

Increasing Adverse Event Reporting (IAER) subproject: Survey report

IAER is a subproject of International Coalition of
Medicines Regulatory Authorities (ICMRA)
Pharmacovigilance (PV) project



Disclaimer: This document has been endorsed as a formal ICMRA document by ICMRA

Purpose of document:

The purpose of this document is to present the of International Coalition of Medicines Regulatory Authorities (ICMRA) Pharmacovigilance (PV) subproject survey results on Increasing Adverse Event Reporting (IAER) which has a focus on suspected adverse drug reaction reporting.

1. Document control

Revision History

This table sets out the revision history.

Version No.	Effective date	Author's Title	Change
0.1	25/05/18	Mitul Jadeja (MJ)	Creation and first skeletal draft with qualitative answers and presentation of survey data via graphs
0.2	20/07/18	MJ	Combined report sections from project team: Formatting of report and graphs – MHRA Raw data – TGA Graphs – MHRA except for TGA sections National Reporting Systems – TGA Reporters and reporting methods – TGA/MHRA ADR stats – TGA, MHRA Benchmarking and awareness levels - MHRA Strategy - MHRA Promotion - MHRA Campaigns and materials - MHRA, TGA Education and e-learning - HC, Medsafe Budget and resource – ANVISA, MHRA Stakeholders – MPA Mandatory reporting - TGA Improving Quality – HC, Medsafe Feedback - HC, MPA Facilitation -TGA Training – All Social Media Campaign - TGA, MHRA, HC, ANVISA Recommendations and future work - MHRA Qualitative responses in Annex 2 - MHRA
0.3	31/07/18	MJ	1 st draft circulated for comments due back 17/08/18.
0.4	07/08/18		Post MF verbal comments 01/08/18
0.5	20/08/18		Post AIER project team written comments 20/08/18.
1	20/08/18, 24/10/18	MJ	20/08/18 Circulated to ICMRA. 24/10/18 Revised post comments from ICMRA consultation. Final version.

Consultation

Who	Date
Mick Foy & AIER project team	31/07/18 - 17/08/18
ICMRA members	20/08/18. All members 30/08/18. Plenary 12/09/18

Abbreviations

ADR – adverse drug reaction or suspected adverse drug reaction
 ANVISA - National Health Surveillance Agency in Brazil
 CADRM – Centre for Adverse Drug Reactions Monitoring in China
 CFDA - China Food and Drug Administration (CFDA)
 COFEPRIS - Federal Commission for the Protection against Sanitary Risks in Mexico
 EMA - European Medicines Agency
 HC - Health Products and Food Branch Health Canada (HPFB-HC)
 HCPs - Healthcare professionals
 HCs – healthcare institutions
 HSA - Health Sciences Authority in Singapore
 MHLW - Ministry of Health, Labour and Welfare in Japan
 MHRA - Medicines and Healthcare Products Regulatory Agency in UK
 MPA - Medical Products Agency in Sweden
 PIL – Patient Information Leaflet
 PMDA - Pharmaceuticals and Medical Devices Agency in Japan
 PV – Pharmacovigilance
 SCOPE - Strengthening Collaboration for Operating Pharmacovigilance in Europe
 SmPC – Summary of medicinal Product Characteristics
 TGA - Therapeutic Goods Administration in Australia
 UMC – Uppsala Monitoring Centre, a WHO collaborating centre for International Drug Monitoring
 WHO - World Health Organisation

IAER team

The Increasing Adverse Event Reporting (IAER) subproject team consists of representation from:

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WHO are observers of this ICMRA PV IAER subproject via Shanti Narayan Pal.

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2. Executive Summary

This report outlines the collection and analysis of information gathered from a questionnaire completed by National Competent Authority (NCA) on increasing awareness levels and improving quality and their associated activities in relation to pharmacovigilance (PV) information. The survey forms the initial activity of the ICMRA PV IAER subproject that focuses on national ADR reporting systems. Results and findings from the survey are intended to inform the development of recommendations and guidance, including highlighting best practice and tools for ICMRA members to adopt to increase awareness about ADR reporting and to improve the quality of ADR reports.

A web-based questionnaire was developed by the IAER team. Following a period of review and testing, it was officially launched on 16 February 2018 and the initial deadline for submitting the completed questionnaire was set as 28 February 2018. However, the deadline was approved by ICMRA to be extended for another month to allow more members to complete the survey. The IAER subproject is thankful to the 11 ICMRA members that took time to complete the IAER survey on increasing suspected ADR reporting and improving quality. These were: Medical Products Agency (MPA) (Sweden), European Medicines Agency (EMA), Medicines and Healthcare Products Regulatory Agency (MHRA) (UK), Ministry of Health, Labour and Welfare (MHLW) / Pharmaceuticals and Medical Devices Agency (PMDA) (Japan), Health Science Authority (Singapore), National Health Surveillance Agency (ANVISA) (Brazil), Federal Commission for the Protection against Sanitary Risks (COFEPRIS) (Mexico), Health Products and Food Branch Health Canada (HPFB-HC) (Canada), Therapeutic Goods Administration (TGA) (Australia), Medsafe (New Zealand) and China Food and Drug Administration (CFDA) that runs the Centre for ADR monitoring (CADRM) (China). The European Medicines Agency responded to parts of two questions on ADR reporting figures in EU and stakeholders engaged; and so, are excluded in the bulk of this analysis.

Major findings from the survey including highlights, common themes and gaps emerging from the survey results are:

Area	Highlights, themes, or gaps
Awareness levels	<ul style="list-style-type: none"> Very low/no formal assessment or benchmarking of awareness levels of their NCA nor ADR reporting systems (10%)
Strategy	<ul style="list-style-type: none"> 60% of NCAs having a strategy to increase reporting/improve quality.
Campaigns	<ul style="list-style-type: none"> 80% have run a campaign in 10 years. 50% of those that ran campaigns measured success. Common trends of measuring included surveys and quantitative analysis of reports before and after the campaign, web analytics, and social media coverage.
E-learning	<ul style="list-style-type: none"> 80% have some form of e-learning materials for education for healthcare professionals or patients.
Budget and resource	<ul style="list-style-type: none"> Although 20% do not have a budget for increasing awareness or improving the quality of suspected ADRs all have access to resource in some form from their PV department by dedicated resource (28%), existing resource (39%), or from their Communications/PR departments or higher ministry departments (33%).

Stakeholder interaction	<ul style="list-style-type: none"> • Most successful initiatives involved stakeholder interaction, e.g. use of communication channels; low/no cost work; two-way engagement; setting up new safety networks; through regional centres, engaging with students. • For most, there has been relatively little engagement or none with patient organisations.
Mandatory reporting	<ul style="list-style-type: none"> • For those that have mandatory reporting in their countries: <ul style="list-style-type: none"> ○ for HCPs, 33% said there was a positive effect and 67% said the effect was neutral. None said it was negative. ○ for Healthcare institutions, 40% said there was a positive effect in reporting and 60% said the effect was neutral. None said it was negative. • NCAs said more positive effects were seen in increased reporting and awareness through mandating reporting at a HCI (67%) level than by mandating healthcare professionals to report (33%). • Many have not measured these effects in detail.
Quality of ADR reports	<ul style="list-style-type: none"> • 60% of NCAs measure the quality of ADR reports. • IT solutions and e-reporting (including integration of reporting into clinical systems) and such case studies are important learning areas.
Feedback	<ul style="list-style-type: none"> • Feedback to reporters is a key area that NCAs wish to improve on. • Meaningful and tailored feedback is key for reporters.
Training	<ul style="list-style-type: none"> • Very high demand for training to improve the quality and increase the quantity of ADR reporting, with all indicating an expression of interest. • Highest areas of interest are (90% requested): <ul style="list-style-type: none"> ○ Promotion - developing and maintaining promotion and communication strategies, general awareness raising on the importance of pharmacovigilance for public health protection, running a communication campaign ○ Facilitation – making reporting accessible, maximising the use of IT ○ Education – raise understanding about the purpose and value of reporting with HCPs and members of the public ○ Improving the quality of suspected ADR reports
Social Media campaign	<ul style="list-style-type: none"> • Six NCAs (60%) indicated interest in participating in a coordinated social media campaign in 2018/19 with ICMRA members that could link into EU and UMC campaigns to increase awareness of ADR reporting in an awareness week.

Future work suggestions for ICMRA and its membership:

- Adopt similar wording to EU legislation for ICMRA members to strengthen their commitment to increasing ADR reporting. This is outlined below:

Article 102 of Directive 2010/84/EU amending Directive 2001/83/EC: *‘The Member States shall... take all appropriate measures to encourage patients, doctors, pharmacists and other healthcare professionals to report suspected adverse reactions to the national competent authority; for these tasks, organisations representing consumers, patients and healthcare professionals may be involved as appropriate;’*

This can be further strengthened to include improve the quality of reports.

- Deliver training in the form of webinars for as many aspects of the areas in section 4. This can include:
 - Experiences of different NCAs in increasing ADR reporting and improving quality
 - Presentation of a common strategy adding to existing work in this area
 - Promotion - developing and maintaining promotion and communication strategies, general awareness raising on the importance of pharmacovigilance for public health protection, benchmarking, working with stakeholders, running a communication campaign and measuring effectiveness.
 - Facilitation – making reporting accessible, maximising the use of IT, integrating reporting into clinical systems
 - Education – raising understanding about the purpose and value of reporting with undergraduates, HCPs and members of the public, including tactics, e-learning tools, information for education for HCPs, useful information and signposting NCAs to educational resources to improve quality and general PV
 - Improving the quality of suspected ADR reports through methodologies, tools and NCA experiences.
- Establish an ICMRA group to develop communications messages to raise awareness through campaigns. This could involve work sharing to build capacity.
- Encourage participation in an annual social media awareness campaign to raise awareness about suspected ADR reporting which usually takes place in November.
- Site/exchange visits to optimise face to face learning an international collaboration - visits can be self-funded between interested NCAs.
 - ICMRA supported secondments or site visits to share and learn from each other to build capacity through an exchange program or site visits which would be facilitated by IAER subproject. Any visits would be self-funding by mutually participating and willing NCAs upon request.
- Exploring the impact of IAER, including the handling of signal detection methodologies and their outcomes for quality.

3. Context and scope

IAER subproject objectives

The IAER subproject team aim to:

- **Enable and facilitate ICMRA members with a set of case studies and template methodologies that can also be policy recommendations, through the sharing of knowledge and establishment of good practice across ICMRA members, to enable members to strengthen their strategies to increase the quantity and the quality of national spontaneous Adverse Drug Reactions (ADR) suspected reports to their systems for human medicines.**
- **Develop a platform for information sharing for ICMRA members to provide practical assistance with how to use any guidance documents or materials developed. These materials may be developed at a national level or via the ICMRA subgroup.**

- **Explore the appetite, encourage and facilitate ICMRA members to run their own national campaign or participate in the annual social media ADR awareness week campaign in November 2018 to increase ADR reporting and awareness levels.**

The above objectives are specific to ICMRA members.

As **WHO are observers on the subgroup**, it is anticipated that the group together may explore how any project outputs can be sustainable, shared and utilised by other National Competent Authorities (NCA) via the WHO's global Pharmacovigilance (PV) programme once the first two objectives are completed.

Scope and rationale

Some regulators have adopted strategies to increase reporting and this ICMRA subproject team was formed to identify the different approaches that have been taken and where these approaches may have had the greatest impact. The ICMRA subproject team decided to focus on suspected ADRs rather than the broader issue of adverse events. This is because national PV systems are primarily concerned with suspected ADRs rather than 'adverse events' which may be associated with an ADR but not a direct result of the medicine.

The effectiveness of spontaneous suspected ADR reporting systems to detect drug new safety signals is dependent upon sufficiently high-quality data being made available for NCAs and national PV centres to conduct PV activities to protect public health.

ADRs present a burden on healthcare systems and the resulting harm to patients from ADRs can sometimes be avoidable. There is therefore a need for appropriate education about ADRs and the importance of reporting them. Education in this way, is often associated with awareness levels about PV activities and regulatory outputs to ensure the safer use of medicines. In addition, it is recognised that the definition of an ADR has broadened in recent years, at least in Europe, to include the reporting of incidents that are from error. There is also an increased focus on overdose and product misuse and abuse.

Under-reporting of suspected ADRs is an inherent problem for all NCAs and PV centres globally since reporting systems are reliant on healthcare professionals and patients being vigilant in not only identifying suspected ADRs, but also reporting them. Improving the reporting of suspected ADRs to spontaneous reporting systems usually focuses on improving the volume and quality of ADR data through many methods.

Objectives of this report

Results from the survey have been used to identify the range of practice across those NCAs that completed the survey. This information is analysed to direct next steps and recommendations for delivery of guidance/training for ICMRA members help them raise awareness to improve the number and quality of ADR reports. This is to support NCAs in meeting their requirements set out in the EU PV legislation and provides suggestions for NCAs outside who wish to further improve their own ADR systems in these areas.

Challenges bringing this report and data together

To achieve the objectives described above, there were a number of challenges faced to bring this report together. One of the main challenges was to get enough NCAs to complete the survey. Another was the potential interpretations of questions and terminology e.g. the definition of 'strategy' and 'campaign'. There are large overlaps between areas that were connected to increase reporting and quality of suspected ADR reporting. This meant there were some duplication of answers for some questions for respondents e.g. electronic reporting that can cover both areas. The generalisability of results and comparison of responses could be impacted by differences in interpretation. For recommendations themselves, there will always be the potential for challenges for national adoption with the significant difference in the range of contexts, stakeholders and other factors in different countries. Acting upon or adopting any recommendations or adopting any good practice that will be shown in this report or from the delivery of training will depend on national appetite, prioritisation, and availability of resources.

4. Survey results

Each section will display a summary of results and discuss findings.

4.1. National Reporting Systems

Questions 1, 2 and 3 were introductory questions asking for country, institution, population, number of regional centres and contact details for the person(s) responsible for completing the questionnaire.

Table 1 - shows responses from each NCA indicating their population, staff and regional centres

NCA	Population (millions)	PV staff numbers	Regional centres	PV staff per million population
HSA - Singapore	5.6	38	1	6.8
HC - Canada	35.0	60	7	1.7
TGA - Australia	24.5	30	-	1.2
MHRA - UK	66.4	145	5	2.2
MHLW/PMDA - Japan	127	200	-	1.6
COFEPRIS - Mexico	131.8	20	32	0.15
ANVISA - Brazil	207	14	14	0.1
MPA - Sweden	10	43	-	4.3
Medsafe – NZ	4.8	8	-	1.7
CADRM/CFDA – China	1,383	58	34	0.04

Although the EMA is not an NCA this information was supplied:

EMA	500.0	45	-	0.09
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4.2. Reporters and reporting methods

Summary

Reporters

- All NCAs (10) collect suspected ADR reports from doctors, nurses and pharmacists and other HCPs.
- 20% (2 NCAs) do not collect patient ADR reports.

Reporting methods

- All agencies continued to use traditional paper-based reporting methods, but many no longer use certain resource intensive methods such as email and telephone.
- Most members have adopted some form of web-based reporting.
- Newer methods of internet and software-enabled reporting (e.g. mobile apps (2 NCAs), clinical software integration (4 NCAs) are being used by some members.

Question 4 asked about who can report a suspected ADR to your national PV system.

Figure 1 – shows the reporter types that have the authority to report a suspected ADR to each NCAs national PV system

Who can report a suspected ADR to your national PV system?

Organisation/Institution	Patients	Carers	Parents	GP	Hospital doctor	Physician (speciality unspecified)	Hospital pharmacist	Community pharmacist	Pharmacist (speciality unspecified)	Nurse (speciality unspecified)	Hospital nurse	Midwife	Other HCPs, please specify
Medical Products Agency	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
MHRA	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
MHLW/PMDA				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Health Sciences Authority				✓	✓	✓	✓	✓	✓	✓	✓		✓
Medsafe	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
ANVISA Brazilian Health Regulatory Agency	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Therapeutic Goods Administration	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
COFEPRIS	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Health Canada	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Center for ADR Monitoring in China	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	

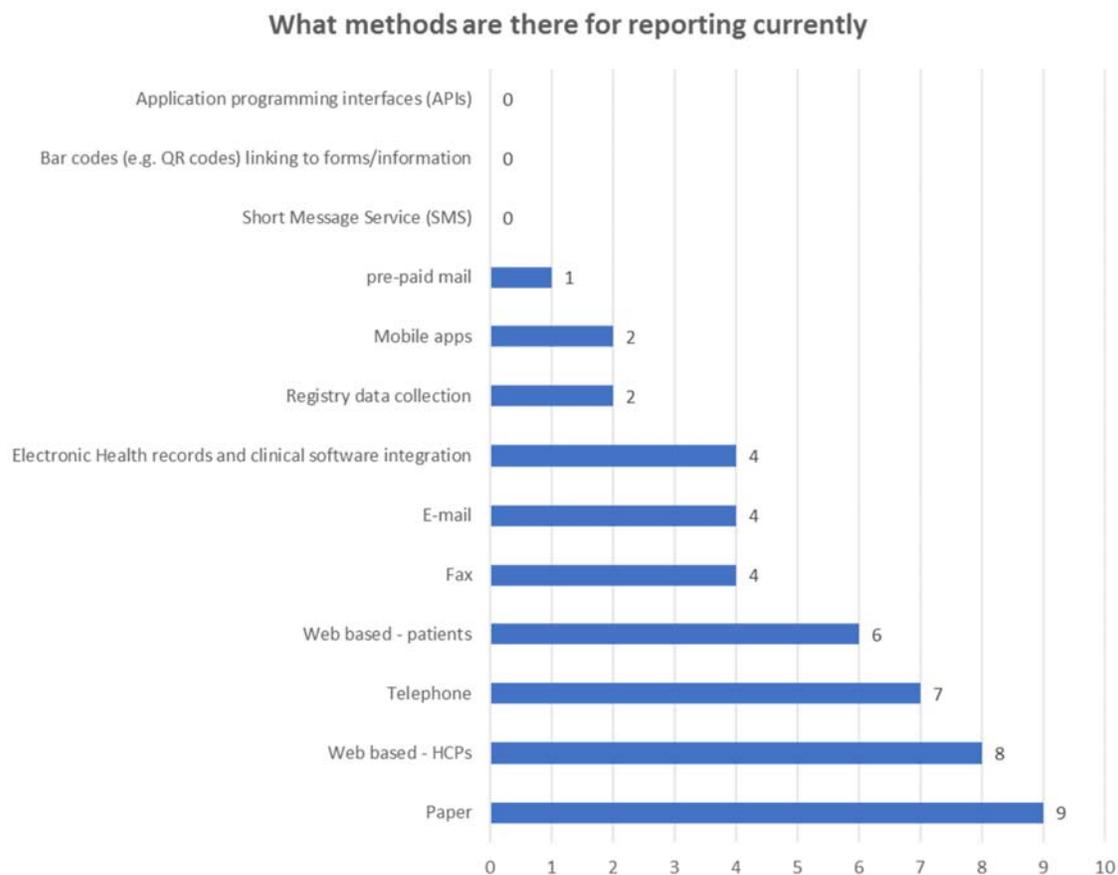
All NCAs collect reports from GPs, hospital doctors, physicians (speciality unspecified), hospital pharmacists, community pharmacists, pharmacists (speciality unspecified), hospital nurses, nurses (speciality unspecified). 2 NCAs (20%) do not have patients, carers or parents reporting suspected ADRs.

