMWR Recomm Rep. 2001 Jul 27;50(RR-13):1-35; quiz CE1-7.

F. 健康危険情報

特になし

G. 研究発表

1)論文発表

2)学会発表

特になし

H. 知的財産権の出願・登録状況

1)特許申請

2)実用新案登録

3)その他

特になし

(表1)

※FAXで報告する場合、送付状は必要ありません

感染症等症候群別報告書

避難所名＿＿＿＿＿＿＿＿　平成23年　月　日～平成23年　月　日分

有症者数を記入してください。
(0人の場合は0と記入し、不明の場合空欄にして下さい)
内訳がわからない場合、合計だけでもかまいません

記載者＿＿＿＿＿＿＿＿　連絡先＿＿＿＿＿＿＿＿

①…5才未満　②5才以上65才未満　③65才以上

	症状	月曜日				火曜日				水曜日				木曜日				金曜日				土曜日				日曜日			
		①	②	③	計	①	②	③	計	①	②	③	計	①	②	③	計	①	②	③	計	①	②	③	計	①	②	③	計
1	下痢・血便・嘔吐																												
2	インフルエンザ(疑いも含む)																												
3	咳、微熱等の風邪症状 気管支炎や肺炎等																												
4	発熱を伴う赤い発疹 全身の水疱																												
5	意識障害・けいれん 口が開きにくい・物が飲み込みにくい																												
6	指と指の間の 強いかゆみを伴う発疹																												
7	ケガに伴う発熱や膿																												
8	全身のだるさを伴い 白眼や皮膚の色が黄色くなる(黄疸)																												
9	死亡(原因不明の死亡)																												
10	避難者全体の数																												

特記事項:

宮城県石巻保健所　Tel:0225-95-1430
疾病対策班　Fax:0225-94-8982

(表2)

石巻管内避難所サーベイランス集計表(6月27日～7月3日)

		下痢 嘔吐	インフル エンザ	咳 風邪	麻疹 水痘	破傷風	疥癬 白癬	創傷 関連	黄疸	死亡	報告 避難所 件数	避難者計
石巻市	本庁	5	0	34	0	0	1	1	0	0	34	2,262
石巻市	総合支所 河北	0	0	2	0	0	0	0	0	0	3	495
石巻市	総合支所 河南	0	0	3	0	0	0	0	0	0	3	185
石巻市	総合支所 桃生	0	0	0	0	0	0	0	0	0	1	7
石巻市	総合支所 雄勝	0	0	0	0	0	0	0	0	0	3	127
石巻市	総合支所 牡鹿	0	0	0	0	0	0	0	0	0	1	17
石巻市	総合支所 北上	0	0	1	0	0	0	0	0	0	3	89
石巻市 計		5	0	40	0	0	1	1	0	0	48	3,182
東松島		0	0	0	0	0	0	0	0	0	1	63
女川		0	0	0	0	0	0	0	0	0	6	803
合計		5	0	40	0	0	1	1	0	0	55	4,048

※1 現在避難所数は石巻市80ヵ所、東松島市40ヵ所、女川町13ヵ所。
※2 報告は各避難所リーダー・巡回医師・看護師・保健師による。
※3 やや「咳・風邪」に該当する患者の多い避難所もあったが、全て症状は軽症で感染傾向はみられなかった。
※4 「創傷関連」1件は転倒による擦り傷。治療により回復傾向。神経症状なし。

別紙１

石巻感染症情報（避難所版）

平成23年7月6日　宮城県石巻保健所

石巻地域内避難所の感染症の動向

・石巻保健所管内の避難所55ヵ所（避難者数4,048人）からの報告によると、第26週（6月26日～7月3日）は消化器症状は、前週に引き続き減少傾向です。呼吸器症状は前週と同じ水準の報告です。
・呼吸器症状の報告が多い避難所に状況を確認した結果、多くは軽症の咳症状で、高熱や痰を伴う方はいませんでした。
・感染症の拡大防止のために、うがい・手洗い・マスク等の咳エチケットを行いましょう。

避難所サーベイランス情報（第26週：平成23年6月27日～7月3日）

	消化器症状（下痢、嘔吐等）	インフルエンザ	呼吸器症状（風邪等）	発熱を伴う発疹（はしか、水ぼうそう等）
報告数（人）	5	0	40	0

※　現在避難所数：石巻市80ヵ所、東松島市40ヵ所、女川町13ヵ所、計133ヵ所

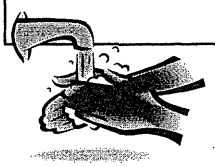
《　食中毒に気をつけましょう!!　》

夏になり気温が上がる中で、これからの時期に増える食中毒への対策が避難所でも重要となってきます。
今週は黄色ブドウ球菌による食中毒について、原因、症状、予防などをお知らせします。

◎黄色ブドウ球菌による食中毒とは・・・
黄色ブドウ球菌が産生する毒素により起こります。黄色ブドウ球菌は、健康な人でも皮膚や鼻の粘膜に存在し、特に傷や化膿したところに多くいます。このため容易にヒトの手を介して、食品に細菌が付着します。付着した細菌が毒素を産生し、汚染された食品を食べたヒトに食中毒の症状が引き起こされます。

