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Integrating pharmacies into public health program planning for pandemic influenza vaccine response

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Abstract

Background—During an influenza pandemic, to achieve early and rapid vaccination coverage and maximize the benefit of an immunization campaign, partnerships between public health agencies and vaccine providers are essential. Immunizing pharmacists represent an important group for expanding access to pandemic vaccination. However, little is known about nationwide coordination between public health programs and pharmacies for pandemic vaccine response planning.

Methods—To assess relationships and planning activities between public health programs and pharmacies, we analyzed data from Centers for Disease Control and Prevention assessments of jurisdictions that received immunization and emergency preparedness funding from 2012 to 2015.

Results—Forty-seven (88.7%) of 53 jurisdictions reported including pharmacies in pandemic vaccine distribution plans, 24 (45.3%) had processes to recruit pharmacists to vaccinate, and 16 (30.8%) of 52 established formal relationships with pharmacies. Most jurisdictions plan to allocate less than 10% of pandemic vaccine supply to pharmacies.

Discussion—While most jurisdictions plan to include pharmacies as pandemic vaccine providers, work is needed to establish formalized agreements between public health departments and pharmacies to improve pandemic preparedness coordination and ensure that vaccinating pharmacists are fully utilized during a pandemic.

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Disclaimer

The findings and conclusions in this paper are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.

Conflicts of interest

The authors have no conflicts of interest to disclose.

Appendix A. Supplementary material

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.vaccine.2016.09.020>.

1. Introduction

An influenza pandemic with high morbidity and mortality is a serious threat to the US public, especially given the persistent detection of highly pathogenic influenza A strains in humans and the recent detection of novel avian influenza A virus infections in US domestic and wild bird populations [1–3]. If a severe influenza pandemic emerges, a well-coordinated vaccination campaign using a safe and effective pandemic influenza vaccine would need to be quickly implemented to reduce morbidity and mortality [4]. One pandemic vaccination campaign strategy is for public health programs to use points of dispensing (PODs) or mass vaccination clinics, but these may be inadequate to vaccinate necessary numbers of people over an extended vaccination campaign, as personnel and other resources may become exhausted. Healthcare providers in office or clinic settings may become too overwhelmed treating sick patients to focus heavily on vaccination efforts. Additional strategies should be considered to rapidly vaccinate the public during a severe influenza pandemic.

Leveraging pharmacists as pandemic influenza vaccine providers is an increasingly popular strategy as pharmacists are trained to vaccinate [5]. Pharmacists' authority to vaccinate, particularly against influenza, has expanded throughout the US and, as a result, pharmacists are able to vaccinate in some way in every state, District of Columbia (D.C.), and Puerto Rico, and are increasingly familiar with vaccine management and delivery [6]. In fact, one in four adults who receives a seasonal influenza vaccine does so in a pharmacy or retail setting [7]. Furthermore, in the US, there are over 67,000 community pharmacies, 297,000 vaccinating pharmacists, and 86% of the population lives within five miles of a pharmacy [8–10].

For pharmacies to be ready to provide vaccinations during a severe pandemic, it is important for them to understand planning and logistical differences between seasonal and pandemic influenza vaccination. During typical influenza seasons, vaccine providers purchase vaccine from wholesalers, distributors, and manufacturers. During an influenza pandemic, as occurred during the 2009 influenza A (H1N1) pandemic, the Federal government will likely procure all pandemic vaccine directly from manufacturers, and each state public health department will be provided a pro-rata allocation [11]. Healthcare providers who wish to provide pandemic influenza vaccinations, including pharmacists, must coordinate and enroll with their jurisdictions' public health program, rather than with their typical vendors, to order and receive pandemic vaccine [11]. To determine each provider's allocation, public health departments need providers' physical shipping addresses and information such as patient population sizes and demographics, as well as vaccine storage and handling capacities.