NCAs were asked to specify which types of other HCPs* report:

- MPA – any HCPs
- MHRA - dentists, optometrists, coroners, healthcare assistants, paramedics, chiropodists, medical students and other non-specified health professionals
- MHLW/PMDA – dentists
- Medsafe - dentists, optometrists, coroners, healthcare assistants, paramedics, chiropodists, medical students and other non-specified health professionals
- HSA - Traditional Chinese Medicine Practitioners

Question 5 asked what current methods are available for reporting.

Figure 2 – Overview of current modes to report a suspected ADR to national PV systems



Many NCAs (90%) have traditional paper-based reporting methods, followed by web-based reporting (where applicable for HCPs and members of the public), and telephone reporting. Four (40%) NCAs responded that Electronic Health Records and clinical software integration were available and only two NCAs (20%) indicated having a mobile app. Two NCAs (20%) indicated registry data collection.

Figure 3 – A detailed breakdown of reporting methods indicated by individual NCAs

What methods are there for reporting currently?

	<i>Web based - patients</i>	<i>Web based - HCPs</i>	<i>Electronic health records and Clinical software integration Mobile apps</i>	<i>Registry data collection</i>	<i>Paper</i>	<i>Telephone</i>	<i>Other, please specify</i>	<i>Other, please specify - Text</i>
Medical Products Agency	✓	✓		✓	✓			
MHRA	✓	✓	✓	✓	✓	✓		
MHLW/PMDA					✓		✓	✓
Health Sciences Authority		✓	✓		✓	✓	✓	✓
Medsafe	✓	✓	✓	✓	✓	✓	✓	✓
ANVISA Brazilian Health Regulatory Agency	✓	✓						
Therapeutic Goods Administration	✓	✓	✓		✓	✓		
COFEPRIS				✓	✓	✓		
Health Canada	✓	✓			✓	✓	✓	✓
Center for ADR Monitoring in China		✓			✓	✓		

4.2.1.ADR stats

Summary

Total numbers of suspected ADR reports

- CADRM/CFDA receives the most suspected ADRs (1.43 million reports) from all sources.
- HSA receives the most reports per 100,000 inhabitants
- 6 respondents showing an increasing trend in reports (CARM, EMA, MHRA, HSA, TGA, and ANVISA)

Members of the Public reporting suspected ADRs directly to NCAs

- MHRA receives the most suspected ADRs from members of the public, including parents, carers and patients.
- MPA receives the most reports per 100,000 inhabitants
- There is a generalised increasing trend in the numbers of reports from members of the public to NCA PV systems.
- 30% of NCAs (MHLW/PMDA, HSA, ANVISA) do not accept reports directly from members of the public.

HCP reporting suspected ADRs directly to NCAs

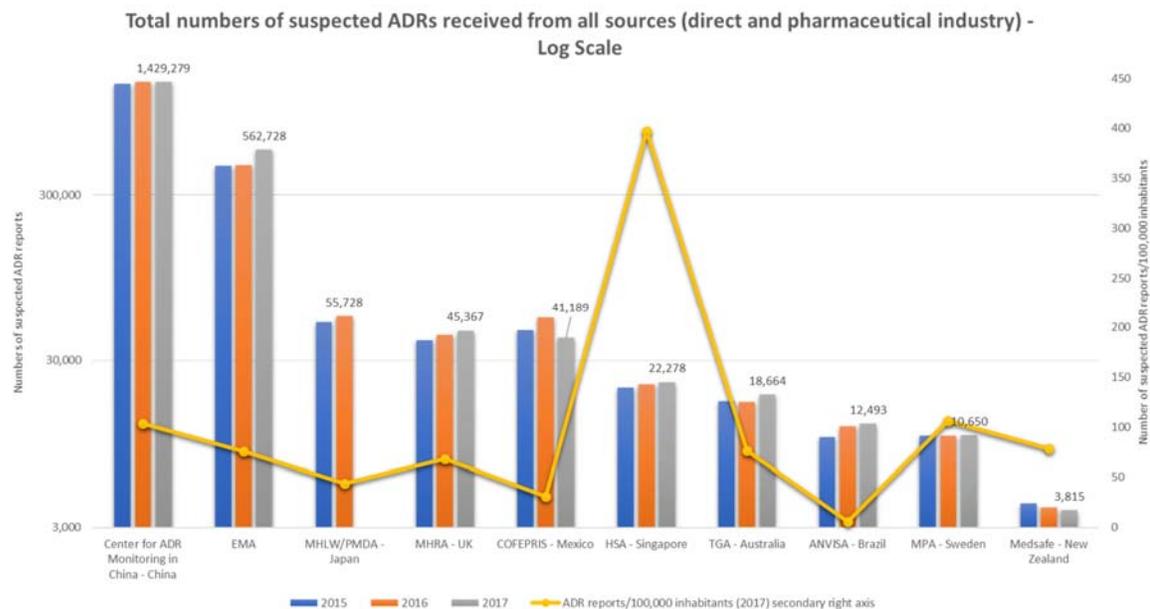
- CADRM/CFDA receives the most total suspected ADRs directly from HCPs (1.26 million reports). The next is MHRA (22,845) and HSA (21,726)
- HSA receives the most reports per 100,000 inhabitants
- 40% NCAs are showing a increasing trend (CARM, MHRA, HSA, ANVISA).

Total numbers of suspected ADR reports

At the start of the questionnaire NCAs were asked to provide numbers of suspected ADR reporting figures for the total number of ADRs from all sources, including a breakdown of

industry reporting as well as direct reports by HCPs and members of the public. These are illustrated in the following graphs.

Figure 4 - Total numbers of suspected ADRs received from all sources (direct and indirectly via pharmaceutical industry) on a log scale x-axis by NCAs including the number of suspected ADRs per 100,000 inhabitants



The CAdRM/CFDA receives the most suspected ADRs (1.43 million suspected ADR reports) from all sources.

HSA receives the most suspected ADR reports per 100,000 inhabitants.

Although it is known reporting rates are very variable between Member States in EU, if 2017 European Medicines Agency (EMA) figures of 562,728 suspected ADR reports are split between 28 Member States, there is an ‘estimated average’ of 20,097 suspected ADR reports per NCA. MHRA figures (45,367 suspected ADR reports) account for 8.1% of EMA ADR data, contributing to 125% more than the estimated ‘average’ number for an NCA. The MPA (10,650 suspected ADR reports) account for 1.9% of EMA data.

It is also evident that although the numbers of suspected ADR reports are lower for some NCAs their actual number of suspected ADR reports per 100,000 inhabitants is higher than other NCAs e.g. HSA, MPA, and Medsafe.

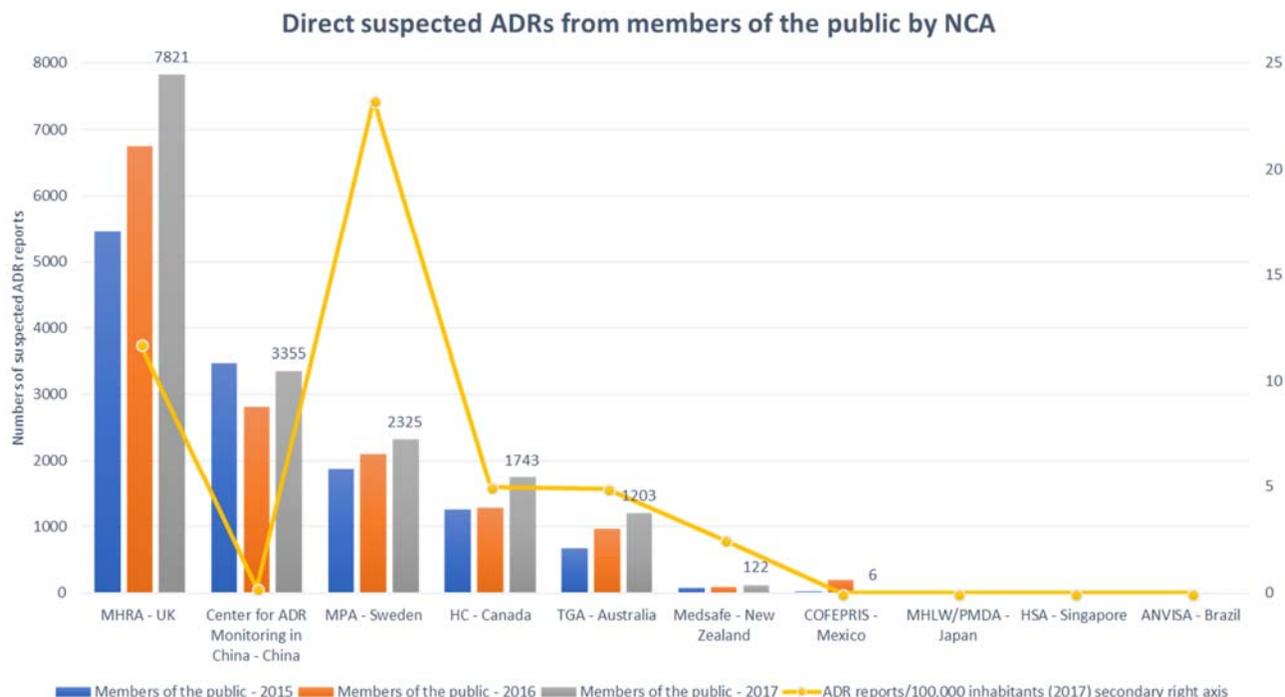
It is important to note that this project focuses on a subset of this data – direct suspected ADR reporting by health professionals/their facilities and direct reporting by members of the public.

Members of the Public reporting directly to NCAs

MHRA receives the most suspected ADRs from members of the public, including parents, carers and patients. MPA receives the most reports per 100,000 inhabitants. There is a generalised increasing trend in the numbers of reports from members of the public to NCA PV systems.

30% of NCAs (MHLW/PMDA, HSA, ANVISA) do not accept reports directly from members of the public. 30% of NCAs (MHLW/PMDA, HSA, ANVISA) do not accept reports directly from members of the public.

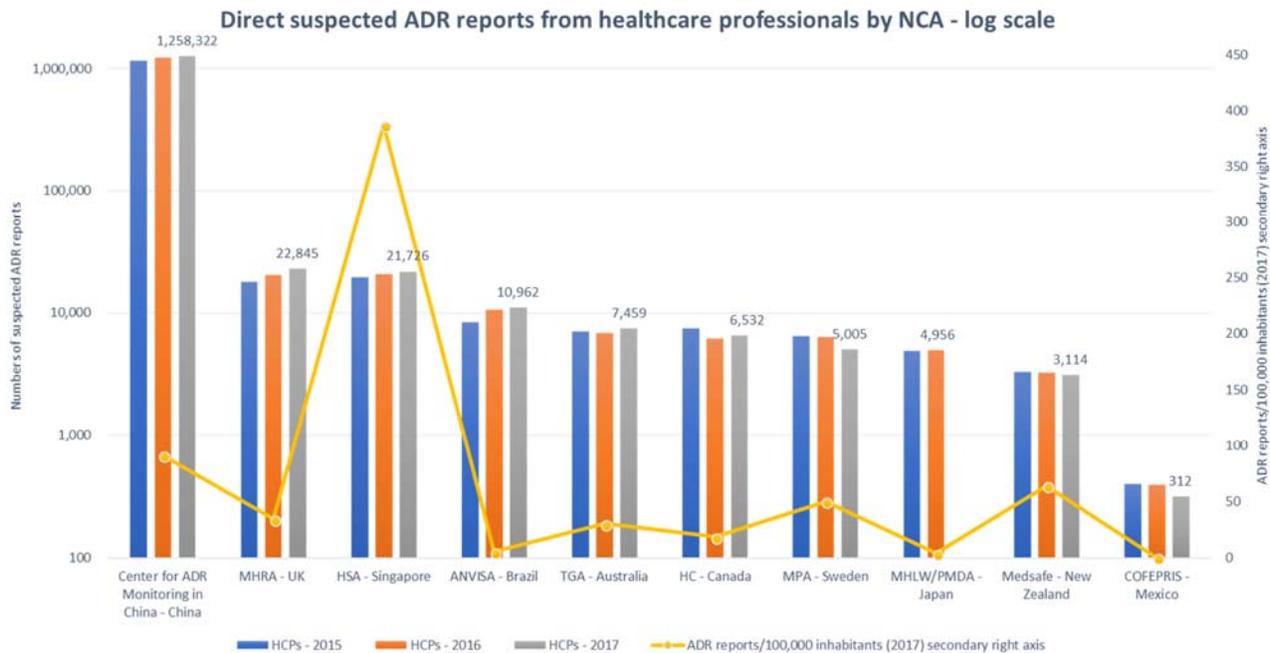
Figure 5 – Suspected ADR reports received directly by NCAs from members of the public



Direct suspected ADR reporting by HCPs to NCAs

The CADRM/CFDA receives the most total suspected ADRs directly from HCPs (1.26 million reports). The next is MHRA (22,845) and HSA (21,726). HSA receives the most reports per 100,000 inhabitants. 40% NCAs are showing an increasing trend (CARM, MHRA, HAS, ANVISA) over a three-year period. The number of suspected ADR reports per 100,000 are lower than totals for HCP reporting by NCA.

Figure 6 – direct suspected ADR reports from HCPs by NCA on a log scale



Combined reporting from each physicians, pharmacists, nurses and other HCPs

High level observations in trends from the following graph are:

- There is an increasing trend in from all reporter groups, especially from pharmacy and physicians reporting suspected ADRs through the MHRA’s Yellow Card Scheme. Pharmacy proportions of suspected ADR reports are increasing. Keystone reporters are doctors, followed by pharmacy and nurses with steady proportions of other HCPs reporting.
- Large proportion are pharmacy reporters to MHLW/PMDA with increasing trend in proportions of reports. Steady proportions of other HCPs reporting and nurses.
- Majority of reporting is through physicians to HSA with large numbers. Steady proportions of other HCPs reporting and nurses.
- Large proportion of nurse reporting (more than pharmacy) to Medsafe. Steady proportions of other HCPs reporting
- ANVISA only receives pharmacy reports with a marked increase in 2017, although low levels of reporting.
- Similar to MHLW/PMDA, TGA have more pharmacy reporting than physicians. HC also have this trend.
- HC have the largest proportion of other HCPs reporting compared to other NCAs. There is a decreasing trend in pharmacy reporting and from physicians. However, reporting from nurses is increasing.
- CADR/CFDA have large numbers of reports compared to any other NCA. Large decrease in reporting from pharmacists seen in 2017. However, there is an increasing trends in physicians and nurses reporting suspected ADRs.

Figure 7 – The proportion of suspected ADR reports submitted directly by doctors, pharmacists and other HCPs* for each NCA (where ADR reporting figures were supplied by the NCA).

Proportions of suspected ADR reports submitted directly for combined HCPs specialities to each NCA



4.3. Benchmarking and awareness levels

Summary

Baseline awareness levels of NCA

- 10% of NCAs (1) have conducted formal assessments to estimate the awareness levels of their NCA with HCPs
- 10% of NCAs (1) have conducted formal assessments to estimate the awareness levels of their NCA with members of the public

Baseline awareness levels of NCAs national ADR reporting scheme

- 20% of NCAs (2) have conducted formal assessments to estimate the awareness levels of their respective national ADR information relating to PV with HCPs
- 10% (1) has estimated awareness levels of their respective national ADR information relating to PV with members of the public

Tools and techniques utilised by those few that had:

- telephone interviews, workshops, questionnaires, campaigns surveys, polls
- range of small surveys in settings to large national omnibus surveys and with selected reporter groups and HCPs

Question 11 asked NCAs whether any formal assessment of awareness levels had been conducted for its NCA and reporting system, and if so with which target group (healthcare professionals or members of the public).

MHRA is the only NCA that has benchmarked awareness levels of their NCA and their suspected ADR reporting system with HCPs and members of the public. This was found beneficial for campaign work and also stakeholder engagement.

MHLW/PMDA also has estimated awareness levels of their suspected ADR reporting system with HCPs.

Question 12 asked for an overview of how this was conducted, including information about individual reporters, sample sizes, if the data was published and also what the NCA did with such data.

From the practice presented, a robust method to survey is via an unbiased third party professional company to conduct national polls. It is recognised that online survey tools such as survey monkey can also be useful. There are also limitations to using survey tools online and there is also value and benefit in stakeholder engagement for advice.

It can be beneficial to have baseline information about medicines experience of the person completing the survey and their concern about medicines. MHRA used the same set of template questions to benchmark awareness about ADR reporting, these are also incorporated into campaigns to measure effectiveness before and after. Example answers to questions can be broken down into predefined options to make it easier to capture information.

A good way is to breakdown the context of the extent to which each type of HCP is actually aware of the NCA as an organisation, and their perceptions and attitudes. The same questions should be asked periodically to enable comparisons and to identify any changes over time.

Qualitative responses can be found in Annex 2.

4.4. Strategy

Summary

Strategy

- 60% of NCAs (6) have a strategy to raise awareness levels of suspected ADR reporting or improve the quality of suspected ADR reports. One NCA described this as a work in progress.
- 40% (4) NCAs do not have a strategy to raise awareness levels of suspected ADR reporting or improve the quality of suspected ADR reports.
- EMA responded to this question indicating a strategy for systematic quality checks on samples (of suspected ADR reporting) and feedback to stakeholders; and regular interactions with stakeholders.