【症状】
感染源と考えられる食品を摂取後、1～6時間してから激しい悪心・嘔吐、急激な腹痛・下痢が起きます。症状は2～8時間くらい続き、1日以内には回復します。
【治療】
脱水を改善するための輸液療法などの対症療法が中心となります。毒素が原因のため、抗生剤は効きません。
【予防方法】
食中毒の予防として避難所で出来ることは、
食中毒菌を ① つけない！ (手洗い 、おにぎりを握るときはラップで包んで握る)
② 増やさない！ (室温で長時間放置しない)
③ やっつける！ (しっかり加熱 、ふきんや洗浄スポンジの殺菌)　です。

～　もしも、症状が出てきた場合は、早めに医療機関を受診しましょう　～



※御質問などは石巻保健所疾病対策班までお願いします。
電話：0225－95－1430　FAX：0225－94－8982

平成24年度厚生労働科学研究費補助金(健康安全・危機管理対策総合研究事業)
「健康危機事象の早期探知システムの実用化に関する研究」

分担研究報告書
「保育所の発疹集団発生におけるコクサッキーA群9型の検出・同定」

分担研究者
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要旨
【目的】
2012年10月に、保育所の発疹集団発生において早期、すなわち流行前半の段階でコクサッキーA群9型(CA9)の確認がされた事例から、早期の病原体確認について検討する。
【方法】
疫学情報は、国立感染症研究所感染症情報センターが開発した保育園サーベイランスを使う東京都A保育所が使われた。発疹発症者2から、医師より説明後保護者の同意を得て行った。発疹発症後(医療機関受診後)に、便及び咽頭ぬぐい液を採取した。Hyper PCRによりエンテロウイルスを確認し、CODEHOP PCRを実施して、PCR産物の塩基配列を決定した。
【結果】
A保育所の発疹流行は、2012年10月6日に発疹発症者が急増、10月26日までに、42名の発疹の発症者が確認された。検体が採取された2歳児クラスの2名は、早期に、園児A,BともにCA9が確認された。
【考察】
これまで発疹の施設内流行がみられても不明発疹の流行で終わっていたが、保育園サーベイランスによる早期探知によって病原体診断が可能になると、保育所内での症状での流行の原因を明らかにすることができる可能性がある。早期の段階で確認できることによって、保育所内及び地域内の対策に役立つと思われる。

A. 研究目的

2012年10月に、保育所の発疹集団発生において早期、すなわち流行前半の段階でコクサッキーA群9型(CA9)の確認がされた事例から、早期の病原体確認について検討する。

CA9は、100以上あるエンテロウイルスの血清型1つで、国内での通常の法律に基づいた病原体サーベイランスでは、定点機関からの報告でCA9は把握されているため、

施設内の流行はとらえられないことが多い。CA9は無菌性髄膜炎および発疹症の病原として知られている。

B. 材料と方法

疫学情報は、国立感染症研究所感染症情報センターが開発した保育園サーベイランスを使う東京都A保育所が使われた。

病原体診断は発疹集団発生早期の探知段階で、発疹発症者2名、医師より説明後保護者の同意を得て行った。発疹発症後(医療機関受診後)に、便及び咽頭ぬぐい液を採取した。発疹発症後(医療機関受診後)に、便及び咽頭ぬぐい液を採取した。

Hyper PCRによりエンテロウイルスを確認し、CODEHOP PCRを実施して、PCR産物の塩基配列を決定した。

国立感染症研究所倫理指針による「医療機関における診療の一環として採取された患者試料について、医療機関の求めに応じて確定診断や病原体等の解析などの検査のみを行う場合」に該当するため、倫理審査は不要であった。

C. 結果

A保育所で発疹の流行のあった2階にあるクラスは0歳、1歳、2歳クラスである。2012年10月6日に発疹発症者が急増、10月26日までに、42名の発疹の発症者が確認された(図1)。

検体が採取された2歳児クラスの2名は、早期に、園児A,BともにCA9が確認された。園児A(女)は、発症0日目に頭、首が痛いという主訴があり、腹部に発疹が出現した。発症1日目に38.9℃、下肢、背部発疹が出現し、医療機関受診した。頬部発疹があり、咽頭発赤なし、風疹(-)突発性発疹(-)ウイルス性発疹と診断された。発症2日目に下痢があった。発症5日目に発疹が消失した。園児B(男)は、発症0日目に顔に数個の発疹が出現し、発症1日目には発疹消失、発症3日目に37.5℃あり、頭が痛いという主訴があり、嘔吐2回があった。医療機関受診をし、ウイルス性発疹と診断された。発症4日目に38.5℃、発症5日目に36.9℃であった。園児A,Bは、保育所と自宅以外で過ごしていない。園児A,Bは、保育所内での感染による発症であると思われる。

D. 考察

一般的には、保育所内で発疹の流行がみられても、現状では病原体確定ができないことが多い。保育園サーベイランスは、保育所内の発疹をはじめ発熱、呼吸器症状、下痢、嘔吐などの症候群サーベイランスが行われ、感染症の早期探知が可能となっている。現在全国の4800園で導入されている。また、2012年12月に厚生労働省から出された「保育所における感染症対策ガイドライン」でも位置づけられている。これまで発疹の施設内流行がみられても不明発疹の流行で終わっていたが、この保育園サーベイランスによる早期探知によって病原体診断が可能になると、保育所内での症状での流行の原因を明らかにすることができる可能性がある。早期の段階で確認できることによって、保育所内及び地域内の対策に役立つと思われる。