Given these important differences between seasonal influenza vaccination and planning for vaccination delivery during a pandemic, it is essential for public health programs and vaccine providers, including pharmacies, to coordinate these logistics in advance to ensure that the population is rapidly vaccinated against a pandemic. Initially, public health programs should identify and maintain up-to-date points of contacts (POCs) at their pharmacy partners and engage them in discussions to improve routine immunization delivery as well as pandemic preparedness. Formal agreements, such as memoranda of

understanding (MOUs), may be important planning documents to then clarify coordination in pandemic vaccine program planning in order to fully leverage pharmacies' strengths. State public health immunization programs are ideally situated to develop these agreements with pharmacies, as they will likely receive Federally purchased vaccine and maintain oversight of its allocation, distribution, and administration throughout their jurisdictions. However, little is known about the type of coordination between state and city public health programs and pharmacies in pandemic influenza vaccine response planning.

We assessed existing relationships and planning activities of public health programs with pharmacies by analyzing data collected by the Centers for Disease Control and Prevention (CDC) from 2012 to 2015 from state and city jurisdictions that receive public health emergency preparedness and immunization funding [12,13].

2. Methods

CDC monitors public health program activities through a number of mechanisms, including the Annual Report of immunization program activities (hereinafter Annual Report), as well as ad hoc evaluations conducted in preparation for and response to influenza outbreaks and potential pandemics [12]. During the 2013 CDC response to the initial identification of influenza A(H7N9) among humans in China, CDC's Immunization Services Division conducted a survey, the 2013 H7N9 Vaccination Response Planning and Needs Assessment (hereinafter H7N9 Needs Assessment) among 65 state and city jurisdictions that receive preparedness or immunization funding [12,13]. In 2015, CDC's Division of State and Local Readiness conducted a follow-up survey, the Pandemic Influenza Readiness Assessment (PIRA), which included a section on vaccination planning, among 62 jurisdictions that receive Public Health Emergency Preparedness program funding [13].

We conducted a descriptive analysis of pandemic vaccine preparedness and response data from Annual Reports in years 2012–2014 (the most recent years available), the 2013 H7N9 Needs Assessment, and the 2015 PIRA to assess integration of pharmacies and pharmacists into public health pandemic vaccine response planning. We used absolute counts and proportions for all 50 states, D.C., New York City, and Chicago, for a total of 53 jurisdictions that are awarded funding for both immunization and preparedness programs [12,13]. Eight territory and freely associated states' public health and pharmacy infrastructures vary greatly from those presented here, and were excluded from the analysis. In some cases, respondents wrote information in the comments section which did not correspond to their selected answer, or would not select an answer and write in comments. Here, authors coded jurisdictions' free text responses to the appropriate answer. When reported proportions did not total 100%, we recalculated responses by dividing each individual response by the reported total so each jurisdiction's responses totaled 100%. We performed analyses using Microsoft Excel and SAS 9.3. Pharmacies are defined in this analysis as independent and chain community pharmacies (including those located in retailers), excluding hospitals and compounding pharmacies.

Results were grouped into 3 main domains: (1) engaging, recruiting, and enrolling pharmacists as pandemic vaccine providers; (2) vaccine allocation and distribution planning; and (3) policy, formal agreements, and memoranda of understanding.

3. Results

3.1. Engaging, recruiting, and enrolling pharmacists as pandemic vaccine providers

In the 2014 Annual Report, 20 (37.7%) of 53 jurisdictions had identified POCs for all pharmacy partners (including state or local pharmacy boards and associations and independent and chain community pharmacies) in their jurisdictions, 18 (34.0%) had identified POCs for more than half, but not all pharmacy partners, 12 (22.6%) had identified POCs for less than half, and three (5.7%) had no POCs for pharmacy partners in their jurisdictions (Table 1). In the H7N9 Needs Assessment, 43 (81.1%) of 53 jurisdictions reported that they maintained a list of healthcare providers and facilities in their jurisdiction that could potentially be recruited as pandemic vaccine providers; of those, 40 (93.0%) included pharmacists. Twenty-four (45.3%) jurisdictions reported that they had formal processes for recruiting pharmacists (Table 1).