Approaches that worked well

- Having a clear documented strategy with objectives that evolves, is reviewed periodically and is flexible to change for continuous improvement over time.
- Electronic integration of ADR reporting into clinical systems, education of reporters including e-learning, engaging with HCPs through a variety of methods including conferences, promotional materials, periodic safety bulletins, and information in annual reports.

What has not worked well

- Time and resource challenges, engaging with certain reporters e.g. GPs, in not being able to report directly from the medical systems or journals, using 'real patients',

Future approaches

- Improving feedback on reports on signals and regulatory action
- Campaign drives to improve quality

Question 13 to asked if NCAs have a strategy to increase awareness levels of suspected ADR reporting; and/or to improve the quality of suspected ADR reports. 60% (6) NCAs said they do. It must be noted that no documented strategies or principles were shared with exception to MHRA's Yellow Card Strategy which is identified as good practice in this area.

A wide range of activities are described as strategic efforts to increase suspected ADR reporting and improve quality by the remaining 4 NCAs:

- roadshows/campaigns in the various hospitals to the HCPs to encourage and explain the rationale of ADR reporting, citing numerous case studies where reporting has resulted in good regulatory outcome
- periodic bulletins for HCPs on safety issues encouraging suspected ADR reporting and published articles on regulatory action and suspected ADR reporting.
- annual reports summaries of suspected ADRs received by national systems.to show the impact of reporting and strategic initiatives.
- Brochures are also developed as marketing collateral for roadshows, conferences and campaigns to educate HCPs on reporting of ADRs.
- Updating legal framework for HCPs

- use of regional centres for promotion and education
- Education of HCPs was a key focus for NCAs and this is tied into improving the quality of reports:
 - HCPs educated on the various fields to complete and why when submitting an ADR report.
 - instructions on how to fill out a report available online on websites
 - workshops at universities for undergraduate HCPs, hospitals, and the interaction with pharmaceutical industry.
 - educational documents of ADRs of interest (eg. anaphylaxis, cutaneous drug reactions) to assist HCPs in reporting.
 - educational material marketing material in the form of brochures.
 - e-learning modules: HC and MHRA
 - HC indicated review of the current training for HCP students on ADR reporting demonstrated the need for vertical integration of ADR reporting into the health professional curriculum at universities and colleges to design a curriculum that, as a continuum over the years of study.
 - delivering information on ADRs through the undergraduate curriculum. HC targets students along different points of their learning career by engaging continuing professional development programs to create modules to support practicing HCPs maintain the skills and knowledge to report ADRs.
 - standards and codes of conduct for HCPs endorsed by professional regulators of HCPs and their associated bodies/colleges.

Qualitative responses can be found in Annex 2.

Question 14 asked about what NCAs felt has not worked so well and what would you do differently next time.

Responses highlighted a number of challenges:

- lack of time for the HCPs to prioritise ADR reporting and related education
- difficulty in reaching information to all reporters and targeting selected reporters
- difficulty in not being able to report directly from the medical systems or journals
- changing the lack of knowledge about the importance of reporting ADRs by reporters
- activities need to be sustained, periodic and continuous - not just one type of activity unless it has a good lasting impact e.g. electronic reporting integration.
- difficulty in getting 'real patients' into case studies to show the value of reporting on mass media e.g. television.
- limited resource to do all strategic activities

Some aspects NCAs would focus on in future:

- campaign drives to improve quality via a targeted and focussed HCP campaigns
- more media work, more publications, unfortunately it is resource dependent
- feedback on reports on signals and regulatory action
- the use of technology in HCP engagement sessions, for example, the use of animated video to educate on established reporting steps, and use of e-voting interactive tool to foster 2-way communication
- expanding the channels and content of training

Qualitative responses can be found in Annex 2.

4.5. Promotion

Summary

ADR promotion

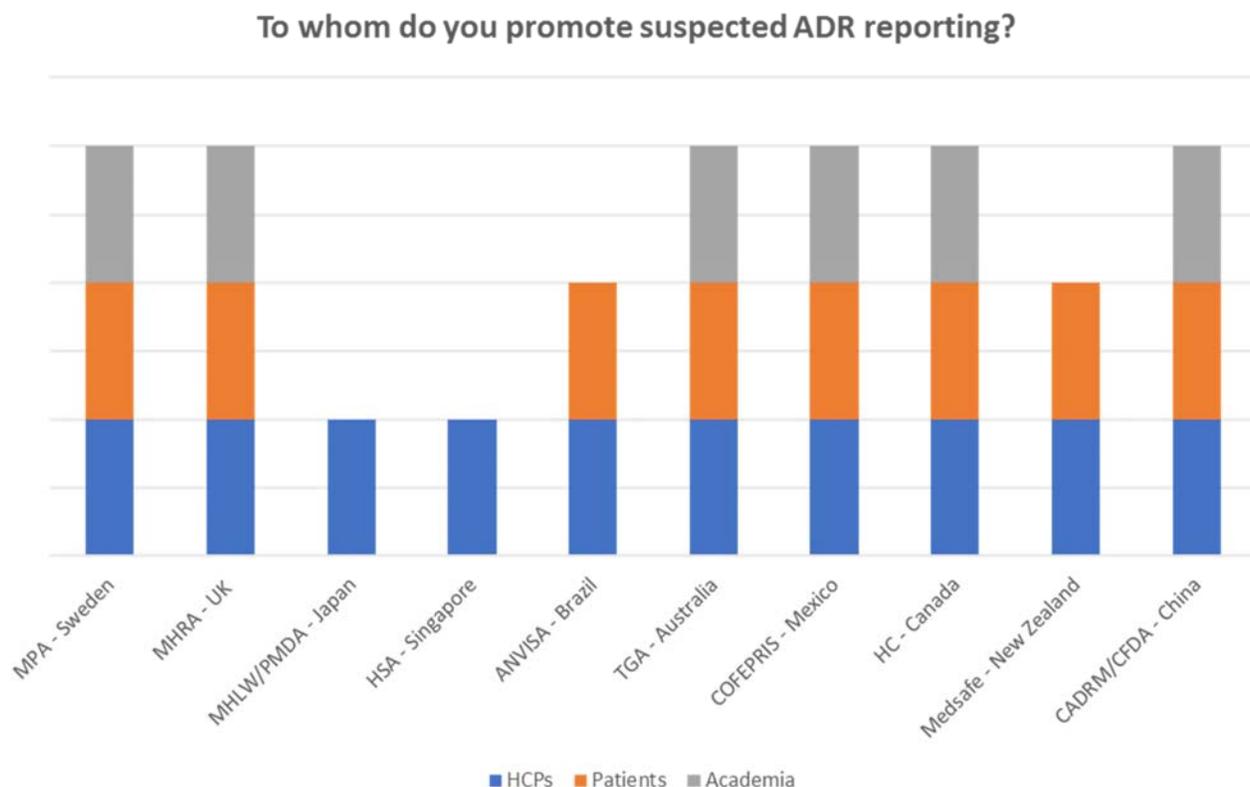
- All NCAs promote suspected ADR reporting to HCPs (100%), 8 (80%) to members of the public and 6 (60%) to Academia.
- The top method of promotion was having information on reporting on NCAs (10) web pages (100%)
- The least common methods of promotion used by NCAs to encourage suspected ADR reporting is through e-learning (40%), during regular telephone or written queries (30%) and educating parents and children about suspected side effects (10%).

Approaches that worked well

- Social media is a good way to raise awareness about suspected ADR reporting
- E-learning is a sustainable approach to raise awareness and improve the quality of suspected ADRs. It also helps to explain the importance of PV to reporters..

Question 16 asked to whom you promote suspected ADR reporting. All NCAs promote reporting to HCPs (100%), 8 (80%) promote to members of the public and 6 (60%) to Academia.

Figure 8 – shows a breakdown of individual NCAs and the reporters they promote suspected ADR reporting to



Question 17 asked about how NCAs promoted suspected ADR reporting

The top method of promotion was having information on reporting on NCAs web pages (100%), followed by through congresses/meetings/conferences/other public events (e.g. posters, exhibits), lectures with focus on ADR reporting as part of continuous education for HCPs and a call for ADR reporting in educational materials and DHCP letters all at 80% each.

Having information on an NCAs website is important but is not a proactive method of promoting reporting unless people are directed to actively view it.

The least common methods of promotion used by NCAs to encourage suspected ADR reporting is through e-learning (40%), during regular telephone or written queries (30%) and educating parents and children about suspected side effects (10%).

Figure 9 – methods used by NCAs to promote suspected ADR reporting

How you promote suspected ADR reporting?



With regard to using social media to promote suspected ADR reporting good practice was identified for participation in a social media awareness week coordinated by MHRA in 2016 and 2017. NCAs indicated use of the following social media channels: Twitter, Facebook and YouTube. One NCA also uses Instagram.

NCAs may wish to consider adopting some of these methods to strengthen promotional methods to encourage suspected ADR reporting, for example through newsletters, working with HCP bodies and their organisations, and initiatives like mandating pharmaceutical industry required to have information about reporting on the product information such as PILs/SmPCs.

4.6. Campaigns and materials

Summary

Campaigns and materials

- Two NCA's (20%) have not run an ADR campaign in the last 10 years
- Eight NCA's (80%) had run a total of 61 campaigns. One NCA ran 37 campaigns, accounting for 61% of all campaigns.
- Half of the eight NCAs (50%) had formally measured success – One used a ranges of methods, common trends of measuring included surveys and quantitative analysis of reports before and after the campaign, web analytics, and social media coverage.

Approaches of the most successful campaigns

- Direct engagement with health professionals and facilities.
- Targeted audience-focused internet advertising (social media, locational, search engine).
- Coordinated campaigns such as the annual ADR awareness week that the MHRA has lead with UMC.

What has not worked well & what NCAs would do differently based on hindsight

- Passively relying on the agency's website to get the message out.
- The importance of targeting the right audience at the right time for effective dissemination of information.
- Repeating ADR campaign messages and using social media frequently – at least through an annual campaign.

Questions 18-21 asked if ICMRA members had run campaigns to promote suspected ADR reporting, the main messages and evaluations.

The main campaign messages were how to report and where with less NCAs using messages regarding specific medicines/vaccines of interest

Figure 10 – summary of campaign messages used by NCAs

What were the campaign messages

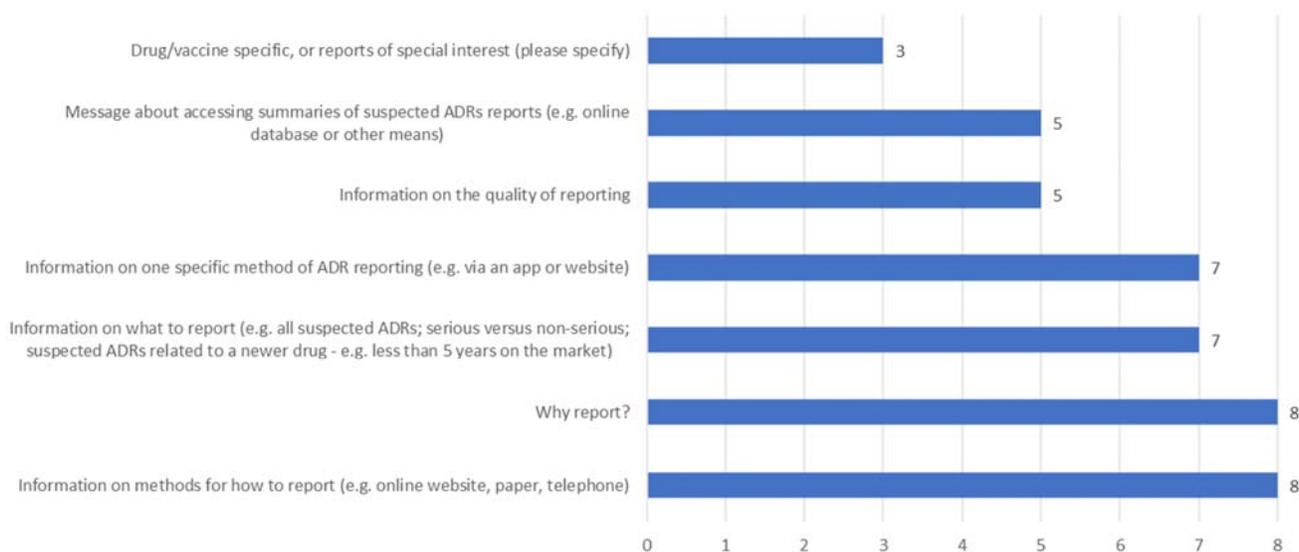


Figure 11 – detailed breakdown by NCA and campaign messages used

	What were the campaign messages?								
	Information on methods for how to report (e.g. online website, paper, telephone)	Information on what to report (e.g. all suspected ADRs; serious versus non-serious; suspected ADRs related to a newer drug - e.g. less than 5 years on the market)	Information on one specific method of ADR reporting (e.g. via an app or website)	Information on the quality of reporting	Why report?	Message about accessing summaries of suspected ADRs reports (e.g. online database or other means)	Type of feedback information provided to reporters	Drug/vaccine specific, or reports of special interest (please specify)	
MPA	✓	✓	✓		✓	✓			
MHRA	✓	✓	✓	✓	✓	✓		✓	
MHLW/PMDA									
HSA	✓	✓	✓	✓	✓	✓		✓	
Medsafe	✓				✓				
ANVISA									
TGA	✓	✓	✓	✓	✓	✓			
COFEPRIS	✓	✓	✓	✓	✓				
HC	✓	✓	✓	✓	✓				
CADRM/CFDA	✓	✓	✓	✓	✓	✓	✓	✓	

Question 23-24 asked which approaches worked well and which did not.

What worked well?

MPA – Sweden:

- Collaboration with dedicated and educated personnel at hospitals
- Animated films for consumers in social media, waiting rooms and similar environment.
- E-learning material available on the MPA's website.
- Regional centres' education of HCPs.
- A yearly pharmacovigilance day where the MPA meet with industry and HCPs.

MHRA:

- A social media ADR awareness week campaign. In the UK, a month after the campaign launch there was an increase of 16% in suspected ADR reports received directly from healthcare professionals and consumers.

HSA:

- A roadshow simulcast (live broadcast) on ADR reporting conducted to a cluster of polyclinics island wide.

CADRM/CFDA - China

- 'Cosmetic propaganda day': The main channels included holding forums, volunteer diagnosis and consultation by specialists.
- International Day Against Drug Abuse and Illicit Trafficking: Held in a town square area, most of the audiences are members of the public including students.

TGA

- Ran a multi-channel internet campaign (Google search and internet 'display' advertising, social media, locational audience targeting, and traditional 'banner' ads on health journals) from April to June 2018 to raise awareness of the newly introduced Black Triangle logo.
- TGA is undertaking a baseline survey to evaluate awareness.
- TGA's Black Triangle webpage experienced a 10,000% increase in traffic (from 18 visits daily to 1800) during the campaign.

What was less successful?

MPA – Sweden

- Only publishing information on the NCR's web site is not sufficient enough to promote ADR reporting.

HSA – Singapore

- We recognise the importance of targeting the right audience at the right time for effective dissemination of information.
- There were times when the HCP turn up weren't great due to clash with other important in-house meetings.
- It is also important to understand the difference in ADR reporting culture in different healthcare institutions for outreach to the right audience.

The full qualitative responses can be found in Annex 2.

4.7. Education and e-learning

Summary

Education and e-learning

- 8/10 (80%) NCAs have some form of e-learning package (set of materials developed for specific educational needs) for HCPs.
- types of e-learning provided includes presentations, interactive modules and videos
- most e-learning packages attract continuing education credits/points
- Of the 8 NCAs, only 2 NCAs (25%) offer full interactive e-learning modules for HCPs (MHRA and HC).
- only 3 NCAs (30%) have experience with educational materials for patients and their organisations
- the success of e-learning is challenging to measure in terms of ADR reporting. One NCA (MHRA) asks their reporters: 'where did you hear about us?' One of these options is e-learning. Their e-learning modules are coupled with a user survey post completion to measure effectiveness of the unit. Another NCA (TGA) measures the completion rate for the e-learning module.

Educational approaches that worked well

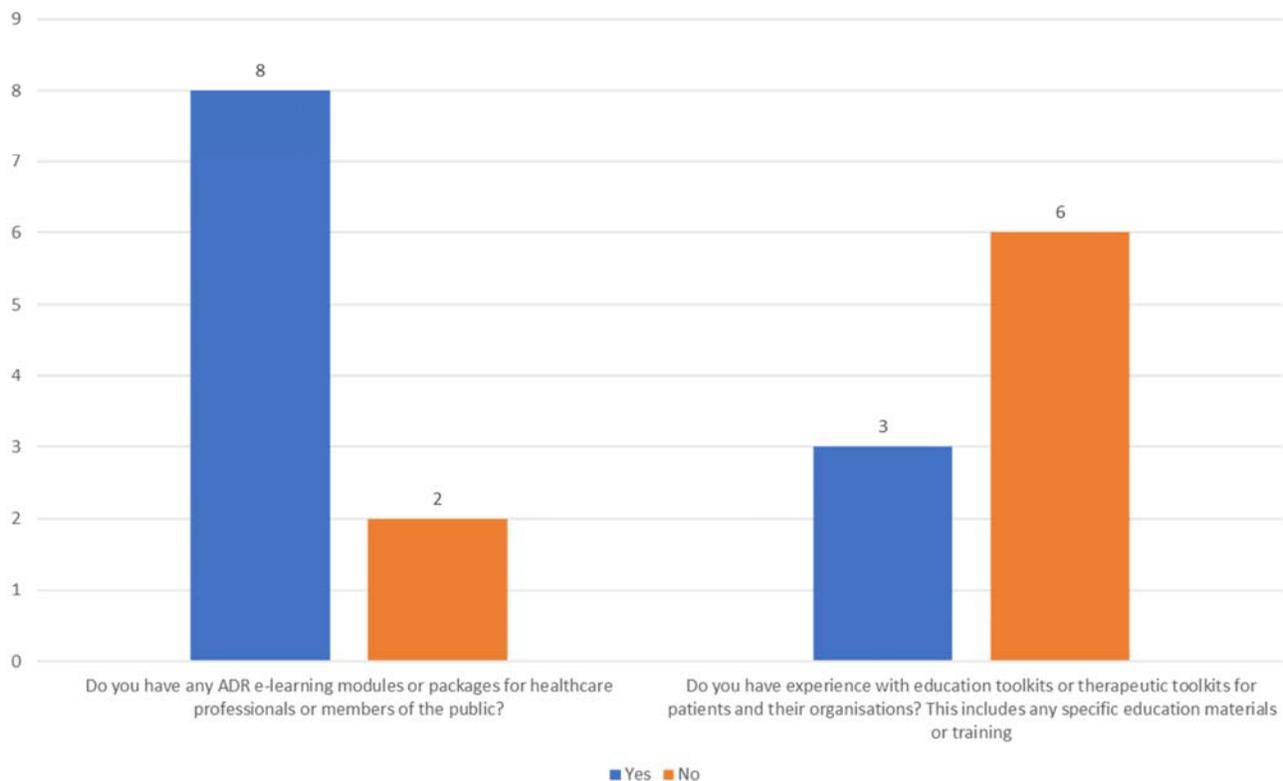
- activities that involved face to face interaction
- incorporating reporting in professional standards
- placing obligations on institutions regarding reporting
- including in undergraduate training

What has not worked well

- presentation at conferences without a stall
- remote learning without human interactions

Question 26 asked respondents to describe their e-learning modules or packages, whether they had measured the effectiveness of e-learning and to supply any relevant details including effect on reporting.