もちろん確認された2名以外がCA9であった証明はできない。しかしながらその可能性もまた否定されない。したがって本事例ではCA9による流行として対応することが可能であったと考えられる。特に、本事例では発症したすべての園児が欠席して

いないために、重症化のリスクがあるCA9であることが早期に分かれば、登園自粛を促すことによって患者数を減らせる可能性があったと考えられる。

本報告での限界は、当該保育所は、地域での取り組みではないので、地域の状況が不明であり、地域流行があったかどうかは、わからない。2歳児が頭痛および頸部痛を訴えることは稀であり、髄膜炎を引き起こしていた可能性が考えられたがその証明は出来なかった。

E. 結論

感染症の早期探知が可能となれば、病原体診断との連携がしやすくなる。早期の段階で確認できることによって、施設及び地域内の早期対策に役立つと思われる。

F. 健康危険情報

特になし

G. 論文発表

論文発表

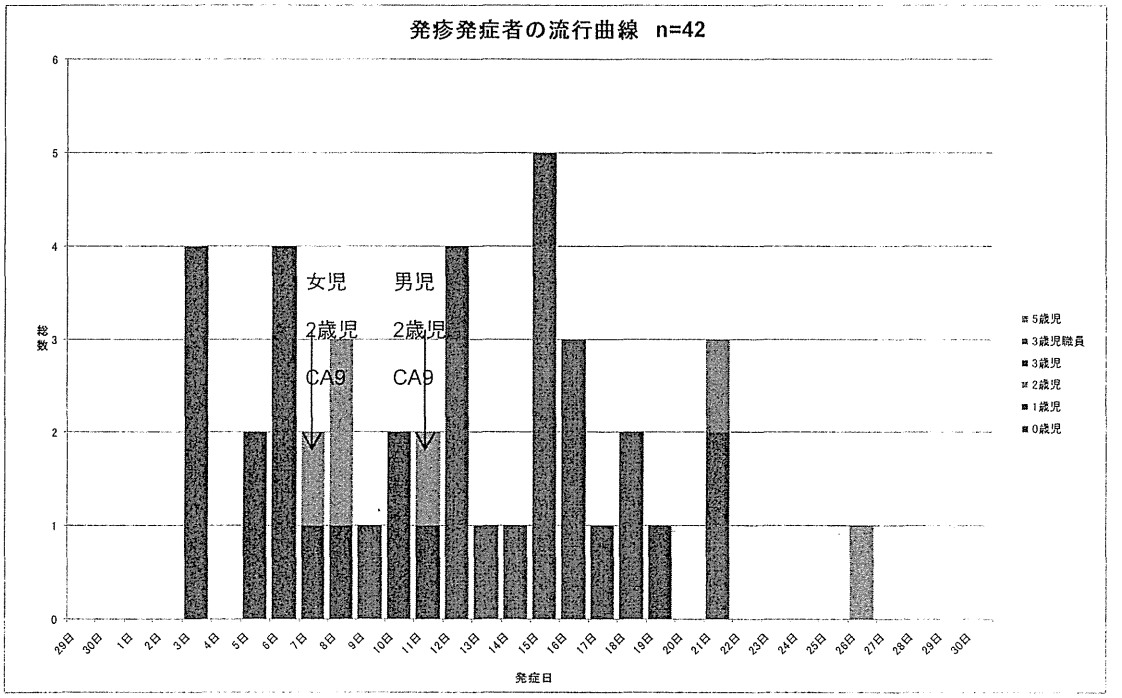
学会等での報告

H. 知的財産権の出願・登録状況

（予定を含む）

特になし

図1



Ⅲ　研究成果の刊行に関する一覧表

書籍

著者氏名	論文タイトル名	書籍全体の編集者名	書 籍 名	出版社名	出版地	出版年	ページ

論文

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
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菅原民枝、藤本嗣人、大日康史、杉下由行、小長谷昌未、杉浦弘明、谷口清州、岡部信彦:病原体診断を伴うリアルタイムサーベイランスによる流行抑制の可能性_保育園での手足口病流行での事例検討	病原体診断を伴うリアルタイムサーベイランスによる流行抑制の可能性—保育園での手足口病流行での事例検討—	感染症学雑誌	86(4)	405-410	2012
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Ⅳ　研究成果の刊行物・別刷

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Research Article

Prescription Surveillance and Polymerase Chain Reaction Testing to Identify Pathogens during Outbreaks of Infection

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Syndromic surveillance, including prescription surveillance, offers a rapid method for the early detection of agents of bioterrorism and emerging infectious diseases. However, it has the disadvantage of not considering definitive diagnoses. Here, we attempted to definitively diagnose pathogens using polymerase chain reaction (PCR) immediately after the prescription surveillance system detected an outbreak. Specimens were collected from 50 patients with respiratory infections. PCR was used to identify the pathogens, which included 14 types of common respiratory viruses and *Mycoplasma pneumoniae*. Infectious agents including *M. pneumoniae*, respiratory syncytial virus (RSV), rhinovirus, enterovirus, and parainfluenza virus were detected in 54% of patients. For the rapid RSV diagnosis kit, sensitivity was 80% and specificity was 85%. For the rapid adenovirus diagnosis kit, no positive results were obtained; therefore, sensitivity could not be calculated and specificity was 100%. Many patients were found to be treated for upper respiratory tract infections without the diagnosis of a specific pathogen. In Japan, an outbreak of *M. pneumoniae* infection began in 2011, and our results suggested that this outbreak may have included false-positive cases. By combining syndromic surveillance and PCR, we were able to rapidly and accurately identify causative pathogens during a recent respiratory infection outbreak.