In the 2013 H7N9 Needs Assessment, 40 (75.5%) of 53 jurisdictions reported that registering and enrolling healthcare providers and facilities (such as pharmacists and pharmacies) to become pandemic influenza vaccine providers was a state health department activity, while 11 (20.8%) indicated that it was a joint activity between state and local health departments (LHDs). Two (3.8%) jurisdictions reported that LHDs are responsible (Table 1). Forty-five (88.2%) of 51 responding jurisdictions reported in the 2015 PIRA that this was the responsibility of the city or state awardee health department, and 6 (11.8%) reported that LHDs were responsible for this activity (Table 1). There was no response option for this being a joint activity on the 2015 PIRA. Of the 11 programs reporting joint responsibility in 2013, nine reported that this was a state responsibility in the 2015 PIRA, and two reported that it was a local responsibility. Three programs that reported that this was a state responsibility in 2013 then reported that it was a local responsibility in 2015.

3.2. Vaccine allocation and distribution planning

In the 2012 Annual Report, 47 (88.7%) of 53 jurisdictions reported including pharmacies as pandemic vaccine providers in their vaccine distribution plans. Thirty-one (58.5%) reported including pharmacies during early phases of their pandemic vaccine campaign compared to 16 (30.2%) that include them only during late phases of their campaign. Six (11.3%) indicated that pharmacies were not included in pandemic vaccine response plans at all. In the 2013 H7N9 Needs Assessment, 47 (88.7%) of 53 jurisdictions reported that they would request pandemic vaccine be shipped directly to pharmacy locations using the CDC contracted distributor rather than allow pharmacies to use their own vaccine management and distribution infrastructure. Eight (16.0%) of 50 jurisdictions reported in the 2014 Annual Report that they would allow pharmacy companies to allocate and distribute pandemic vaccine to individual stores using their existing systems rather than have the public health program manage their store allocations, while 13 (26.0%) indicated that this would depend on supply and availability (Table 2).

Forty jurisdictions indicated in the 2013 H7N9 Needs Assessment that they had a list of potential pandemic influenza vaccine providers which included pharmacies (Table 1); of which, 12 (30.0%) reported having information on the numbers of patients those pharmacies served, 20 (50.0%) had information on the types of patient populations they served, and 14 (35.0%) had information on their vaccine storage and handling capacities (Table 2). Two (5.0%) jurisdictions indicated that they had pharmacists on their list of potential pandemic vaccine providers, but would not request to have vaccine shipped directly from CDC's contracted distributor to these providers during a pandemic. Four (10.0%) reported having pharmacists as potential pandemic vaccine providers, but did not know if they would request shipments by CDC's contracted distributor to them during a pandemic. Two (5.0%) did not report having pharmacists on their lists of potential vaccine providers, but reported that they would request that vaccine be shipped to pharmacies during a pandemic, and another (2.5%) did not know if pharmacists were on their list of potential pandemic vaccine providers, but would request that vaccine be shipped to them.

Thirty-two (61.5%) of 52 responding jurisdictions in the 2015 PIRA reported that more than 20% of their jurisdiction's vaccine allocation would be dispensed at PODs (Table 2). When asked to estimate the proportion of their jurisdiction's weekly vaccine allocation that they plan to allocate to different provider types, 29 (60.4%) of 48 respondents intended to provide 20% or more of their jurisdiction's weekly pandemic vaccine allocation to mass vaccination clinics or PODs (Table 3). Thirty-four (70.8%) jurisdictions reported that they planned to send less than 5% of their weekly vaccine supply to retail-based clinics, 18 (37.5%) planned to send less than 5% to large pharmacies, and 32 (66.7%) planned to send less than 5% to local pharmacies. One (2.1%) jurisdiction reported planning to send 20% of its vaccine to retail-based clinics, and 8 (16.7%) reported plans to send 20% or more to large pharmacies. No jurisdictions reported planning to send 20% or more of its weekly vaccine supply to local pharmacies.

3.3. Policy, formal agreements, and memoranda of understanding

Seven (13.5%) of 52 responding jurisdictions reported in the 2014 Annual Report that pharmacists would be directed to vaccinate all patients regardless of a patient's insurance status or ability to pay for vaccine administration. Three (5.8%) programs would instruct pharmacists to refer these patients to health departments for vaccination, and 32 (61.5%) had not clarified this issue.