E-learning modules/packages and Education/therapeutic toolkits



Of the 8 NCAs who provide e-learning, only one has material specifically aimed at members of the public (MHRA) in the form of presentation on their reporting website and this is adapted for local use by its regional centres. Two NCAs have a range of interactive e-learning modules specifically designed on e-learning platforms for different healthcare professionals such as doctors and pharmacists (MHRA and HC). The majority of the e-learning modules take the form of an interactive presentation, however one NCA has developed a video presentation (HSA). Four of the e-learning programmes state that they provide continuing professional development credits/points for at least one group of healthcare professionals – MHRA, HC, TGA and Medsafe.

Most NCAs are not measuring effectiveness. However, one NCA captures an additional field on their ADR reporting webform regarding e-learning under ‘where did you hear about us’ and also includes feedback surveys on completion of the module (MHRA). Another NCA measures the completion rate for the e-learning module (TGA).

Question 27 asked about what approaches to educating healthcare professionals worked well.

A number of themes emerged from the answers to this question. Face to face interaction either through lectures, workshops or individual conversations were noted to be very successful. A number of NCAs have regional centres or champions who have responsibility for these activities. Incorporating reporting in professional standards/codes of conduct or placing obligations on institutions were also considered successful. Finally incorporating this topic in undergraduate training was also noted as a successful activity.

Conversely the least successful approaches were considered to be isolated lectures, conference presentations without stalls and remote learning without human interaction.

Question 29 asked about effective engagement with healthcare professionals at advanced stages of their careers.

Many of the responses to this question reiterated the learning opportunities already described, including continued education (CPD) programmes. However, it also appeared that NCAs engage more experienced healthcare professionals by collaborating with this group for example by co-writing articles, seeking advice on safety signals and providing feedback on outcomes of reporting and/or auditing number of reports provided by them or their teams.

Question 30 asked about the impact education has made on reporting and how this is measured.

Most NCAs are not measuring this. Two NCAs use methods such as a field on their webform, surveys, participant feedback, and other effects on reporting rates of ADRs (MHRA, TGA).

Question 32 asked about experiences with education toolkits for patients and their organisations.

Three NCAs responded to this question. For two organisations, education was provided about reporting ADRs and the consumer reporting form (MPA, CADRM). One NCA had explored this activity further providing a toolkit relating to the safety of a medicine (MHRA), in particular, sodium valproate.

It is possible that NCAs interpreted this question differently to what was originally intended.

Qualitative responses can be found in Annex 2.

4.8. Budget and resource

Summary

Budget

- Two NCAs (20%) do not have a budget for increasing awareness or improving the quality of suspected ADRs.
- Five NCAs (50%) indicated they have a set budget with 3 (30%) NCAs indicating a business case is needed for each activity.

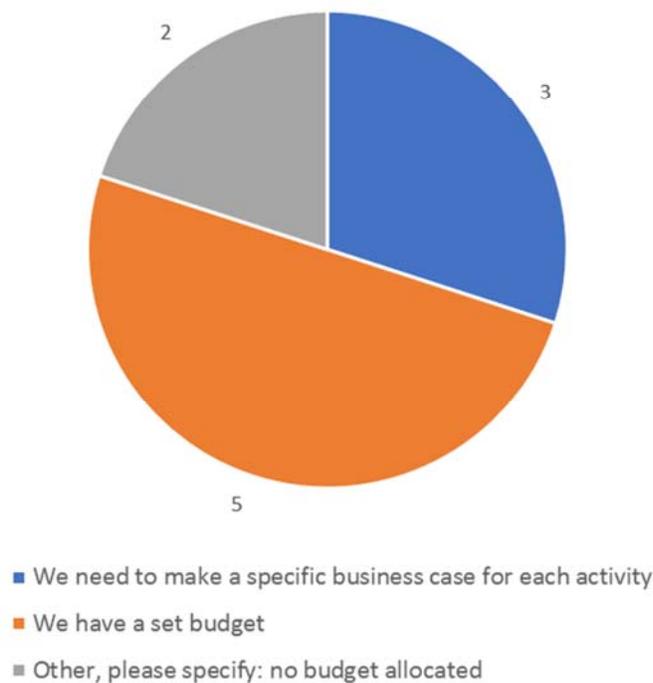
Resource – all NCAs have access to resource in some form

- Seven NCAs (39%) resource is from existing resource within PV departments
- Six NCAs (33%) indicated they have resources from their Communications, Public relations or other department or ministry departments
- Five NCAs (28%) indicated they have a dedicated resource within PV department.

Question 33 asked what type of resources are allocated to NCAs for increasing and improving quality of suspected ADR reports. Eighty percent of NCAs (8) either have an allocated budget or have to make a business case for each activity. Twenty percent of NCAs (2) do not have a budget for increasing and improving quality of suspected ADR reports.

Figure 12 – Types of resources allocated to NCAs for raising awareness and improving quality of reports

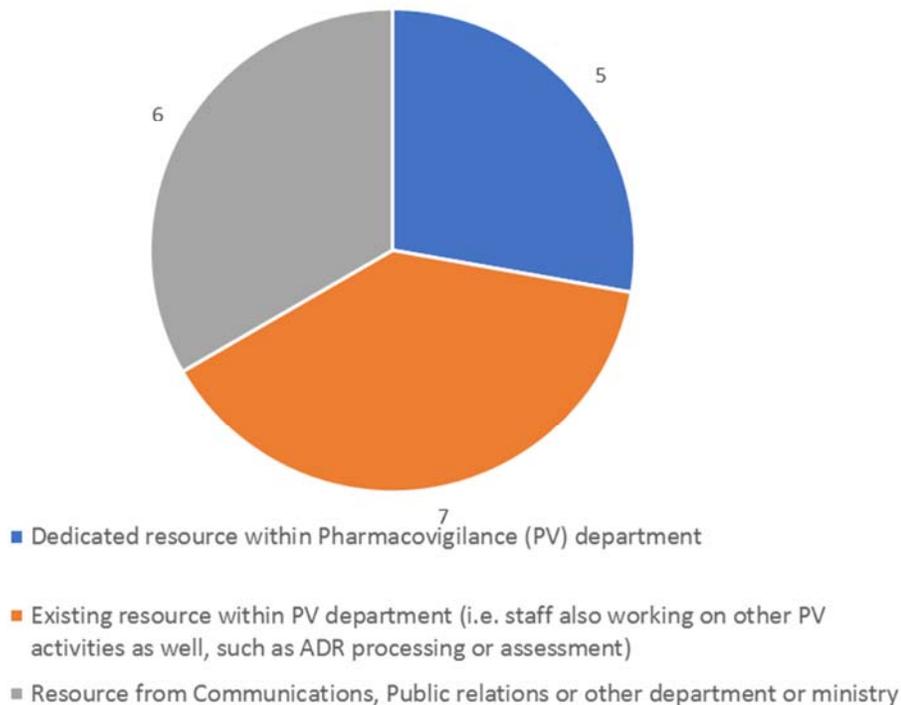
What type of resources are allocated to you for increasing and improving quality of suspected ADR reports?



Question 34 asked for the types of specific resources available for increasing reporting and improving quality activities. For many NCAs (7, 39%) this resource comes from existing resource within PV departments (i.e. staff also working on other PV activities as well, such as ADR processing or assessment) with five NCAs indicating they have a dedicated resource within PV department (5, 28%). Six NCAs (33%) indicated they have resources from their Communications, Public relations or other department or ministry departments also.

Figure 13 - specific resources NCAs have for awareness raising activities for improving quality and quantity of reports.

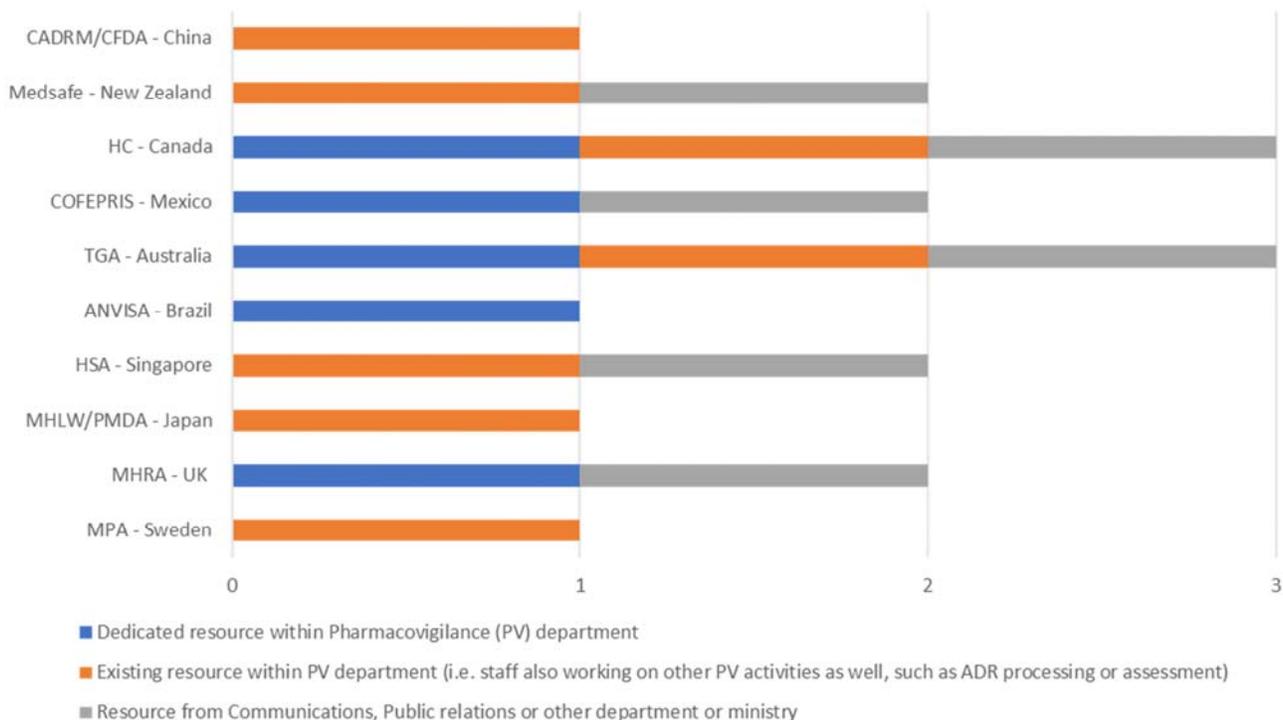
Please identify the specific resources available for awareness raising activities for improving quality and quantity of reports.



HC and TGA were the only NCAs indicating all options. Although the two NCAs that indicated they have no budget (ANVISA and Medsafe), their resource for such activities comes from existing PV resource (both) and is supported by Comms/Ministry (Medsafe). In this way all NCAs have access to some resource in some form to increase ADR reporting and quality of reports.

Figure 14 – detailed breakdown by NCAs indicating their resource levels

What type of resources are allocated to you for increasing and improving quality of suspected ADR reports?



Question 34 also asked NCAs to describe how they handle the situation to improve reporting and quality if they had no resource. As all NCAs said they had some form of resource this aspect was not in the responses.

4.9. Stakeholders

Summary - Stakeholders

- Direct communications e.g. through education, specifically designed information and campaigns via available channels are identified as appropriate ways to increase the awareness and knowledge of ADR-reporting with different stakeholders
- To have partnership / cooperation with national professional bodies is fruitful for awareness raising and to improve the quality of reports.
- Most successful initiatives involved stakeholder interaction, e.g. use of communication channels; low/no cost work; two-way engagement; setting up new safety networks; through regional centres, engaging with students.
- For most, there has been relatively little or no engagement with patient organisations.

Approaches that worked well

- Easily accessible and safe systems for reporting are basic and important
- Face-to-face interaction with stakeholders, including the possibility to have hands on experience with e.g. ADR case studies, gives precepts and is educational

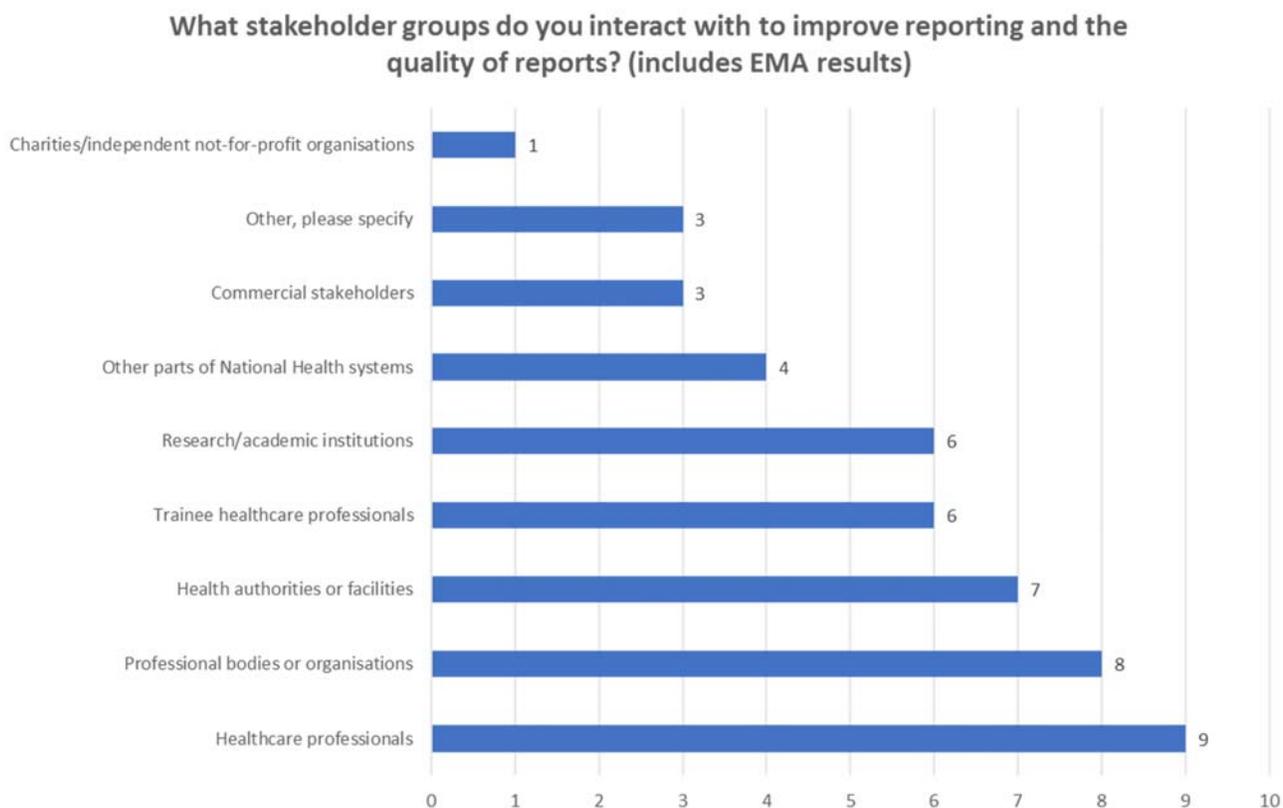
What has not worked well & what NCAs would do differently based on hindsight

- To perform benchmarking before and after campaigns
- To measure success (or not) in relation to stakeholders' awareness
- To clarify the Stakeholders unclear roles and responsibilities in ADR-reporting

Question 35 asked what stakeholder groups do you interact with to improve reporting and the quality of reports?

The results from the survey were used to identify the range of different ways to approach the stakeholders engaged in ADR-reporting. All NCAs in the survey have interactions with Healthcare professionals. There are however different levels of engagement with other parts of the national systems for health care in the participating countries. For most, there has been relatively little engagement or none with patient organisations. EMA described their stakeholders as NCAs within the EU network, MAHs and sponsors of clinical trials. Two respondents described these as patient organisations and therapeutic disease specific groups to support patients; and provincial/Regional Ministries of Health, Patient Safety and Quality Councils respectively.

Figure 15 – groups of stakeholders NCAs interact with to improve the numbers and quality of suspected ADR reports



Question 36 asked NCAs to describe these interactions including what's been the most successful and why including any challenges of their approaches.

Healthcare professionals, physicians in particular, might be the stakeholder that has the most limited amount of time to perform the important activity of reporting adverse reactions. In order to facilitate reporting, to increase the awareness of the importance of ADR-reporting

and to improve the quality and quantity in relation to the reporting, the agencies that participated in the survey have described different modes of action. Besides from the basics i.e. to educate and to have lectures and courses for HCPs, the NCAs use different ways of communication directly and indirectly with the stakeholders.

It can be concluded that specifically designed information and face-to-face communication seems to be a preferred way to increase the awareness amongst stakeholders. The different channels used in communication are described as online information, campaigns, general press and media, social media, bulletins, leaflets, brochures, videos, training material, workshops, articles with case studies etc.

Also, to cooperate and/or have partnership with other professional bodies has been noted as a way forward to increase the stakeholders' awareness. Other professional bodies could be helpful by e.g. promote reporting via their own channels. Regional centers also seem to have a role in educating primarily the HCPs.