1. Introduction

Japanese traditional surveillance is based on definitive diagnosis and is enforced by the infection control laws in Japan for the early detection of agents of bioterrorism and outbreaks of emerging infectious diseases. After the infectious disease is diagnosed at sentinel medical institutions, at least 10 days are required until it is announced nationwide. Therefore, a major fault of this surveillance system is the delay in disseminating information.

A surveillance system that can identify the early stages of an outbreak of infectious disease is necessary. Therefore, syndromic surveillance systems have been implemented in many countries since 1995 [1]. Syndromic surveillance monitors changes in the number of patients according to symptoms such as fever, vomiting, diarrhea, and rash for further investigations. Information regarding the identification of local infectious disease outbreaks, such as school absenteeism, emergency room visits, and prescriptions of therapeutic drug against infectious diseases, are also subjects of the survey [2]. Syndromic surveillance can offer a rapid method to detect an outbreak of infection compared with traditional surveillance; such surveillance systems are currently used worldwide [3, 4].

In some cases, an infectious outbreak can be detected on the same or the following day. Although syndromic surveillance provides rapid results, it has the disadvantage that

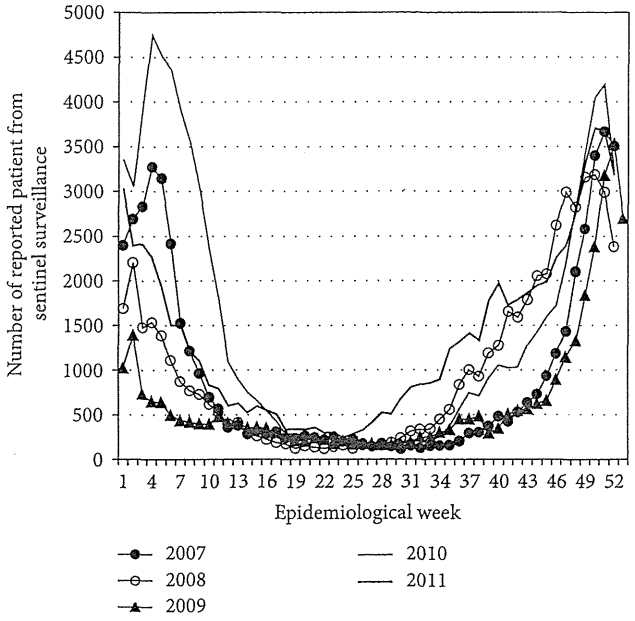

FIGURE 1: Number of reported RSV cases from sentinel medical institutions in Japan. There are approximately 500 sentinel medical institutions in Japan, which are selected from those equipped with departments of pediatrics and internal medicine and with more than 300 beds.

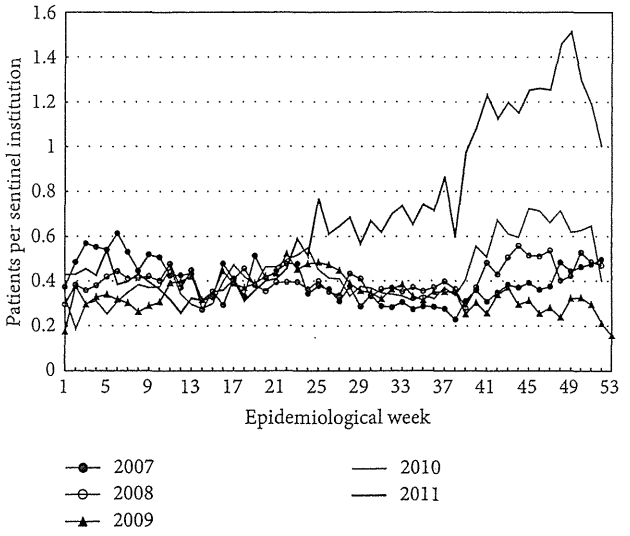

FIGURE 2: Patients per sentinel medical institution reporting *M. pneumoniae* infections.

definitive diagnoses are not considered. In other words, in general, its specificity may be lower than that of traditional surveillance systems. Laboratory testing performed on all symptomatic patients can yield a very high specificity, but is cost prohibitive, whereas laboratory testing on selected patients for syndromic surveillance can detect some specific aberrations at a lower cost, thereby overcoming the shortcomings of both systems. The current study highlights an example to further analyze this possibility.

In the fall of 2011, the number of patients with symptoms of upper respiratory tract infections markedly increased in Japan. Infectious disease weekly reports (IDWRs) (http://www.nih.go.jp/niid/ja/idwr.html in Japanese), which constitute the traditional and official Japanese sentinel surveillance system, reported a higher incidence of respiratory syncytial virus (RSV) (Figure 1) and *M. pneumoniae* infections (Figure 2). A primary feature of *M. pneumoniae* respiratory infections is the degree of the symptom worsening from mild upper respiratory tract inflammation to pneumonia. *M. pneumoniae* infection is associated with exanthem, hemolytic anemia, gastrointestinal damage, arthritis, and various neurological symptoms [5].