Seventeen (35.4%) of 48 responding jurisdictions indicated in the 2013 Annual Report that they had established or provided support for LHDs to establish MOUs or formalized preparedness agreements with pharmacies to distribute and administer vaccine during a pandemic (Table 4). Five (9.6%) of 52 responding jurisdictions in the 2014 Annual Report reported establishing pandemic influenza vaccine MOUs for all pharmacies in their jurisdictions, five (9.6%) established them for over half, but not all, pharmacy groups, while six (11.5%) established such agreements for less than half of pharmacy groups. Thirty-three (63.5%) jurisdictions had no agreement in place, and three (5.7%) did not know (Table 4). Nine jurisdictions who did not respond or did not have pharmacy MOUs in 2013 reported

having one with any pharmacy in 2014, while eight that had indicated having or supporting an MOU with pharmacies in 2013 reported that they did not have one in 2014.

4. Discussion

CDC supports the role of pharmacies in pandemic influenza vaccine planning and response [14]. Our analysis of self-reported data from public health programs collected by CDC from 2012 to 2015 suggests that most programs view pharmacies and pharmacists as valuable partners in pandemic vaccination activities and do plan to include pharmacists as vaccinators during the next pandemic, but significant planning gaps remain. These include incomplete identification of POCs, inconsistent processes for recruiting pharmacists as pandemic vaccinators, lack of clarity on the responsibility for outreach to and enrollment of pharmacists as pandemic vaccinators, inconsistencies in jurisdictions' pandemic vaccine allocation and distribution plans to pharmacies, and limited information on pharmacy patient populations and storage and handling capacity needed to make rapid vaccine allocation decisions. In addition, issues such as vaccinating uninsured patients in pharmacies have not been clarified, and few jurisdictions have formal agreements or MOUs in place to improve pandemic vaccine response logistics. Perhaps the biggest pandemic vaccine program planning gap is that most public health programs appear to be underestimating the value and potential vaccination capacity pharmacies and pharmacists might have in rapidly vaccinating the public during a pandemic. For example, most programs reported that they would allocate only a small portion of their pandemic influenza vaccine supply to pharmacies despite the fact that pharmacies have demonstrated their ability to vaccinate much larger portions of the public for seasonal influenza, now vaccinating roughly 25% of adults who receive seasonal influenza vaccine [7].

While pharmacists provided vaccinations to the public during the 2009 influenza A(H1N1) pandemic, that vaccine did not become widely available to pharmacies until December 2009, after the disease had peaked in October 2009 and public demand for vaccination had waned [15]. Biggerstaff et al. found that in a modeled vaccination campaign during a severe pandemic, assuming vaccination at a constant rate, the timing of the start of vaccination was the greatest factor in reducing morbidity and mortality, and vaccination beginning just prior to or at disease peak would have little impact in mitigating deaths and hospitalizations associated with the pandemic [16]. Schwerzmann and colleagues found that including pharmacies in a pandemic influenza vaccine campaign, despite high participation from other vaccinators, can significantly reduce the time necessary to vaccinate 80% of US adults with a single dose, from 18 to 11 weeks, assuming high demand for vaccination and sufficient supply [17]. However, in our analysis we found that some public health programs plan to include pharmacists as vaccinators later in a pandemic vaccine response, rather than earlier.

While Stergachis et al. found that 94% of pharmacists would be willing to work during an influenza pandemic, Seib and colleagues found that 2009 H1N1 vaccine providers who had participated in emergency training or response were more willing to respond to a public health emergency [18,19]. In another study by Pederson et al., the only factor influencing pharmacists' opinions regarding their level of involvement in emergency preparedness and response was previous participation in local or state emergency preparedness and response

activities [20]. As part of the disaster health workforce with specialized training and skills, it is vital for pharmacists to be familiar with public health core competencies and considered in planning stages [22]. However, a 2012 poll showed that 68% of pharmacists working in community settings had no contact with health department staff in the previous year [21].

Our findings are subject to several limitations. Survey respondents were predominantly immunization and emergency preparedness programs at the state level, but many states have local or regional health departments which maintain jurisdiction over public health activities. No data were collected from pharmacies, pharmacists, or pharmacy boards. The data presented here are self-reported, come from a variety of sources, and might have been interpreted and answered differently, depending on the person or program responsible for completing any particular assessment, all of which may limit comparability. On the Annual Report, respondents are able to skip questions, and data are not verified. The 2013 H7N9 Readiness Assessment was distributed with relatively little time to complete it, while also requiring coordination between preparedness and immunization staff. The wording of questions on the same assessment differ from year to year, making temporal trends difficult to assess.