In order for the stakeholders to feel comfortable with the ADR-reporting, including personal and therefore sensitive health-data, the 'reported data' must be safe and confidential. Further, to be successful, it is important to have easily accessible system for the reporting, preferably electronic system. It is further noted that it is an advantage to have systems that have linking possibilities (current or planned) with public systems, with consideration taken to the General Data Protection Regulation (GDPR). It is also successful to have face-to-face interactions with different stakeholders including to have hands on experience with the assessment of case-reports and case studies. This requires the NCAs to have designed training material for the different stakeholders.

The challenges posed from the interpretation of the survey are described as the plan and consideration of performing benchmarking before and after campaigns.

To measure success (or not) in relation to the awareness of stakeholders before and after information- and/or communication activities is also a challenge for most NCAs.

Unclear roles and responsibilities of the stakeholders are mentioned as another challenge. This includes both lack of awareness of ADR reporting and knowledge of the actual reporting procedures for different stakeholders.

The general time constraints for physicians and other health care professionals is a well-known fact. The challenge in this case is to overcome the barrier and to reach out with the message of the importance of reporting adverse reactions to the national agencies for the ongoing signal detection activities in relation to a relevant material of good quality.

Qualitative responses can be found in Annex 2.

4.10. Mandatory reporting

Summary

Mandatory reporting - HCPs

- 67% of NCAs indicated the effect of mandating reporting was neutral with HCPs
- Where reporting is mandated, doctors, nurses and pharmacists are HCPs required to report. In some countries, dentists are included, and hospital pharmacists are mandated to report.

Mandatory reporting – HCIs

- 60% NCAs indicated the effect of mandating reporting was neutral with healthcare institutions (HCIs).

Overall

- From the qualitative responses it appears that the clinical culture in various countries influences whether there are mandatory reporting requirements (i.e. in some countries it is not within the remit the NCA to regulate clinical decision making).
- One NCA pointed to a reluctance to enforce mandatory reporting as a collaborative approach was preferred.
- Several NCAs reported that there was still under-reporting despite it being mandatory.
- Most NCAs (63%) indicated the effect of mandating reporting was neutral. Why? No formal assessment conducted, no effect on reporting numbers, it is not enforced with HCPs - instead a collaborative approach is taken. Although one NCA indicated positive effect in reporting from hospital institutions
- Two NCAs indicated mandatory reporting had a positive effect in reporting from health facilities.

Those that have not mandatory reporting requirements

- Most NCAs (60%) have considered mandatory reporting and decided against it with HCPs and 40% have not considered mandatory reporting with HCPs.
- For HCIs it is split at 33.3% between having considered mandatory reporting and decided against it, those that have not considered mandatory reporting and NCA that is currently considering mandatory reporting for HCIs.

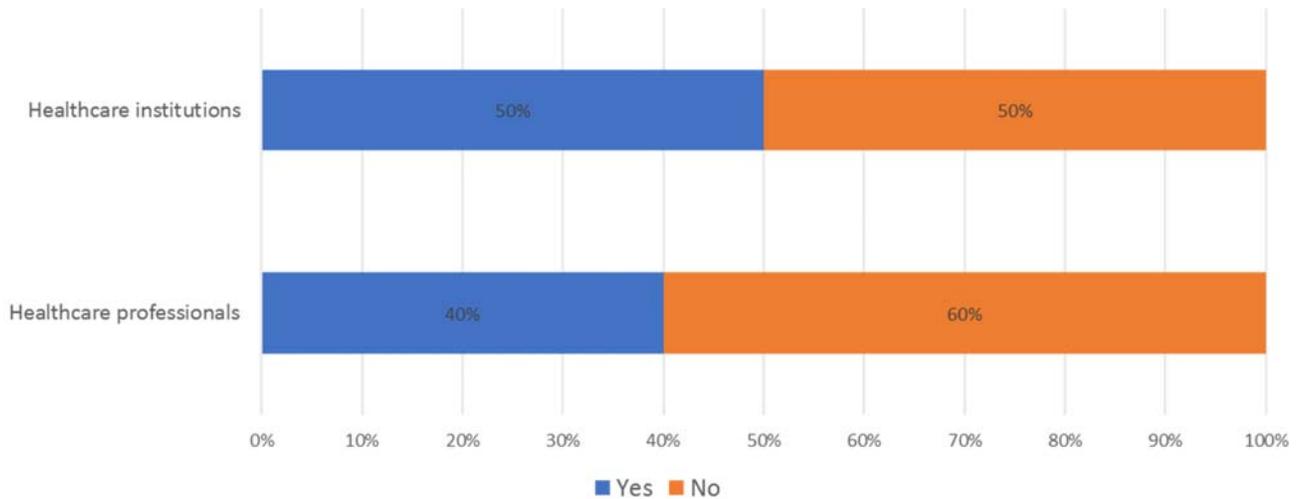
These questions asked when NCAs had mandatory reporting requirements and, if so who they applied to, and what effects these requirements had.

Question 37 asked NCAs if there were mandatory reporting requirements in their jurisdiction for HCPs and healthcare institutions (HCIs). From the responses:

- there was a 50/50 split in responses where HCIs are mandated to report or not. HCIs are mandated to report suspected ADRs in 5 countries: Sweden, Japan, Brazil, Mexico, and China.
- Four NCAs (40%) indicated it was mandatory for HCPs to report suspected ADRs in their countries: Sweden, Japan, Singapore, and Mexico. This can be compared to six NCAs (60%) that indicated it was not mandatory for HCPs to report suspected ADRs in their countries.

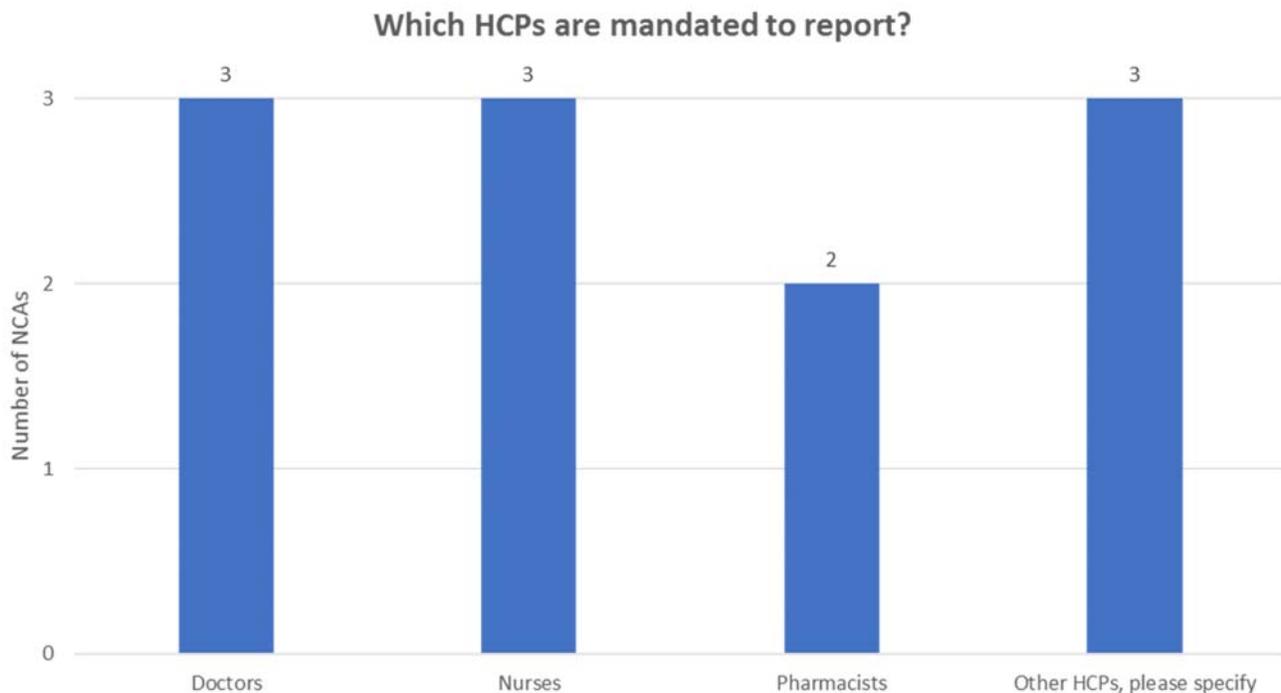
Figure 16 – proportions where ICMRA members have indicated mandatory reporting requirements for HCPs and HCIs

Are there mandatory reporting requirements in your jurisdiction for:



Question 38 then asked which HCPs are mandated to report. Doctors and nurses were the highest responses, followed by pharmacists. Those that selected others HCPs were asked to specify which HCPs and these were: hospital pharmacists (MPA - Sweden), dentists (MPA and MHLW/PMDA - Japan). COFEPRIS indicated that all suppliers of medicines are mandated to report, irrespective of their profession.

Figure 17 – Types of HCPs that NCAs have mandatory reporting requirements



Question 39-41 asked NCAs to provide a brief description of the mandatory reporting requirements for HCPs and HCIs and to describe how it is mandated, enforced and audited.

Qualitative responses can be found in Annex 2. None of the NCAs indicated how mandatory reporting was enforced or audited.

Question 42 asked what effect mandatory reporting has had on reporting. 67% of NCAs indicated the effect of mandating reporting was neutral with HCPs and 60% NCAs indicated the effect of mandating reporting was neutral with HCIs.

Question 43 asked for their reasons for their choices shown in the table below:

NCA	Reasons for responses
MPA - Sweden	No formal assessment has been done.
MHLW/PMDA – Japan	No effect on the numbers of reports.
HSA – Singapore	We do not really enforce mandatory reporting by healthcare professionals, as a more collaborative approach is preferred. Hence, the mandated reporting did not really have an effect on reporting by HCPs.
ANVISA – Brazil	We have noticed an increase in the number of reports from hospitals. (positive experience)
COFEPRIS - Mexico	The report and the analysis of the notifications allow the Ministry of Health, through the National Pharmacovigilance Center (CNFV), to carry out the functions of control and monitoring of the quality of the medicines that are commercialized in the country.
CADRM/CFDA -China	Mandatory reporting improved the knowledge of the medical institution of ADR, but underreporting status is still the same.

Question 44 asked the reasons there are no mandatory reporting requirements. There were eight responses.

- For mandating HCPs to report, the majority of NCAs, 60% considered mandatory reporting and decided against it and 40% have not considered mandatory reporting for HCPs.
- For mandating HCIs to report, one NCA (33.3%) indicated that mandatory reporting was considered and decided against it, one NCA (33.3%) has not considered mandatory reporting and one NCA (33.3%) is currently considering mandatory reporting for HCIs.

4.11. Improving Quality

Summary - Improving Quality

- Six NCAs (60%) measure quality of ADR reports, for example, through the assignment of a completeness score.
- Four NCAs (40%) do not measure the quality of suspected ADR reports received.

- Most common methods used to improve quality of ADR reports is through reporting guidance, developing easier to use reporting forms, educational activities for HCPs pre and post-graduate studies, IT/technical solutions, e-learning and feedback.
- Five (5) NCAs indicated future plans for improving quality and four (4) of them elaborated on methods. Themes included: IT systems (integration and improving webforms), awareness promotion. One NCA indicated a pilot study using Clinical Documents (CliniDoc) methods considering both the completeness of the case in terms of the information provided and the strength of the case in terms of signal management.
- IT solutions and e-reporting (including integration of reporting into clinical systems) and such case studies are important learning areas.

Approaches that worked well

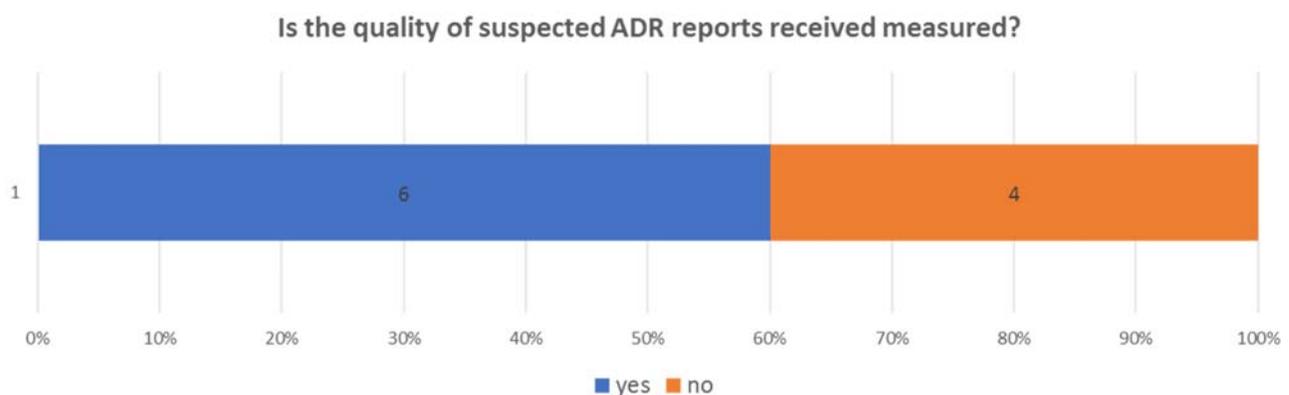
- Increasing electronic methods and acquiring IT solutions for easier reporting.
- Having mandatory fields on reporting forms to ensure sufficient information is provided.
- Increasing HCP training and standardising terminology selections to improve consistency.
- The use of HCP networks, educational activities and e-learning, auditing internal records, updating national standards.

What has not worked well & what NCAs would do differently based on hindsight

- One NCA reported in difficulties to include pharmacovigilance as a subject in some universities.

Question 45 asked respondents Is the quality of ADR reports measured? (for example, through the assignment of a completeness score) It also asked ICMRA members to describe how the quality of an ADR report is measured. 40% NCAs (4) do not measure the quality of reports compared to the 60% (6) that do.

Figure 18 – Yes/No responses indicating if NCAs measure the quality of their suspected ADR reports



Six (6) NCAs responded with their strategy for measuring quality and referenced multiple different methods such as the use of the Uppsala Monitoring Centre's (UMC's) VigiGrade Completeness Score, unique algorithms, automatic quality checks and automated rejection of reports submitted online if they have insufficient information. The UMC is a WHO collaborating centre.

In looking to the future, one NCA reported on plans to test a Clinical Documentation tool (ClinDoc) and their own tool to assess the completeness of the case. Following are the key points from each responding NCA:

MPA – Sweden:

- Automatic quality check built-in for registered reports
- Quality check in relation to the validity of incoming report

MHRA – UK:

- Through assessment and follow up for completeness
- Use of UMC's VigiGrade Completeness scores
- Planning to introduce a study of the quality of reports received using Clinical Documentation tool (ClinDoc) and its own tools developed for the purpose. The purpose is to consider both the completeness of the case in terms of the information provided and the strength of the case in terms of signal management. The study includes a control based on the quality of cases from other clinical systems.

HSA - Singapore

- Use of UMC's VigiGrade Completeness scores

COFEPRIS – Mexico

- Compliance with the maximum degree of quality of the report is encouraged through training
- Rejection of report through the online system if the information is not sufficient

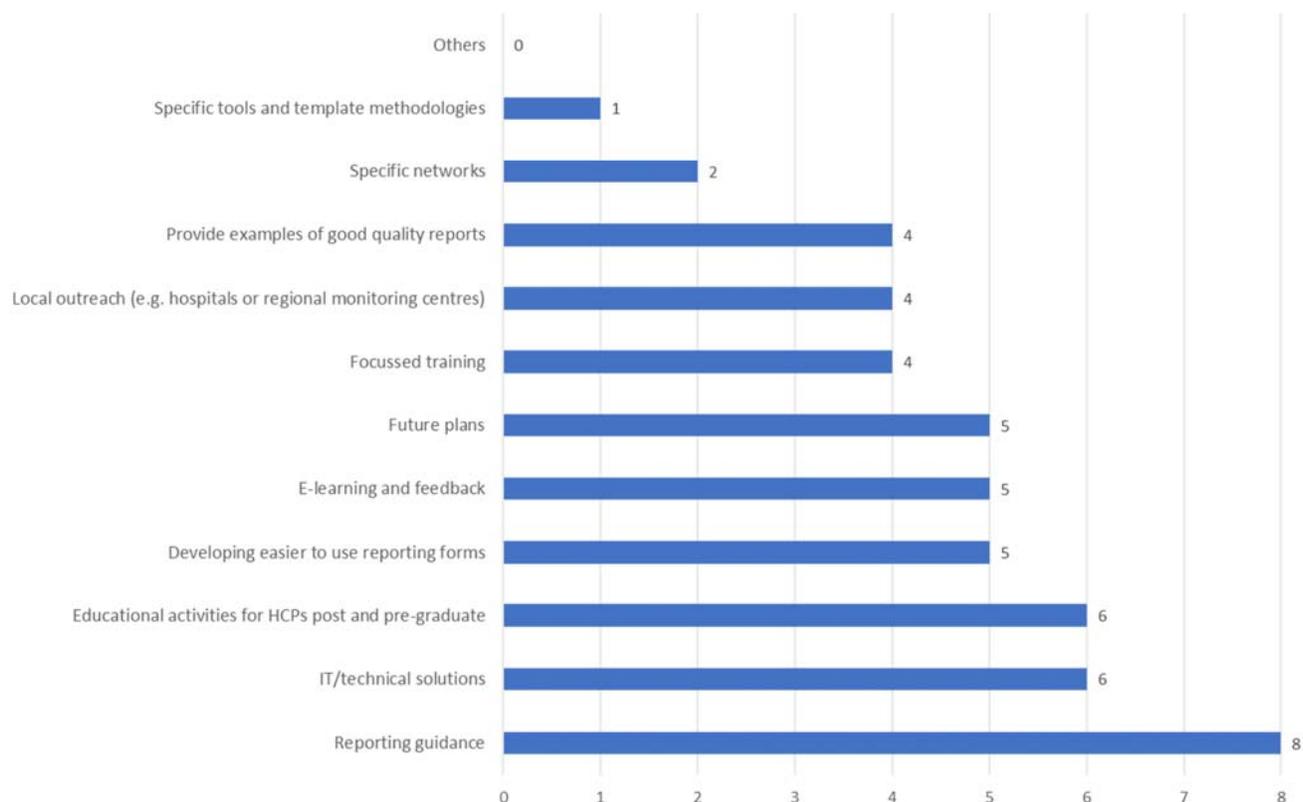
HC - Canada

- Use of algorithm to measure completeness of reports on a scale from 1 to 5 based on the existence of data in certain key fields
- Use of UMC's VigiGrade Completeness scores

Question 46 asked respondents to describe the methods that they use to improve the quality of reports. The following areas were provided for the responses: reporting guidance, IT/Technical Solutions, the development of easier to use reporting forms, educational activities for pre and post-graduate HCPs, e-learning and feedback methods, focused training, the prevalence of specific networks, local outreach projects, examples of high quality reports, specific tools and template methodologies, and future plans for improving quality.