Outbreaks of *M. pneumoniae* persisted throughout June 2012, although it is unclear why this organism has continued to be responsible for such a widespread national outbreak in Japan since the fall of 2011 [6]. Koike et al. [7] detected only 40 patients (14.5%) among 275 suspected cases of *M. pneumoniae* infection from 2006 to 2008 in Japan. A clinical diagnosis of *M. pneumoniae* infection is difficult without laboratory confirmation. In many sentinel hospitals, the *M. pneumoniae*-specific IgM antibody rapid detection test is used, but during screening, a positive result in the test does not always indicate acute infection by this organism. We suspect that the outbreak of *M. pneumoniae* infection included false-positive cases [7, 8].

IDWRs are very important for clinicians, enabling them to identify the seasonal prevalence of known diseases. However, these reports become available after a minimum of 10 days following patient examinations. Therefore, traditional and official surveillance systems have the distinct disadvantage of being slow and are limited to reporting pathogens chosen in advance.

In the fall of 2011, by monitoring the increase in the number of combination cold medications (active ingredients: salicylamide, acetaminophen, anhydrous caffeine, and promethazine methylene disalicylate) prescribed since 2009, the prescription surveillance system detected an increase in the number of patients with symptoms of upper respiratory tract infections. On September 26, 2011, we noticed the first unusual peak and began to carefully monitor the real-time prescription surveillance system and observed a second peak on October 3, 2011 (Figure 3). However, monitoring prescriptions for combination cold medications does not lead to the identification of the pathogens responsible for the illnesses being treated. Thus, we conducted pathogen identification using the PCR method after being alerted by the prescription surveillance system on October 4, 2011 (the following day).

The purpose of the present study was to evaluate whether the PCR method triggered by the results of the prescription surveillance system can rapidly and accurately identify causative pathogens of local outbreaks of infection. Our results allowed for earlier diagnoses at medical facilities and the dissemination of this information among other institutions to avoid inappropriate use of antibiotics and instigate measures against the spread of infectious diseases.

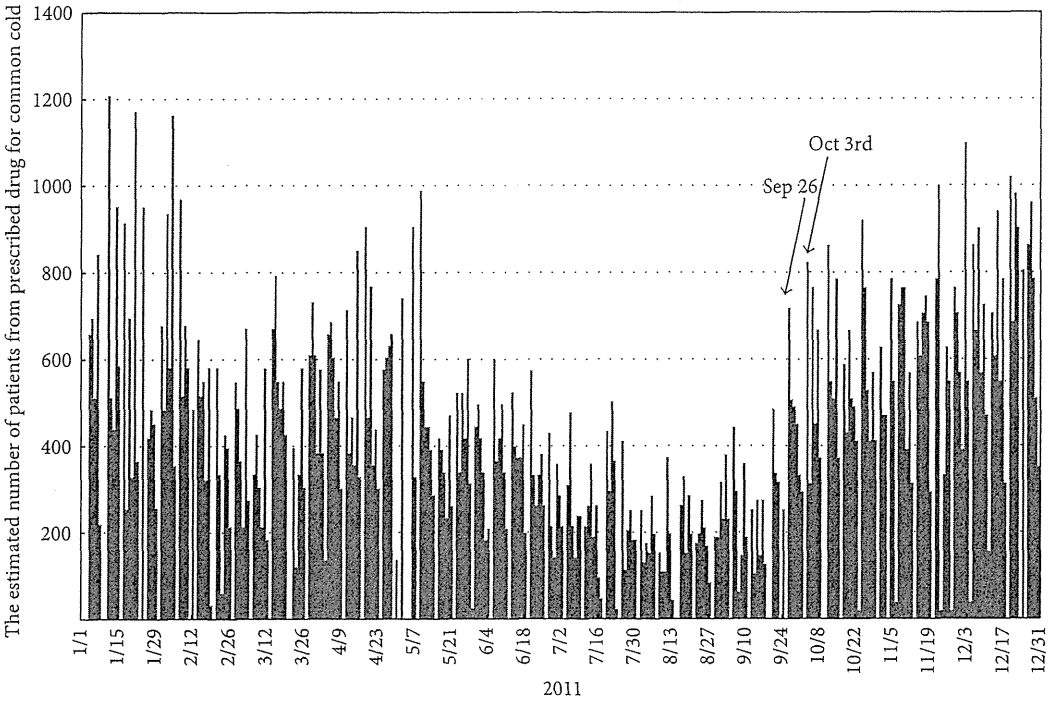

FIGURE 3: Combination cold medication prescriptions recorded by the prescription surveillance system over time. On September 26, 2011, we noticed an unusual peak and then carefully monitored the real-time prescription surveillance and found a second peak on October 3, 2011. We confirmed this abnormality and began this study on the following day (October 4, 2011).

2. Materials and Methods

2.1. Prescription Surveillance. Although very common in the US and other countries, there is no nationwide syndromic surveillance system to electronically monitor medical records in Japan. Because of the low prevalence of electronic medical records and a restrictive privacy policy, we perform prescription surveillance nationwide for syndromic surveillance by monitoring the number of prescriptions for certain types of drugs such as anti-influenza medications.