It is crucial that roles and responsibilities between public health programs and pharmacies are outlined in advance to ensure clarity and consistency in a pandemic vaccine response, but our analysis suggests this may not be occurring regularly or with a consistent approach. One way to ensure a more consistent approach is by formalized pre-pandemic agreements, such as MOUs, between public health departments and pharmacies. The Association of State and Territorial Health Officials (ASTHO), in collaboration with representatives from CDC, the pharmacy industry, and immunization programs, developed a template MOU to serve as a model to outline roles and responsibilities between public health programs and pharmacies in preparing for a pandemic influenza vaccine response. The template MOU outlines best practices for recruiting and training vaccine providers, vaccine allocation and distribution to pharmacies, vaccine administration data and tracking, and pandemic vaccine cost and payment issues [23]. The template provides a standardized approach for coordination between state public health programs and pharmacies operating in many states, but allows for flexibility in implementation to meet unique jurisdictions' needs. As of September 2016, the template is being piloted by three states. CDC and ASTHO are working with their immunization and preparedness partners to disseminate and raise awareness of this preparedness tool [23].

Our analysis underscores gaps in efforts to improve planning efforts between public health programs and pharmacies, a partnership which may be vital to achieving sufficient vaccination coverage during a severe pandemic. While state public health programs appear willing to work with pharmacies to improve pandemic vaccine preparedness and response, it is important to develop strategies allowing for early and ongoing involvement in planning and response activities in order to minimize vulnerability to and optimize their jurisdictions' preparedness for a pandemic. Improved and formalized relationships between public health programs and pharmacies may allow for the widespread use of pharmacists as vaccinators during the next pandemic, greatly increasing vaccination coverage and reducing morbidity and mortality associated with the pandemic.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Public health program plans for recruiting, enrolling, and registering pharmacists as pandemic influenza vaccine providers.

Assessment	No. (%)	Total responses ^a
Primary responsibility for activities related to registering and enrolling healthcare providers and facilities to become pandemic influenza vaccine providers, 2013 ¹		
State health department	40 (75.5%)	53
Local health departments ^c	2 (3.8%)	53
Joint activity between state and local health departments	11 (20.8%)	53
Primary responsibility for activities related to registering and enrolling healthcare providers and facilities to become pandemic influenza vaccine providers, 2015 ²		
Awardee state or city health department	45 (88.2%)	51
Local health departments ^d	6 (11.8%)	51
Identified points of contact for pharmacy partners in jurisdiction ³		
Yes, for all pharmacy partners	20 (37.7%)	53
Yes, for more than half, but not all, pharmacy partners	18 (34.0%)	53
Yes, for less than half of pharmacy partners	12 (22.6%)	53
No	3 (5.7%)	53
Has a list of potential healthcare providers that could be recruited to provide pandemic vaccine ¹	43 (81.1%)	53
List of potential healthcare providers includes pharmacists ¹	40 (93.0%)	43 ^b
Formal process for recruiting pharmacists as pandemic vaccinators has been established ¹	24 (45.3%)	53

Data sources:

¹: 2013 H7N9 Needs Assessment;

²: 2015 Pandemic Influenza Readiness Assessment;

³: 2014 Annual Report.

^aSubset of above assessment.

^bResponses do not always equal 53 due to missing responses from jurisdictions.

^cLocal health departments include directly funded cities (Chicago, New York City, and Washington, D.C.).

^dLocal health departments **do not** include directly funded cities.

Table 2

Public health program plans for vaccine allocation and distribution of pandemic vaccine to community pharmacies.