Figure 19 – high level methods used to improve the quality of suspected ADR reports by NCAs

Which methods do you use to improve the quality of reports?



An overview of qualitative responses for this section and areas above can be found in Annex 2. However, the following is a high-level summary of the responses under each area:

Reporting Guidance:

- Providing guidance documents to reporters which describe how to fill out a complete report is the most common method to improve the quality of the reports.
- Some of the guidance specifies the types of reports that are most important, such as report that are serious, medically significant or resulting in harm; reports associated with newer drugs and vaccines and reports for paediatric population.
- The target audience for the guidance is either HCPs, the general public or both.
- Statements about reporting are included in key codes of practice for HCPs and within related supporting guidance e.g. reference materials.

IT/Technical Solutions:

- The main IT/Technical Solutions that NCAs referenced were mandatory fields, drop down fields for medicines and reactions and smart, predictive fields on reporting forms as the reporter types the contents.
- Clinical integration into reporting was a main method indicated by at least two NCAs to improve reporting figures and maintain and improve quality. See facilitation section for more information.
- One NCA provided information on the specific tools and templates they use, which include internal quality audits and audits on reports from industry.
- HSA – Singapore reported on the current production of an informational video to guide reports that will be published online.

Educational activities for pre and post-graduate HCPs

- NCAs typically conduct outreach with both pre and post-graduate HCPs in a meeting or lecture setting. The use of summer university placements schemes was also noted by one NCA.

E-Learning and Feedback

- Six (6) NCAs discussed their use of e-Learning to improve the quality of reports, citing that it reinforces the importance of submitting quality reports to participants.
- One NCA in addition to e-learning modules already described, created a document available on-line and linked digitally through partnership organisations to promote ADR reporting. It highlights the numerous important safety issues that ADR reporting has helped to identify and the value of reporting through case studies, which even aimed also for different reporters e.g. patients, doctors and pharmacists.
- Two NCAs mentioned the role that feedback plays in improving the quality of reports. Methods included feedback through an app, and calling reporters back to ask clarification questions, which foster working relationships.
- One NCA also reported on a regional online training program developed in partnership with regional stakeholders.

Focused training

- One NCA has provided focused training to IT suppliers with a goal to continue to support the integration of the reporting into other clinical systems and improve the quality of the reports.
- One NCA (HC-Canada) reported on workshops with pharmacy students.

Specific Networks

- One NCA, described insight into the use of two networks (Medication Safety Officers and Medical Device Safety Officers) which are based in hospitals in England which includes guests from Wales, Scotland and Northern Ireland for learning. More specifically:
 - These networks are used as forum to discuss potential and recognised safety issues, identifying trends and actions to improve the safe use of medicines and medical devices and encourage safety reporting including ADRs.
 - The value of the network is shown through the identification of many signals of improved patient safety that might not have been captured or reported through usual channels.
 - The networking takes place mainly through monthly webinars as well as an online forum.
 - In addition to the two main networks, smaller networks, discussion groups and online information forum in specific regions, clinical specialities and some health care settings have been created.
 - An annual conference and local meetings are organised by the networks. These networks represent an important new route for HCPs to raise potential safety signals which have resulted in regulatory action for both medicines and medical devices incidents as well as an increase in reporting and the quality of the reports.
 - This network also considers national initiatives e.g. how it can align more with the WHO Global Patient Safety Challenge on Medication Safety launched in March 2017.

Developing easier to use reporting forms

- The main approach cited by NCAs is to refine forms, some of which are developed with non-HCP reporters in mind, using simple language and patient friendly terms.
- The use of question bubbles on their reporting forms to make it easier to report specific elements such as medication errors and ADRs during pregnancy.
- User testing of new form was also noted as a means to enhance the reporting form.
- TGA – Australia will be introducing new forms as part of a new Adverse Events Management Systems.

Local outreach

- Three (3) NCAs acknowledge the role that regional centres play in connecting with and educating HCPs for example through regional workshops.
- Other NCAs discussed the use of educational roadshows and interaction with potential stakeholders through networks or committees.
- One NCA described use of quarterly trending data for the five regional Yellow Card Centres (YCC), which enables the YCCs to focus their strategy and efforts on areas where a drive or campaign is needed locally. The YCCs have developed their own e-learning modules available on their website which have been used further to motivate and educate regional reporters. The YCCs often run their own campaigns based on the interests of local reporters. YCCs are also getting more involved with patient organisations and specific disease areas to promote reporting through campaigns and mini-projects.

Providing examples of good quality reports

- Providing examples of good as well as poor quality reports and case scenarios at workshops was referenced by three (3) NCAs as a successful way to highlight the importance of quality and encourage better reporting.
- One NCA reported on the use of “crib sheets” through campaigns to highlight what to report and the importance of including various fields.
- Roll-out of standard wording in patient information leaflets to report ADRs to raise awareness contributed to significant increase in reporting (measured through “where did you hear about us” in on-line reporting module).

Future plans to improve quality of reports

- The majority of NCAs noted the enhancement of electronic reporting forms and integration into HCP software.
- One NCA reported on the current development of a long-running survey that will provide a “baseline” for awareness of ADR reporting for HCPs and consumers, and its ability to track changes over time in subsequent years.
- As described earlier, one NCA reported on a pilot program of which they will be conducting (ClinDoc), developed by the Netherlands Pharmacovigilance Centre Lareb, to consider how best to evaluate the quality of their cases. They are also developing a feedback mechanism to reporters about their reports that result in a signal and regulatory action, which will be done through a pilot project. They have future plans to produce APIs for reporting which has many applications.

Question 48 asked about the most successful approaches to improving quality. Simplifying reporting processes for HCPs was identified by NCAs as the most successful approaches to improve quality and seamless reporting to help HCPs manage their patients during consultations. Other approaches that were noted included the use of HCP networks, educational activities and e-learning, mandatory fields on forms, auditing internal records, updating national standards and establishing a secure line for sending reports.

Question 49 asked about the least successful approaches to improving quality. The only specific example identified in response to this question was the introduction of pharmacovigilance as a subject in some universities.

Question 50 asked respondents how they have improved the quality of reports through electronic methods, and what methods have been the most and least successful.

- To improve quality through the use of technology, NCAs report mandatory fields on electronic forms ensure the validation and submission are an ideal method.
- One NCA considered mandatory fields to be a potential reporting deterrent as HCPs may find it too challenging to submit a simple ADR report. The importance to distinguish which are the obligatory fields for the sending of the notification vs which are the necessary fields to enable the evaluation of the reports was noted.
- Other methods that were found to improve quality through the use of technology included the use of drop down codes, the creation of a standard format, and the integration of reporting systems to ease reporting processes.

4.12. Feedback

Summary – Feedback

- 9 NCAs (90%) provide some form of feedback to reporters, with the most common approaches being the provision of acknowledgment letters/emails, newsletters, and safety bulletins, speaking opportunities, and websites.
- Social media, background/guidance documents/campaign materials, networking, individualized feedback on risk mitigation or regulatory action taken, reporting information pamphlets and case studies are not commonly used feedback mechanisms.
- 5 NCAs (56%) indicated future plans to strengthen feedback to improve reporting and quality. Moving forward, NCAs cite the desire to expand personalized feedback and increase engagement with reporters by publishing statistics of reports leading to signal detection or regulatory action. NCAs identified the need to share best practices and are looking to ICMRA to provide leadership.

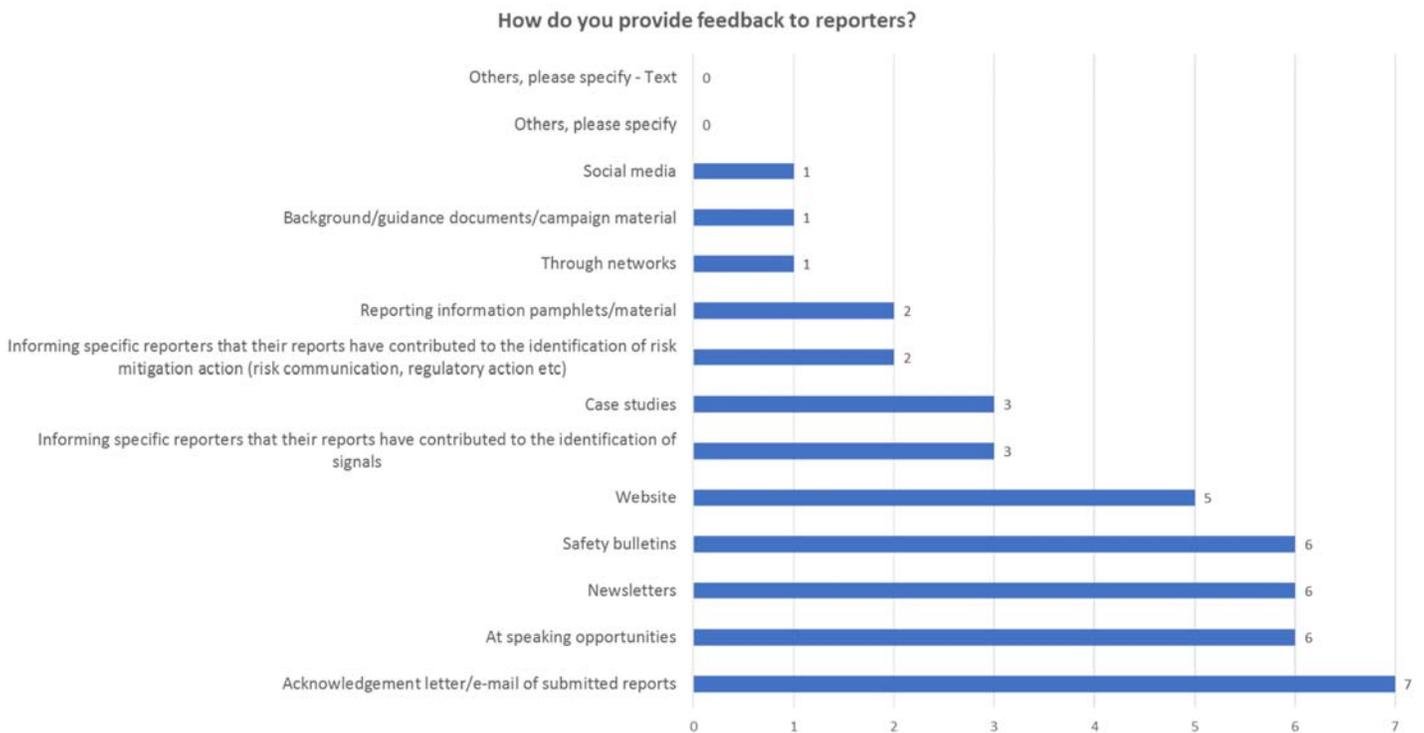
Approaches that worked well

- Feedback must demonstrate the value of reporting
- Direct feedback aimed at informing the reporter of any regulatory action taken
- Connecting with reporters through a variety of mediums including information technology (e.g. apps, iDAP, bulletins), print (pamphlets, acknowledgement letters), and promotion campaigns.
- Leveraging established networks

What has not worked well & what NCAs would do differently based on hindsight

- Posting feedback on a website
- Speaking opportunities
- Providing timely feedback on signal detection in view of regulatory timelines for report assessment

Question 51 asked how NCAs provide feedback to reporters. Of the nine NCAs who responded, all provide some form of feedback to reporters, although they varied in the approach. Common feedback methods include acknowledging the receipt of ADR reports by letter or email, feedback in the form of safety bulletins or newsletters and providing feedback at speaking engagements. This survey also demonstrates the value of the internet for delivering feedback.



Question 52 asked respondents to describe the most successful approaches for providing feedback.

A number of approaches were identified as being successful. A common narrative that unites across NCAs is that feedback must demonstrate the value of reporting because reporters need to know that their efforts are utilized. Many NCAs felt that the most successful forms of feedback were direct and continuous (HSA, COFEPRIS, MHRA and HC).

One NCA (MHRA) reported success in providing feedback through their Interactive Drug Analysis Profiles (iDAPs) on the Yellow Card website which are also available through their reporting app and this also allows another form of feedback of messages on safety for drugs of interest. Each iDAP contains complete ADR data for all spontaneous suspected reactions which have been reported on that particular drug to the MHRA and allows the searcher to interact with the data, so they can understand more about the types of reactions that have been reported, and at a high level about who experienced the ADRs. Another NCA (HSA) suggested the most successful feedback approach would be a process that is more reporter-

centric with direct follow-up, beyond acknowledging a report, to obtain additional information and to inform of any regulatory action taken.

Other feedback tools identified include using case presentations of specific ADRs in promotion, disseminating safety information to the public via information pamphlets, acknowledgement letters, and promotion campaigns, and providing a unique code to the reporter for subsequent follow-up in addition to a copy of the reporting form. Members are also making use of technology (e.g. apps) and leveraging established networks (e.g., healthcare professionals) to enhance the provision of feedback.

Question 53 asked respondents to describe the least successful approaches for providing feedback.

Of the five NCAs who responded to this question, only 3 provided specific examples of unsuccessful approaches. Respondents indicated that feedback should be conveyed to reporters in a timely and direct manner to reinforce the reporting itself. Providing timely feedback on signal detection work has been a challenge due to the lengthy timeframe for report evaluation and posting feedback on a website is not ideal as uptake of information may be low due to a general lack of awareness on the part of the reporter of the availability of published information. Another NCA indicated speaking engagements are not preferable due to minimal opportunities to provide specific feedback to reporters.

Question 54 asked respondents to describe future plans to strengthen feedback to improve reporting and quality.

Respondents are interested in strengthening feedback to improve reporting and quality. Direct and personalised feedback is a unifying theme. Beyond acknowledging a report, NCAs plan to expand individual feedback and increase engagement with reporters by providing information about suspected signals detected, contribution of reports to risk mitigation and regulatory actions taken. Some NCAs are looking at publishing reporting statistics and quality information periodically. NCAs identified the need to learn more about best practices among members and are looking to ICMRA to provide leadership.

Qualitative responses for this section can be found in Annex 2.

4.13. Facilitation

Summary

Facilitation

- A common theme was that NCAs were moving towards implementing a variety of IT solutions. & e-reporting a key theme through: webforms, apps, integration with clinical systems. Also mention of pre-paid paper forms, telephone lines, online form guides the user to complete important fields and uses drop downs to standardize the data.
- Six NCAs said they had implemented e-reporting to support the increasing numbers of suspected ADR reports.
- Common solutions described by NCAs included developing and/or simplifying e-forms, integrated reporting embedded within health professional software, adoption of international standards and terminology, and developing mobile apps.

Most and least successful methods

- Most successful: Integration, the standardisation of the reporting format with international instances such as ICH E2B, and the implementation of MedDRA terminology.
- Least successful: pre-paid postage in one country but operates successfully in another despite a trend toward encouraging more e-reporting

Future plans for e-reporting by NCAs

- Electronic Health Records and clinical software integration Application programming interfaces (APIs), E2B R3 or similar information standards for providers, Optical Character Recognition technology at case intake to automatically enter typed text on submitted AR reports, completable PDF forms that produce E2B compliant xml output for automated data entry.

Question 55 asked what solutions have you implemented to improve the ease of reporting? Which are the most and least successful and why? Nine NCA's (90%) answered this section.

Qualitative responses can be found in Annex 2.

Question 56 asked what process improvements or IT solutions has your organisation taken to support the increasing number of suspected ADR reports and to describe them. Six NCAs said they had implemented e-reporting to support the increasing numbers of suspected ADR reports. Below are a high level summary of these responses.

What worked well?

MPA - Sweden

- E-forms for HCPs and consumers.
- A pilot is planned during 2018 to have direct electronic reporting of ADRs from the HCP's medical record system.

MHRA - UK

- Making as many methods available to report as possible, ensuring forms are widely accessible with relevant information at the right places.
- For paper forms, all have a freepost address on the back. The HCP forms are designed so they can be folded and sealed, and the patient form has a detachable pre-paid envelope that the form can be inserted into. Both types have the address pre-printed on the front side of the envelope. Forms can be downloaded too or sent out. There is a dedicated telephone line for reporting.
- Electronic methods - webform, app, integration into clinical systems are the most successful and popular methods of reporting.
- UK provided an overview of electronic reporting to its Yellow Card Scheme, including:
 - The Yellow Card electronic reporting information standard is based around the ICH E2B(R2) standard. IT suppliers can use this to integrate reporting into clinical systems.
 - The system is for use mainly by primary care systems and has built in triggers to prompt the completion of an electronic Yellow Card.
 - The standard can also be used by pharmacy electronic prescription service systems, patient medical records systems and secondary risk management systems.
 - The use of E2B fields via XML with validations enables high quality reports to come into their database from Electronic Health Records/clinical systems.

- The benefits of reporting directly from clinical systems include improving access to the Yellow Card reporting system; reducing efforts required to complete the form through automatic population of information from the patient record; prompting of HCPs to complete a Yellow Card in specific circumstances (e.g., withdrawing of medication, death of a patient).
- An application (app) which uses similar E2B fields offers several key features for users, including easy submission of side effects directly to the Yellow Card Scheme; an immediate response to confirm receipt of report; mechanism to submit updates on their report; ability to view previous reports that they submitted, view number of reports received by MHRA for medicines of interest and to create a watch list of medications to receive official news and alerts.
- The smart drop-down options are based on existing dictionaries for suspected drugs and MedDRA Lower Level Terms for ADRs which are auto populated as the user types. It also has the option to add free text. Patient friendly MedDRA terms have also been implemented.

HSA – Singapore

- In 2006, HSA implemented the Critical Medication Information Store (CMIS), a national electronic platform in all public healthcare institutions in Singapore. CMIS allows HCPs to record, access ADRs in the patients' medical records online and submit these reports directly to HSA.
- The CMIS allows HCPs to enter allergies and ADRs into the hospital electronic medical records system during routine clinical management of each patient. This information flows seamlessly to HSA on a daily basis, removing the need for HCPs to submit a separate report. There are two forms: the Quick Report which contains fewer fields and can be completed quickly, and the Full Report which allows more information to be entered.
- Since the implementation of CMIS, the number of reports received has increased from around 1,000 per year to 20,000 per year. While the quantity has increased, the types of ADRs reported via CMIS typically lean towards allergies (e.g. angioedema, rash), and often contain limited information.
- Each CMIS report is reviewed by two officers before they are accepted into the ADR database. To streamline the review process, the system has been designed to (1) filter away ADR reports which are invalid (e.g. reports of drug classes, non-drugs or unknown drugs/reaction), (2) automatically code commonly reported ADRs, and (3) highlight possible duplicate reports

NZ – Medsafe

- Web forms.
- iPhone app.
- GP software reporting.