There are approximately 45,000 pharmacies that deliver almost half of the prescribed drugs nationwide and almost all record prescriptions electronically. The prescription surveillance system was developed by the Infectious Disease Surveillance Center of the National Institute of Infectious Diseases in collaboration with EM Systems Co. Ltd. (Osaka, Japan), a leading provider of prescription surveillance used by pharmacies through the Application Server Provider (ASP) system. The ASP system is very useful for syndromic surveillance because data transfer is unnecessary. Thus, it can dramatically decrease costs and maintain a high level of confidentially. Its widespread use started in April 2009, and approximately 6,300 (13%) Japanese pharmacies actively participated in the program as of October 2011.

The ASP system tracks prescription information, but patient symptoms and diagnoses are not recorded. Categories of syndromic surveillance include the type of prescribed drugs. Currently, the syndromic surveillance system monitors several types of drugs, including those for relief of fever and pain due to common colds, as well as antiviral agents, anti-influenza medications (except amantadine), and anti-varicella zoster virus (VZV) drugs. The surveillance of the last two is also classified by age: <15, 16–64, and >65 years. Data collection and analysis are automatically performed every night, and the results are available on the home page of a secure internet site early the next morning.

Monitoring the usage of anti-influenza and anti-VZV drugs is particularly useful for early detection of outbreaks of infection because these drugs are used only to treat specific viral infections.

2.2. Clinical Samples. Between October 4 and 28, 2011, 50 patients were included in the present study who either presented at a single clinic with a chief complaint of respiratory symptoms or fever or were suspected of having respiratory tract infections after being identified through the syndromic prescription surveillance system. In Japan, a rapid diagnosis kit suitable for use at outpatient clinics is currently available, and the costs are covered by the national health insurance program. The tests allow for rapid detection of infections caused by the influenza virus, RSV, and adenovirus. A total of 18 pharyngeal swabs to screen for adenovirus infections and 32 nasal swabs to screen for RSV and influenza viral infections (rapid RSV) were collected [9]. Viruses were extracted from the swabs using immunochromatography (IC) kits with approximately 500 μL of a mucolytic agent provided by the manufacturer. After the assay, approximately 200 μL of the agent remained in the IC-kit tubes. This medical waste was transferred to universal transport medium (359C; Copan Italia S.p.A, Brescia, Italy) and analyzed using

Table 1: Hyper-PCR primers.

Pathogen	Primer	Base sequence (5′-3′)	Polarity	Reference
RSV-A	RSA-F	TGC AAG CAG AAA TGG AAC AAG T	+	[14]
106 bp	RSA-R	AAT AAT GAT GCT TTT GGG TTG TTC A	−	
RSV-B	RSB-F	GATGGCTCTTAGCAAAGTCAAGTTAA	+	[15]
104 bp	RSB-R	TGTCAATATTATCTCCTGTACTACGTTGAA	−	
Parainfluenza 1	PIS1+	CCGGTAATTTCTCATACCTATG	+	[16]
317 bp	PIS1−	CCTTGGAGCGGAGTTGTTAAG	−	
Parainfluenza 3	Para3.1	CTCGAGGTTGTCAGGATATAG	+	[16]
189 bp	Para3.2	CTTTGGGAGTTGAACACAGTT	−	
Rhinovirus	SRHI-1-NIID	CGGGTAGCTTCCACCACCAGCCCTT	+	[16]
549 bp	SRHI-2	GGGACCAACTACTTTGGGTGTCCGTGT	−	
Enterovirus	entR1	ATTGTCACCATAAGCAGCCA	+	[17]
172 bp	entE2	CCTCCGGCCCCTGAATG	−	
H1N1 2009	swH1-F2	TCATGCGAACAATTCAACA	+	Present study
127 bp	swH1-R2	TGGGGCTACCCCTCTTAGTTTG	−	

real-time polymerase chain reaction (PCR) [10] and Hyper-PCR [11], which is a faster technique compared with the previously available PCR applications. Thus, we used Hyper-PCR for the applicable pathogens. The CycleavePCR respiratory infection-pathogenic virus detection kit (Takara Bio, Shiga, Japan) was used to detect 11 types of viruses: human RSV types A and B, human parainfluenza virus types 1–3, human metapneumovirus, influenza A and B viruses, human adenovirus, human bocavirus, and human rhinovirus. The Thermal Cycler Dice Real Time System II MRQ (Takara Bio) was used to detect and identify the 11 types of viruses detected by the CycleavePCR kit [10]. Hyper-PCR [11] was performed using the One Step SYBR High Speed RT-PCR Kit (Hyper-PCR) (Takara) to detect RSV types A, B, human parainfluenza virus types 1, 3, human rhinovirus, enterovirus, and influenza A (H1N1) 2009 (primers are listed in Table 1) using the Hyper-PCR MK IV PCR system (Trust Medical, Hyogo, Japan). The accuracy of the Hyper-PCR methods was confirmed by comparison with other conventional PCR methods. Conventional PCR was used to detect *M. pneumoniae* [12]. In addition, the presence of coronavirus infection was tested in patients from whom no infectious agents were detected [13].

3. Ethical Considerations

This study only collected anonymous information that cannot be associated with individual patients. Patient samples were collected during the course of medical care provided at the participating facilities, and all examinations and testing for pathogens occurred at the request of the medical facilities for the purposes of diagnosis and treatment. This study used only existing medical records and documents, and oral informed consent was obtained from all patients.