Assessment	No. (%)	Total responses ^a
Current pandemic vaccine distribution plans include pharmacists ¹		
Early in a response	31 (58.5%)	53
Later in a response	16 (30.2%)	53
No plans for including pharmacists	6 (11.2%)	53
Program will request pandemic vaccine be shipped to pharmacies from CDC's contracted distributor ²		
47 (88.7%)	53	
Pharmacies allowed to reallocate and distribute vaccine to individual stores using existing system ³		
Yes	8 (16.0%)	50
Depends on vaccine supply and availability	13 (26.0%)	50
Not discussed	14 (28.0%)	50
Other	15 (30.0%)	50
Programs have information needed to make allocation and distribution decisions for pharmacies ^{2,c}		
Physical location/address	37 (92.5%)	40 ^b
Email	29 (72.5%)	40 ^b
Number of patients served	12 (30.0%)	40 ^b
Type of patient population served	20 (50.0%)	40 ^b
Vaccine storage and handling capacity	14 (35.0%)	40 ^b
Plan to provide more than 20% of jurisdiction's vaccine allocation through points of dispensing ⁴		
32 (61.5%)	52	

Data sources:

¹: 2012 Annual Report;

²: 2013 H7N9 Needs Assessment;

³: 2014 Annual Report;

⁴: 2015 Pandemic Influenza Readiness Assessment.

^aResponses do not always equal 53 due to missing responses from jurisdictions.

^bSubset of the 40 respondents who indicated that they had a list of potential vaccine providers that included pharmacies (Table 1).

^c“Select all that apply” question.

Table 3

Public health programs planned weekly allocation of pandemic influenza vaccine, by provider type (n = 48).^a

Provider type	Proportion of pandemic vaccine to be allocated				
	Less than 5%, No. (%)	Greater than or equal to 5%; less than 10%, No. (%)	Greater than or equal to 10%; less than 15%, No. (%)	Greater than or equal to 15%; less than 20%, No. (%)	20% or greater, No. (%)
Mass vaccination clinics/points of dispensing ^b	13 (27.1%)	3 (6.3%)	3 (6.3%)	0 (0.0%)	29 (60.4%)
School-located vaccination clinics	26 (54.2%)	9 (18.8%)	7 (14.6%)	3 (6.3%)	3 (6.3%)
Vaccines for children providers	11 (22.9%)	0 (0.0%)	15 (31.3%)	6 (12.5%)	16 (33.3%)
Non-vaccines for children providers ^c	18 (37.5%)	9 (18.8%)	7 (14.6%)	6 (12.5%)	8 (16.7%)
Local health departments	16 (33.3%)	7 (14.6%)	4 (8.3%)	2 (4.2%)	19 (39.6%)
Retail-based clinics ^d	34 (70.8%)	8 (16.7%)	4 (8.3%)	1 (2.1%)	1 (2.1%)
Large pharmacies ^d	18 (37.5%)	7 (14.6%)	11 (22.9%)	4 (8.3%)	8 (16.7%)
Local pharmacies ^d	32 (66.7%)	13 (27.1%)	2 (4.2%)	1 (2.1%)	0 (0.0%)

Data source: 2015 Pandemic Influenza Readiness Assessment (PIRA).

^a 5 jurisdictions did not provide responses for any categories, and were omitted. Non-responses were coded as 0 when awardees reported intent to allocate to other providers.

^b Combined open and closed points of dispensing.

^c Combined non-VFC adult and pediatric providers.

^d All of these are considered community pharmacies, but were separated out in this manner for the PIRA questionnaire.

Table 4

Immunization policy, formalized agreements, and memoranda of understanding between public health and community pharmacies.

Assessment	No. (%)	Total responses ^a
Regarding uninsured and underinsured patients during a pandemic, pharmacists have been instructed to ¹		
Provide pandemic vaccinations to all patients regardless of ability to pay	7 (13.5%)	52
Refer these patients to the health department	3 (5.8%)	52
Not clarified	32 (61.5%)	52
Other	10 (19.2%)	52
Have or provide support to local health departments to establish memoranda of understanding or formalized agreements with community pharmacies in 2013 ²		
Yes	17 (35.4%)	48
No	21 (43.8%)	48
Other	10 (20.8%)	48
Have or provide support to local health departments to establish memoranda of understanding or formalized agreements with community pharmacies in 2014 ¹		
Yes, for all pharmacy partners	5 (9.6%)	52
Yes, for more than half, but not all, pharmacy partners	5 (9.6%)	52
Yes, for less than half of pharmacy partners	6 (11.5%)	52
No	33 (63.5%)	52
Don't Know	3 (5.7%)	52

Data sources:

¹: 2014 Annual Report;

²: 2013 Annual Report.

^a Responses do not always equal 53 due to missing responses from jurisdictions.