ANVISA - Brazil

- IT solutions to simplify the reporting form and make reporting easier.

TGA - Australia

- Reworking online forms.
- Working towards integrating AE reporting in clinical software.

COFEPRIS - Mexico

- Standardization of the reporting format with international instances such as ICH E2B.
- Implementation of MedDRA terminology.

HC - Canada

- Health Canada offers multiple methods of reporting, including an online form, enterable PDF, postage paid form, etc.
- The most successful method is the online reporting form (<https://hpr-rps.hres.ca/static/content/form-formule.php>).
- Collaboration with the provincial patient safety database to leverage existing patient safety reporting mechanisms to optimise the transfer of information.

What was less successful?

Health Canada

- The least successful is the postage paid form as it is not a straightforward process. This method is being discontinued.

Question 57 asked what your future plans for electronic reporting are and to describe them. Eight NCAs said what these were:

- electronic Health Records and clinical software integration (MPA, MHRA, CADRM/CFDA) or continuing this work (MHRA)
- Application Programming Interfaces (APIs) (MHRA)
- E2B R3 or similar information standards for providers (HSA/ANVISA)
- mobile apps (ANVISA/TGA) or further developing their existing app to report (MHRA)
- Optical Character Recognition technology at case intake to automatically enter typed text on submitted AR reports (HC)
- web-based reporting for HCPs and members of the public (HC)
- completable PDF forms that produce E2B compliant xml output for automated data entry (HC)

4.14. Training for ICMRA members

Summary

Training for ICMRA members

- All respondents welcomed some form of training on improving quality and increasing quantity of ADR reporting
- There is a high demand for training – all 10 NCAs (100%) indicated expression of interest in some form of training on improving quality and increasing quantity of ADR reporting.
- Highest preference areas for training indicated at 90% each were:
 - Promotion - developing and maintaining promotion and communication strategies, general awareness raising on the importance of pharmacovigilance for public health protection, running a communication campaign
 - Facilitation – making reporting accessible, maximising the use of IT

- Education – raise understanding about the purpose and value of reporting with HCPs and members of the public
- Improving the quality of suspected ADR reports

Question 58 asked if NCAs need training on improving quality and increasing quantity of ADR reporting? All ten NCAs (100%) indicating the need for such training.

Question 59 asked which areas NCAs wanted training on.

Figure 20 – Areas indicated by NCAs that they would like training on



Question 60 asked what methods of training would be preferred by NCAs.

Figure 21 – training method preferences

Methods of training welcomed



While face-to-face training would be the gold standard, webinars (an online meeting, web conferencing and videoconferencing application) would be a more realistic and achievable method of delivering training. It is important to note that time zone differences make webinars a challenge to schedule.

A report with case studies is delivered through this survey report and annex 2.

4.15. Social Media Campaign

Summary - ADR Promotion in Social Media

- Six NCAs (60%) indicated interest in participating in a coordinated social media campaign in 2018/19 with ICMRA members, EU and UMC.
- Three NCAs (30%) were not interested in participating in a joint social media campaign, and 1 did not respond. The main issues cited were: the messaging of the campaign- wanting messages to encourage patients to see their HCPs to report rather than patients reporting directly to the NCA. The other barriers were network code, language, and human resources.

Approaches that worked well

- **MPA:** Animated film shared on social media that received positive feedback from consumers.
- **TGA:** Online advertising campaign to promote CPD modules for HCPs that resulted in a higher completion rate during the trial period.
- **MHRA:** Used animations, info graphs and videos that promoted the Yellow Card Scheme and increased ADR reporting on social media platforms like Twitter, Facebook, YouTube, and Forums. Promoted an increase in ADR awareness and

reporting as an increase to medicine safety and public health. The November 2017 campaign reached 2.3 million people and saw a 16% increase in ADR reports, which followed the award-winning November 2016 campaign. Social media was also used to connect with GP's through interactive case studies regarding the Yellow Card Scheme, where 1 817 doctors were reached on two forums.

What has not worked well & what NCAs would do differently based on hindsight

- Small-scale short term online advertising campaigns were found to work well during short trial periods, but lasting and resonating effects were not recorded.

Although no highlighted questions asked exclusively about the previous use of a social media campaign in the survey, all qualitative data was derived from social media information that was given as an answer to other questions.

Question 79 asked respondents whether they would be interested in a coordinated campaign in 2018/2019 with ICMRA members, EU, and UMC to raise awareness on the importance of reporting suspected side effects.

6 NCAs displayed interest in the joint campaign- MPA, MHRA, TGA, COFEPRIS, HC and Medsafe.

MHLW/PMDA, HSA, and CADRM/CFDA were not interested in the joint campaign, citing issues with human resources, network connections, language and the content of the campaign being inconsistent with the messaging of the NCA.

Social Media Strategy

- COFEPRIS and ANVISA both mentioned social media use.
- MPA discussed the promotional video that they shared on social media.
- TGA discussed their limited advertising strategy to promote online modules to HCPs that spanned over 6 weeks in 2016.
- MHRA referenced multiple campaigns that they ran from 2013-2017, to bring awareness to the Yellow Card Scheme. These initiatives targeted both HCPs with communications and interactive case studies as well as consumers/parents with communications posted on multiple different social media platforms (Twitter, Facebook, YouTube, and Parent Forums). Social media has been a core component of awareness campaigns and general communications.
- Four NCAs gave no feedback regarding social media strategy. Multiple NCAs that don't currently have a social media strategy displayed an interest in a joint project in the future, and the NCAs that did not were open to an increased use of technology and/or the internet.

SCOPE Campaign and annual ADR awareness campaign

- 2 NCAs (MHRA and MPA) were part of the EU-wide SCOPE project to raise awareness of adverse reactions. These initiatives targeted HCPs with interactive case studies, and communication were posted on multiple different social media platforms (Twitter, Facebook, YouTube, and Forums), that targeted both consumers and HCPs.
- The first social media campaign, run in November 2016, was deemed very successful.
- In November 2017, the second campaign was launched, which maintained that reporting suspected side effects helped to make medications safer and protected public health. This campaign reached 2.3 million people, and a 16% increase in ADR reports was

observed by MHRA. The campaign also was run with UMC and so reached 27 countries, with 8 countries participating from outside of EU e.g. Medsafe.

Figure 22 – an example of a static version of an animated infographic that was developed by the MHRA for social media campaigns to raise awareness of suspected ADR reporting. This was tailored for other countries.



TGA indicated it would welcome involvement in a social media campaign but notes that each NCA will need the ability to tailor the message to local circumstances. For example, in Australia Product Information and Consumer Medicine Information are not included inside medicine packaging, unlike some other jurisdictions, and any materials produced would need to be able to be tailored appropriately. It is suggested that one NCA could coordinate creation of template materials containing ‘high-level’ adverse event reporting messages and build in the ability for other NCAs to slot in localised messaging. This concept is exactly what MHRA did for the first social media awareness week in EU in November 2016, followed by a jointly led second campaign with UMC and MHRA in November 2017.

5. Recommendations

Based on the results from 37% (11) of ICMRA members that participated in this survey, the following suggestions are highlighted for consideration for ICMRA and its members as future work in this area: Future work suggestions for ICMRA and its membership:

- Adopt similar wording to EU legislation for ICMRA members to strengthen their commitment to increasing ADR reporting. This is outlined below:

Article 102 of Directive 2010/84/EU amending Directive 2001/83/EC: *‘The Member States shall:… take all appropriate measures to encourage patients, doctors, pharmacists and other healthcare professionals to report suspected adverse reactions to the national competent authority; for these tasks, organisations representing consumers, patients and healthcare professionals may be involved as appropriate;’*

- Deliver training in the form of webinars for as many aspects of the areas in section 4. This can include:
 - Experiences of different NCAs in increasing ADR reporting and improving quality
 - Presentation of a common strategy adding to existing work in this area
 - Promotion - developing and maintaining promotion and communication strategies, general awareness raising on the importance of pharmacovigilance for public health protection, benchmarking, working with stakeholders, running a communication campaign and measuring effectiveness.
 - Facilitation – making reporting accessible, maximising the use of IT, integrating reporting into clinical systems
 - Education – raising understanding about the purpose and value of reporting with undergraduates, HCPs and members of the public, including tactics, e-learning tools, information for education for HCPs, useful information and signposting NCAs to educational resources to improve quality and general PV
 - Improving the quality of suspected ADR reports through methodologies, tools and NCA experiences.
- Establish an ICMRA group to develop communications messages to raise awareness through campaigns. This could involve work sharing to build capacity.
- Encourage participation in an annual social media awareness campaign to raise awareness about suspected ADR reporting which usually takes place in November.
- Site/exchange visits to optimise face to face learning an international collaboration - visits can be self-funded between interested NCAs.
 - ICMRA supported secondments or site visits to share and learn from each other to build capacity through an exchange program or site visits which would be facilitated by IAER subproject. Any visits would be self-funding by mutually participating and willing NCAs upon request.
- Exploring the impact of IAER, including the handling of signal detection methodologies and their outcomes for quality.

6. Annex 1

Survey questions:



Questions - ICMRA
IAER survey.xlsx

7. Annex 2 – Qualitative responses from NCAs

Qualitative responses from survey provided by NCAs for most questions are provided below:

Benchmarking and awareness levels - Q12 – Please provide an overview of formal assessment and results, including breakdown of awareness levels by reporter qualifications if applicable, including sample sizes and published results. What did you do with this data?

MHLW/PMDA - Japan

A survey was conducted on 45,007 pharmacists who are members of the Japanese Society of Hospital Pharmacists. Of 3,845 valid respondents, the overall percentage of pharmacists who did not understand the ADR reporting system and the percentage of pharmacists who did not have experience of submitting reports from their institutions was 23.1% and 57.6%, respectively.

MHRA - UK

Conducted for the entire MHRA, four large omnibus surveys were commissioned by three different independent professional research companies. The large polls were carried out with a range of NCA stakeholders between 2006 and 2010 and these are outlined below. Each are referenced at an archived URL link:

<http://webarchive.nationalarchives.gov.uk/20150121113625/http://www.mhra.gov.uk/Publications/Corporate/Research/index.htm>; accessed on 27 Feb 2018.

and are examples of what was thought good practice in measuring baseline awareness levels for patient and HCPs in the SCOPE project. The four polls are outlined below.

1. In 2006, the perceptions, communication and regulation of the risks and benefits of medicines and medical devices was conducted by Ipsos MORI. It showed the perceptions of the general public and of HCPs.

2. Research conducted by two organisations: Opinion Leader (for off-line engagement) and Delib (for on-line engagement) to confirm the desirability of providing regulatory information about medicines online to HCPs and patients. It was also used as an opportunity to explore and gain an understanding of:

- Where patients and HCPs expect to find information
- How they might want to search the data
- The functionality required by the Agency system
- The impact of making this information available.

A survey in 2009 followed on from the 2006 Ipsos MORI baseline survey commissioned by the MHRA to discern and quantify the perceptions of the general public about the risks and benefits associated with medicines, and of how well they are regulated in the UK. The 2009 survey was intended as the first measurement to indicate the direction of travel in public opinion in these areas. Core objectives of the survey were to explore:

- Perceptions of risks, benefits and safety associated with medicines
- Experiences of medicines

- Knowledge of and attitudes towards regulation
 - Attitudes towards the communication of information about medicines
3. Another omnibus survey was undertaken by Ipsos MORI in 2008, set out to discover:
- What pharmacists believe they currently get from MHRA by way of communications and what they think of them
 - What information they want from MHRA
 - How they want this information, taking account of all available channels and sources of communication
 - How often, if at all, they want these various forms of communication.

Some of the results from the surveys above that have helped shaped ADR related awareness raising work included:

Pharmacists are the most likely to spontaneously cite MHRA as the organisation that regulates medicines (52%), followed by one in five GPs (21%) and fewer physicians and surgeons (11% and 8% respectively). For GPs, MHRA is the joint second most commonly mentioned organisation after Committee of Safety of Medicines (CSM)/Commission on Human Medicines (CHM). Subsequent messages, where possible, in campaigns now include that the MHRA runs the Yellow Card Scheme and what the MHRA does, including that the Scheme is run on behalf of the CHM.

Pharmacists would be most likely to turn to the MHRA if they wished to report an ADR (22%), compared to fewer GPs (7%) and hospital physicians (5%). No nurse mentioned MHRA in this regard. Nurses differ more generally in their choice of organisations to report adverse drug reactions to. Bearing this result in mind, it was another driver to develop an e-learning module and also attend conferences aimed at encouraging nurses to report and to identify with the MHRA.

The Yellow Card Scheme is a service provided by MHRA and so it was considered important to look at proportions of HCPs that mention both Yellow Card and or MHRA in the same context. Among GPs, 85% cite the MHRA and/or Yellow Card and this proportion reduces to 84% among pharmacists, 59% among hospital physicians and 26% among nurses. This has helped reiterate messages in promotional articles through their respective professional bodies.

Pharmacists and GPs are most likely to have heard of MHRA, (after prompting) which goes some way to explain why they are most likely to mention MHRA as a regulator, and as the organisation to which they would report an adverse incident with a drug (92% and 62% respectively of Pharmacists and GPs have heard of MHRA after prompting). In contrast, only around 4 in 10 of each of hospital physicians, nurses and surgeons have heard of the MHRA. These results gave an impetus to the drivers on collaborative work with NHS organisations to form networks in future and for ensuing communications activity such as the specific tailored campaigns that were devised for GPs and pharmacists. Over 8 in 10 GPs and pharmacists say they would notify the MHRA or use its Yellow Card Scheme to report an adverse reaction to a medicine but only 6 in 10 hospital physicians and a quarter of nurses would do that. E-learning modules for HCPs developed by the MHRA through collaboration with other organisations have tried to also strengthen and clarify such

messages to raise awareness. MHRA were also able to organise stands at various conferences to raise the Agency's profile using these results as part drivers.

Through a public Ipsos MORI Omnibus poll, 915 people were interviewed using a questionnaire focusing on medicines. Interviews were carried out face-to-face, in respondents' homes, with the aid of Computer Assisted Personal Interviewing (CAPI) terminals (laptops). Fieldwork was conducted between 16 and 21 March 2006. When asked who or which organisation they think regulates medicines to make sure they work and are safe enough to use, around half (49%) say they don't know. In a later poll, 2009, the large majority say they would report an unexpected side-effect of a medicine to their doctor or GP, aside from that, few individuals or organisations are mentioned by any significant number of people. The proportion who would report it to the MHRA remained the same as it was in 2006 at 1% as does those who would fill in a Yellow Card (less than 1%). For this reason, messages to patients now always introduce the MHRA and what the Yellow Card does. It is also the reason for campaigns to promote patient reporting being targeted via GPs and pharmacists, and why the Yellow Card is signposted and explained on trusted webpages referred to by patients.

In 2011, the independent review which formally evaluated patient reporting of ADRs outlines questions that can be adapted for use to gain further insight for patient benchmarking, their experiences and tailoring messages for future campaigns (http://aura.abdn.ac.uk/bitstream/2164/2957/1/mon1520_YCS.pdf - see Appendix of the Health Technology Assessment report 16 to 22). For example, from patients interviewed, almost one-half learned about the Yellow Card Scheme from a pharmacy (n = 667; 49.0%) - this result reinforced the strategy of reaching patients via tailored campaigns with community pharmacists.

Parents were surveyed by a third-party organisation called YouGov before and after the paediatric campaign in November 2013 and May 2014. Results showed that between 14% and 17% parents have heard about the Yellow Card Scheme. The omnibus survey results helped to inform the effective measurement of the communication campaign. It also made it possible to target specific reporter groups with considered and tailored messages for respective key audiences and enable the measurement of any change in behaviours. It has also led to an impetus to strengthen undergraduate and post-graduate reporting. It is one of the factors behind developing e-learning modules for HCPs which also count for CPD credits.

In 2018/19 MHRA plans are underway to run a sustainable and long term Yellow Card campaign based on user research and engagement and benchmarking in this way will help shape future campaigns.

Strategy - Q14 - What approaches worked well from your strategy to increase reporting and improve quality?

MPA - Sweden

To raise awareness of the reporting system and to increase the quality in the reports:

- Education of HCPs via Regional Centres
- Education material related to ADR reporting available on the web site

- Newsletters to HCPs
- Newsletters to pharmacies
- Periodical publication with safety information
- Presentations at conferences and congresses
- Patient and Consumer Working Party meetings at the MPA

EMA

Systematic quality checks on samples and feedback to stakeholders. Regular interactions with stakeholders

MHRA - UK

The MHRA has a documented strategy called the Yellow Card Strategy. It has evolved with periodic review and updated versions to strengthen direct suspected ADR reporting over the years. The key objective of the Yellow Card Strategy which was developed after independent review in 2006, remains the same: to strengthen the reporting of suspected ADRs by increasing both the number and quality of reports. It has adapted to changes in 2012 EU PV legislation and some of the major activities from the strategy are incorporated within the corporate business plans as objectives. Analysis of reporting trends helps identify various areas to focus on.

Following an independent review of the Yellow Card Scheme, the MHRA developed its Yellow Card Strategy after a period of detailed analysis specific to each of the direct reporting groups of the Yellow Card Scheme over 5 years. The report highlighted key issues of concern:

- A 50% reduction in reporting by GPs during that period
- Relatively low levels of reporting by community pharmacists
- Disappointing uptake of reporting by electronic mechanisms
- An increasing trend of reports via the pharmaceutical industry rather than being provided directly to the NCA on Yellow Cards.

Together with the decline in reporting by patients and nurses during 2006, all the above issues were regarded as priorities to be addressed by a specific strategy to strengthen the Yellow Card Scheme. The resulting strategy was developed in consultation with a new Expert Advisory Group specifically set up to review and provide advice on the newly formulated strategy.