4. Results

After testing the specimens, we provided the results to a medical institution within 4 days including the conveyance period. The 50 patients tested in this study included 2 infants (1 male and 1 female, aged <1 year), 25 children (12 males and 13 females, aged 1–6 years), 10 elementary school pupils (6 males and 4 females, aged 7–12 years), 4 minors (2 males and 2 females, aged 13–18 years), 8 adults (3 males and 5 females, aged >18 years), and 1 patient (age unavailable).

Table 2 lists the pathogens detected by the PCR analysis stratified by age in the 27 patients. In children, enterovirus, rhinoviruses, RSV, and parainfluenza viruses were detected, whereas *M. pneumoniae* was detected only in elementary school pupils and minors. In the remaining 23 patients, no pathogens were detected. These 23 patients were also found to be negative for coronavirus.

PCR was used to obtain definitive viral diagnoses via rapid RSV and adenovirus diagnosis kits, and the sensitivity and specificity were calculated for these test kits. For the rapid RSV diagnosis kit, sensitivity was 80% and specificity was 85%. For the rapid adenovirus diagnosis kit, no positive results were obtained; therefore, sensitivity could not be calculated and specificity was 100%.

RSV infections were detected using the rapid diagnosis kit, but rhinovirus, enterovirus, and parainfluenza virus infections were not. The causative pathogens were unknown in many patients, although they were nevertheless treated for upper respiratory tract infections.

Evaluation of the incidence of various symptoms in patients infected with different pathogens showed that rhinoviruses were detected in nasal swab specimens more often than other viruses and patients with rhinovirus infections were less likely to present with fever (Table 3).

All RSV-positive patients were children, 80% of whom presented with coughing. All patients who were tested using the rapid adenovirus detection kit showed negative results. However, all these patients also tested negative for adenovirus using sensitive PCR tests. Thus, adenovirus was not considered to be the causative organism of this suspected outbreak.

Table 2: Numbers of pathogens detected by PCR according to age.

	Infants	Children	Elementary school pupil	Minor (junior high school student or older)	Adult
Enterovirus	0	2	1	0	1
Mycoplasma pneumoniae	0	0	1	1	0
Parainfluenza 1	0	2	0	0	1
Rhinovirus	2	9	0	0	1
Rhinovirus + parainfluenza 1	0	1	0	0	0
Rhinovirus + RSV-A	0	1	0	0	0
Rhinovirus + RSV-A and RSV-B	0	1	0	0	0
RSV-A	0	2	0	0	0
RSV-B	0	1	0	0	0

Table 3: Incidences of symptoms detected in infections according to individual pathogens ($n = 50$).

	Number of infections	Fever	Headache	Nasal discharge	Pharyngeal pain	Cough
Mycoplasma pneumoniae	2	0%	0%	0%	50%	100%
Enterovirus	4	67%	25%	75%	25%	25%
Parainfluenza 1	3	33%	33%	33%	0%	67%
Rhinovirus + parainfluenza 1	1	0%	0%	0%	0%	100%
Rhinovirus	12	20%	0%	67%	0%	83%
Rhinovirus + RSV-A	1	0%	0%	100%	0%	100%
Rhinovirus + RSV-A + RSV-B	1	100%	0%	100%	0%	100%
RSV-A	2	100%	0%	100%	0%	100%
RSV-B	1	100%	0%	0%	0%	0%
None	23	21%	13%	57%	30%	35%

5. Discussion

Here, we examined a combination of syndromic surveillance and PCR testing and showed the potential to identify pathogens during the early stage of an outbreak of respiratory infections. In the future, it would be desirable to develop an *M. pneumoniae* diagnosis kit that can diagnose pathogens from nasal or pharyngeal swabs at outpatient clinics or the bedside of patients.

In Japan, two official pathogen surveillance methods have been conducted under the infection control laws: sentinel pathogen surveillance and active surveillance. The official pathogenic surveillance has been conducted at sentinel medical institutions regardless of outbreaks. On the other hand, in patients with serious diseases, active pathogenic surveillance has sometimes been conducted on the basis of notifications by medical institutions. However, active surveillance is conducted only when an infection spreads widely enough to cause serious problems in a particular region and the surveillance of pathogens may not be timely enough to mount a response to control outbreaks. Pathogenic surveillance for all patients with signs of an infection would detect agents of bioterrorism and emerging infectious diseases; however, the cost would be prohibitive. Therefore, system coordination to perform pathogen surveillance based on early detection of outbreaks is necessary. The scheme proposed by the present study uses PCR testing triggered by detection alerts from syndromic surveillance systems. In general, syndromic surveillance offers earlier detection of infectious diseases than traditional surveillance. Moreover, if the pathogen remains unknown following bedside testing using several rapid tests or other typical examinations, the proposed scheme requires the collection of specimens as soon as possible and sending them to a laboratory for definitive diagnoses. However, it takes a few days to transfer the specimens and a few extra days for the information of the identified pathogen to be shared among medical facilities, public health centers, and local governments in the involved areas. In the proposed scheme, we can use pathogenic information to control ongoing outbreaks and, hopefully, decrease the number of potential infections.

Thus far, syndromic surveillance with pathogenic testing has been conducted by collecting samples from patients receiving telephone consultations [18] and those receiving emergency department consultations [19]. Syndromic surveillance using electronic medical records has been combined with testing for the influenza virus [20]. However, these systems have focused only on rapid testing and are mainly used for influenza monitoring [20, 21]. Therefore, syndromic surveillance trials for nonspecific pathogens using PCR for undiagnosed infectious diseases, similar to the present study, have not been performed before.

In the present study, an outbreak was detected by routine syndromic surveillance, in which samples were regionally collected for PCR analysis. These tests for viral infections allowed for differentiation between bacterial and viral infections, thus facilitating treatment without the unnecessary use of antibiotics. Although the present laboratory tests cannot be performed for all individual clinical diagnoses, the

results were immediately made available to clinicians for the treatment of other patients with similar symptoms.

The symptoms reported in the present study were rather mild; therefore, no patient required hospitalization, and no further testing was performed in undiagnosed patients. However, if severe cases were to occur, careful identification of pathogens would be desirable. Rhinoviruses were detected in nasal swab specimens more frequently than other viruses. Therefore, it is likely that children who present with nasal discharge and mild fever may be reservoirs for rhinoviruses [22]. Testing for respiratory viral infections in emergency room outpatients by PCR analysis showed that the most frequently detected viruses were picornaviruses, including rhinoviruses [23]. When children present with coughing as the main symptom, RSV should be considered as the most likely pathogen.

The finding that *M. pneumoniae* infection was not detected in infants and children, but rather in elementary school pupils and minors, was consistent with reports that *M. pneumoniae* may often cause asymptomatic infections before the age of 5 years, after which immunity decreases as children become susceptible to symptomatic *M. pneumoniae* infections [5].

In Japan, nationwide outbreaks of *M. pneumoniae* began in 2011 and continued as of January 2012, during which time *M. pneumonia*, rhinovirus, enterovirus, parainfluenza virus, and RSV have been identified. Our results suggested that this outbreak may include false-positive cases and subsequent inappropriate prescriptions of antibiotics.

An increased frequency of macrolide-resistant *M. pneumoniae* became widely reported in the Japanese media in the fall of 2011 [24]. Therefore, this news may have induced an abnormal increase in the number of patients (Figure 2). The rapid test available in Japan for *M. pneumoniae* uses sera samples [25]. Although general clinics may outsource *M. pneumoniae* antibody testing and cold hemagglutinin testing, blood testing is usually not performed in cases of mild pediatric illnesses.

In the future, it would be desirable to develop *M. pneumoniae* diagnostic kits using nasal or pharyngeal swabs at outpatient clinics or bedside. Until such kits for the diagnoses of *M. pneumoniae* and other infectious diseases are developed, syndromic surveillance with PCR testing offers a useful countermeasure against infectious outbreaks. In this study, we could not detect single infectious agents that explained the outbreaks; however, our results excluded *M. pneumoniae*.

The present study was limited to a single clinic. Therefore, further studies involving more facilities should be undertaken. It is also necessary to develop a network and sample transportation system among the facilities partaking in the syndromic surveillance system and to adequately staff laboratories with experienced technicians.

Syndromic surveillance data has been mathematically or statistically analyzed in many studies. However, when an abnormal value is reported by syndromic surveillance, there are many cases in which the pathogens cannot be identified by the calculations introduced in these articles.

6. Conclusion

When *M. pneumoniae* and RSV infections were prevalent nationwide during the fall of 2011, we observed an abnormal increase in common cold prescriptions through the Japanese surveillance system and were able to evaluate the incidence of various pathogens via PCR testing.

Authors' Contribution

The authors contributed equally to this paper.

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Original Paper

Real-time Prescription Surveillance and its Application to Monitoring Seasonal Influenza Activity in Japan

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Abstract

Background: Real-time surveillance is fundamental for effective control of disease outbreaks, but the official sentinel surveillance in Japan collects information related to disease activity only weekly and updates it with a 1-week time lag.

Objective: To report on a prescription surveillance system using electronic records related to prescription drugs that was started in 2008 in Japan, and to evaluate the surveillance system for monitoring influenza activity during the 2009–2010 and 2010–2011 influenza seasons.

Methods: We developed an automatic surveillance system using electronic records of prescription drug purchases collected from 5275 pharmacies through the application service provider's medical claims service. We then applied the system to monitoring influenza activity during the 2009–2010 and 2010–2011 influenza seasons. The surveillance system collected information related to drugs and patients directly and automatically from the electronic prescription record system, and estimated the number of influenza cases based on the number of prescriptions of anti-influenza virus medication. Then it shared the information related to influenza activity through the Internet with the public on a daily basis.

Results: During the 2009–2010 influenza season, the number of influenza patients estimated by the prescription surveillance system between the 28th week of 2009 and the 12th week of 2010 was 9,234,289. In the 2010–2011 influenza season, the number of influenza patients between the 36th week of 2010 and the 12th week of 2011 was 7,153,437. The estimated number of influenza cases was highly correlated with that predicted by the official sentinel surveillance ($r = .992$, $P < .001$ for 2009–2010; $r = .972$, $P < .001$ for 2010–2011), indicating that the prescription surveillance system produced a good approximation of activity patterns.

Conclusions: Our prescription surveillance system presents great potential for monitoring influenza activity and for providing early detection of infectious disease outbreaks.

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KEYWORDS

Surveillance; influenza; real-time surveillance; prescriptions; pharmacy; anti-influenza virus; automatic surveillance; early response

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