The strategy recommended four key specific areas to incorporate a number of strands of work so that it could be adapted to the needs of particular reporter groups. These are summarised and commonly referred to as the 4 pillars or elements that make up the UKs Yellow Card strategy:

- Education - raising understanding about the purpose, value and importance of Yellow Card reporting, embedding the Yellow Card Scheme and pharmacovigilance into health professional education programmes, to make reporting of suspected ADRs a more visible aspect of the responsibilities of healthcare professionals.
- Promotion - develop and maintain promotion and communication strategies and campaigns for the scheme

- Facilitation - making reporting easy and accessible to meet the needs of reporters e.g. electronic reporting
- Motivation - making reporters more likely to report through approaches to incentivise reporting through acknowledgment and feedback

The key objective of the strategy was to strengthen the reporting of suspected ADRs both then and into the future. This was envisaged through sustainable improvements in reporting to the Yellow Card Scheme by both HCPs and patients, in line with reporting guidelines and through collaborations with their related organisations.

The general aim of strengthening reporting by all groups was also refined with more specific objectives focussing on particular areas where improvements were sought, namely to:

- halt and then reverse the decline in reporting by GPs
- strengthen reporting by community pharmacists
- halt and then reverse the recent decline in nurse reporting
- further develop patient reporting and awareness
- increase electronic reporting

To make progress on these objectives, efforts were made so that reporters receive appropriate education about the Scheme; to ensure potential reporters have an appropriate baseline level of understanding of the Scheme, as well as to promote the Scheme, to ensure that reporters remain alert to potential ADRs and the need to report them.

However, the work was envisaged to be underpinned by efforts to increase accessibility of reporting, in particular through electronic Yellow Card reporting. This thereby supported the aim of strengthening the Scheme in its then current state for the short to medium term, as well as moving away from the traditional paper-based reporting system in favour of electronic capture and collection of reports for the medium to long term period.

The Yellow Card strategy subsequently informed the HMA strategy which was then adopted in principle as levers to improve reporting rates, and further informed the SCOPE strategy - which has added Collaborations and Partnerships to the strategic mix.

Progress on these strategy objectives is reviewed periodically, at least annually. This involves conducting ADR trend analyses to establish whether reporters are continuing to follow the guidelines on reporting and to monitor changes in the number of suspected ADR reports received by the MHRA from various subsets of direct reporters. It also considers the environment of reporting and stakeholders involved to evaluate where to focus future activity. The aim of this is to evaluate objectives, for any findings to help review and inform the shape of future strategy and review associated resources to improve reporting.

Initially the strategy mainly focused on a patient reporting campaign launched through community pharmacy and GPs, alongside attending national conferences. However, over time, the Yellow Card Strategy has progressed and changed to refocus its objectives and activities. This evolution has a greater emphasis on facilitation and electronic reporting, especially within the GP sector. Continuously improving the webform making it easier to report has also helped, such as smart look up fields for drugs and reactions, help buttons, guides to report, smart fields for reporting in certain situations, as well as using technology such as the app has worked well. The app allows feedback on news for medicines of interest, including access to online interactive drug analysis profiles and being able to report

on the go. Motivation activities are concentrated on greater collaborative work with HCP and patient organisations and setting up national networks to encourage HCPs to report locally and provides a feedback loop. This involves education and joint working with other national organisations. Another aspect includes sustainable approaches through the establishment of quality indicators for reporting suspected ADRs for HCPs - the aim of this being a measure of good patient safety practice. Educational aspects have shifted towards e-learning and showing the value and importance of reporting through case studies, clinical scenarios and incident reviews. The promotional elements have also shifted from the traditional form and poster distributions to reporters and where they can access them readily to more use social media and low or no cost forms of raising awareness. This is mainly due to government marketing restrictions and expenditure. Forms are now distributed through partner organisations such as pharmacy bodies, regional centres and upon request.

Electronic integration into clinical systems - making it easier to report with triggers and guidelines shown proven reversal in the decline of reporting. It also improves quality due to validations which are the same on the webform. Smart forms and continuously improving webforms to better capture data electronically improves the quality, reduces burden on staff and helps make it easier for HCPs and patients to report. Moving towards patient friendly reaction terms (e.g. from 200 MedDRA terms for rash to just 15) has also been recently introduced.

Education has played a key role, use of our 5 regional monitoring centres, codes of practice for HCPs supported by HCP organisations, quality indicators, e-learning modules, prescribing courses, guidelines on what to report.

Adding information about ADRs and where to report them in the SmPC and the patient information leaflet have also helped alongside having the right information accessible online in trusted sources and publications.

Creating the Yellow Card brand makes it easier to promote rather than the spontaneous suspected Adverse drug reaction reporting system for the UK.

Over the last five years, reporting increased by 43% (13,253 reports). This increase corresponds to the increase in direct reports, 77% (12,873 reports), received from healthcare professionals and members of the public (including patients, parents and carers) as a result of many planned strategic efforts and campaigns to improve the quantity and quality of reports.

[HSA - Singapore](#)

HSA has conducted roadshows/campaigns in the various hospitals to the HCPs to encourage and explain the rationale of ADR reporting, citing numerous case studies where reporting has resulted in good regulatory outcome. In addition, to improve the quality of reports, HCPs will also be educated on the various fields to fill in when submitting an ADR report.

Another approach would be via our HSA ADR bulletin that is sent to all HCPs on safety issues where they are encouraged to report. We have used our bulletin to educate our HCPs and generate interest in AE reporting. For instance, we have an article published periodically called AE-in-Focus where we educate HCPs on interesting clinical cases involving AEs and drugs. We also publish an annual summary of the AE reports we received from AE reporters

so that they realise the impact of their reports.

ADR forms with instructions on how to fill them are also readily available online on our HSA website, with educational documents of AE of interest (eg. anaphylaxis, cutaneous drug reactions) to assist HCPs in reporting these AEs. Brochures are also developed as collaterals during roadshows to educate HCPs on reporting of ADRs

COFEPRIS – Mexico

The legal framework has been updated, dissemination workshops are given in universities, hospitals, and the pharmaceutical industry. Informative material such brochures is also prepared.

HC – Canada

Lectures to HCP students. The ADR reporting education module is designed to provide HCP students with specific knowledge of the ADR reporting process in Canada by promoting familiarity with the Canada Vigilance Program, as well as demonstrate appropriate use of the adverse drug reaction reporting form. It is likely that, through contact early in their academic careers, these future health professionals will continue to engage in professional activities, such as ADR reporting, once they start practicing.

A review of the current training for HCP students on ADR reporting demonstrated the need for vertical integration of ADR reporting into the health professional curriculum at universities and colleges. **The goal is to design a curriculum that, as a continuum over the years of study, allows students to build on practical knowledge gained in each previous year enabling them to learn how to integrate ADR reporting into their workflow.**

In order to reinforce the information delivered through the undergraduate curriculum, Health Canada targets students along different points of their learning career by engaging continuing professional development programs to create modules to support practicing HCPs maintain the skills and knowledge to report ADRs.

CADRM/CFDA – China

Good propaganda and training

Strategy - Q15 - What do you feel has not worked so well and what would you do differently next time?

MPA - Sweden

- Lack of time for the HCPs to prioritize ADR reporting and related education
- Difficulty in reaching with information to all concerned parties
- Difficulty in not being able to report directly from the medical journal system
- Lack of knowledge about the importance of reporting ADRs

MHRA - UK

This is a continuous process, not just one activity or one hit wonder.

[See paragraph above about evolution of the strategy and shifting of activities.](#)

It would be good to focus on quality, more media work, more publications, unfortunately it is resource dependent. Although such messages on quality, are often coupled with specific campaign messages, articles or when lectures/workshops are given to HCPs.

It has been hard to get patients into case studies to show the value of reporting on media e.g. TV.

We haven't focused on targeted campaigns to improve quality yet or with a real focus on reporting requirements, more development of feedback on reports would be good and signals. We are working on this area. ICMRA feedback is welcomed.

HSA - Singapore

We recognise the importance of engaging HCPs with relevant and concise information for ADR reporting and have been exploring the use of technology in our HCP engagement sessions, for example, the use of animated video to educate on established reporting steps, and use of e-voting interactive tool to foster 2-way communication

CADRM/CFDA – China

To expand the channels and content of training.

Campaigns and materials - Q23 - Please describe the most successful campaigns or activities, including the audiences, duration, methods, stakeholders, or partnerships formed, any challenges, what worked well, what didn't work well and why. Please include any relevant results. Please email any campaign materials, reports or relevant URLs to mitul.jadeja@mhra.gov.uk.

Only campaign materials from one NCA (MHRA) were shared despite 61 campaigns that were indicated took place.

MPA - Sweden

We think that the collaboration with dedicated and educated personnel at hospitals in relation to ADR reporting is the most successful way to approach important reporters.

We have had good feedback from consumers watching the animated films showed in social media, waiting rooms and similar environment.

We have also had good feedback from the educational sites for HCPs regarding the e-learning material available on the MPA's website.

We believe that the regional centres education of HCPs is fruitful due to the fact that their close presence to the regional sites are facilitating the ADR reporting.

The yearly pharmacovigilance day - arranged by the MPA - where the agency meet with the pharmaceutical industry and the HCPs respectively leads to good opportunities to discuss pharmacovigilance issues e.g. ADR reporting.

MHRA - UK

See campaign case studies for patient campaigns, GP and pharmacy, paediatrics, parents and carers all detailed within SCOPE document:

<http://www.scopejointaction.eu/assets/files/WP4.3-Raising-Awareness-of-National-ADR-Reporting-Systems-Case-Studies-layout-draft-4-final.pdf>

An evaluation of the EU wide social media campaign to raise awareness of national spontaneous ADR reporting systems: <http://www.scopejointaction.eu/assets/files/2017-01-17-SCOPE-ADR-social-media-campaign-evaluation-FINAL-Mitul-Jadeja.pdf>

Building on the success of the award winning social media campaign in November 2016 led by the MHRA through the SCOPE project, the MHRA, in collaboration with World Health Organisation Upsala Monitoring Centre, led its second a social media ADR awareness week campaign in November 2017 to raise general awareness of the Yellow Card Scheme with the public. The campaign reached nearly 2.3 million people involving 27 medicines regulators, of which 8 were outside EU. In the UK, a month after the campaign launch saw an increase of 16% increase in suspected ADR reports received directly from healthcare professionals and members of the public compared to the same time period the year before. The campaign was supported by the animation and other [supporting infographics to promote reporting](#). The main message was that the reporting of suspected side effects helps the safe use of medicines to protect public health. The 2017 campaign focused on over-the-counter medicines; however, the messages were applicable to those on general sale. This was supported by contacting over 250 UK stakeholders and networks, including a Drug Safety Update article to raise awareness with healthcare professionals. <https://www.gov.uk/drug-safety-update/support-our-second-social-media-campaign-for-suspected-adverse-drug-reactions>

See also Q36 of qualitative responses in Annex 2 on stakeholder interactions.

HSA - Singapore

One successful roadshow was a simulcast (live broadcast) on ADR reporting conducted to a cluster of polyclinics island wide. HSA leveraged on this technology set up by the polyclinic. It was a real-time broadcast streaming of the presentation made on site from one polyclinic and was effective in reaching out to a big group of stakeholders including doctors and nurses. Through this roadshow, HSA was also able to build and foster good working relationships with both health care professionals and the organising committee of the polyclinic cluster.

TGA - Australia

While we have ticked the "Yes" button, we haven't undertaken a "campaign" as such, but we have undertaken various activities and this seemed the best section to describe them. We have not directly measured the success of these activities.

We have printed two brochures regarding AE reporting for medicines (separately aimed at HCPs and consumers) and have distributed them through various channels (mainly via

conferences, in response to one-off requests from various organisations, and distributed with some mailed correspondence).

We have been working with various prescribing/dispensing software makers to facilitate reporting from within the software. We have only had one pharmacy software provider institute this so far, but we are making progress towards getting it integrated into GP software. This has only had a small impact so far, but has the potential to be much more important once GP software options are available.

In 2014 we developed AE reporting online modules offering CPD credit for doctors, nurses and pharmacists.

In 2016 we undertook a limited trial of online advertising to promote these CPD modules and refresh awareness. This was small scale and only lasted for 6 weeks or so, but resulted in a pleasing upsurge in module completion while it lasted.

We have printed large numbers of "Script covers" with adverse event reporting messages. These are used by pharmacists to enclose "repeat" prescriptions that consumers take home with them. These covers were distributed through community and hospital pharmacies.

We regularly attend conferences and undertake webinars, providing speakers and staffing booths where materials are distributed.

In 2015 we ordered several thousand TGA-branded USB sticks containing information about AE reporting. These proved to be exceedingly popular "collateral" sought out by conference delegates.

We send speakers to academic institutions to speak to both undergraduate and postgraduate trainees.

We introduced the Black Triangle Scheme on 1 January 2018 to stimulate reporting on newly registered medicines and medicines being used for the first time in significantly different patient groups.

We have established a partnership with www.healthdirect.gov.au to promote adverse event reporting to consumers seeking health information.

Medsafe – New Zealand

The one campaign was a participation in the EU SCOPE campaign in which success was measured overall.

CADRM/CFDA – China

'Cosmetic propaganda day': The types and scales of the campaign are varied according to provincial situations. The main channels include holding a forum, volunteer diagnosis and consultation by specialist and so on. Some provinces carried propaganda by brisk walking and going into community.

'International Day Against Drug Abuse and Illicit Trafficking': Holding in square area, most of the audiences are citizens and students. It lasts one day usually. The main methods include delivering propaganda materials and questionnaire, consulting by specialists, advertising by large screen in main road and circulating propaganda cartoon in bus. The actions enhance the relationship between the National Centre and provincial centres. The

activities have not been questioned and worked well.

Campaigns and materials - Q24 - Please describe the least successful campaigns. What would you do differently as a result?

MPA - Sweden

We have not made any formal assessment of our campaigns. However, we believe that only to publish information on the web site will not be sufficient enough to promote ADR reporting in a successful way.

MHRA - UK

A targeted campaign to reach GPs who are busy HCPs was challenging. Instead we adopted novel approaches to use social media site to pose problems interactive clinical case studies which was small but successful and outlined below. It was decided to continue to engage with Royal Colleges but further pursue electronic integrated methods to increase ADR reporting. Now the approach is to look at validation and appraisals.

Interactive case studies were used as part of the campaign to encourage doctors to report more and increase awareness of the Yellow Card Scheme. This was taken forward through collaboration with BMJ doc2doc organisation. Polls and voting were methods used to measure reactions of medics on the collaborating organisations website. Extra information was additionally posted to spark discussion around the specific topic of ADRs.

An email was drafted and sent to the Royal College of GPs, NICE, and the regional centres to promote use of the forum. A pre-determined PV team responded within 24 hours to any questions posted on the discussion forum by doc2doc members during the two-week duration of this initiative. Senior management cleared necessary new lines to take.

This first pilot initiative of its kind reached 1,817 doctors that clicked onto the two forums created to view or take part in the discussion and provide specific feedback on reporting experiences. It has been the most successful way of reaching doctors and interacting with them as part of the Yellow Card campaign via social media. Voting results: 75% of people would complete a Yellow Card for the answers in response to case study 1. 90% of people would complete a Yellow Card although 45% would wait for medical notes to do so in response to case study 2.

HSA - Singapore

We recognise the importance of targeting the right audience at the right time for effective dissemination of information. There were times when the HCP turn up weren't great due to clash with their important inhouse meeting. It is also important to understand the difference in ADR reporting culture in different healthcare institutions for outreach to the right audience.

Education and e-learning – Q26 - Please describe the e-learning modules or packages and share any links. If the e-learning has been measured for effectiveness, please supply any relevant details including any effect on reporting.

MPA – Sweden

This link goes to the educational material available on the MPA's web site and it describes why, to whom, how and when you should report ADRs. The material also describes current rules and regulations, background and history for reporting. There is a number of ADR cases included to give examples of typical cases to report.

<http://79.99.0.79/lakemedelsverket/biverkningsrapportering/#start>



ADVERSE REACTION REPORTING

Training

- **Adverse drug reporting in practice**
 Why, what, how and who?
- **Adverse Drug Reaction Monitoring**
 Here you will gain more insight into the importance of adverse drug reporting in the safety work on drugs.
- **Laws and regulations**
 Here you will get an insight into the most important rules that cover drug safety.
- **Background and History**
 Here you can read about historical events that underlie today's pharmacovigilance.

Case reports

- ▶ **Gustav, 12 years old**
 Hyponatremia, can it hurt children?
- ▶ **Karin, 77 years old**
 Plaster can also cause side effects.
- ▶ **Bertil, 70 years old**
 A report can change the product? Summary / FASSI
- ▶ **Gösta, 65 years old**
 Are there any side effects not listed in the Summary of Product Characteristics / FASS?
- ▶ **Beata, 84 years**
 Can osteonecrosis be caused by? Drugs?
- ▶ **Eve, 62 years old**
 Biological drug

MHRA - UK

Presentation on website for public: <https://yellowcard.mhra.gov.uk/downloadable-information/guidance-on-yellow-card-reporting/>

<https://www.gov.uk/guidance/the-yellow-card-scheme-guidance-for-healthcare-professionals>

Further guidance and online learning

[Guidance on adverse drug reactions](#) (PDF, 78.9KB, 7 pages)

[Contribution of Yellow Cards to identifying safety issues](#) (PDF, 165KB, 10 pages)

[Pharmacovigilance – how MHRA monitors the safety of medicines](#) (PDF, 72.4KB, 5 pages)

[E-learning module: pharmacovigilance – identifying and reporting adverse drug reactions: in association with MHRA](#)

- New e-learning module for doctors

We have created a new free e-learning module for doctors to learn about the importance of reporting suspected adverse drug reactions (ADRs).

The European Accreditation Council for Continuing Medical Education (EACCME), part of the European Union of Medical Specialists (UEMS), has given the module the highest order of accreditation. Doctors are awarded 1 EACCME credit (1 hour CPD) on completion of the 45 minute ADR e-learning module.

[‘Adverse Drug Reactions: reporting makes medicines safer’](#)

The module was developed as part of the SCOPE Joint Action project to raise awareness levels of ADR reporting.

Initial results are between 13 Feb 2017 and 28 Sep 2017 (6.5 months) high level findings from those learners that selected answers are:

- 95% said the learning objectives set out at the start were met
- 93% said the content helped them gain a clearer understanding about the importance of reporting suspected adverse drug reactions
- 95% rated the quality of the content as Excellent (51%), Very good (36%), Good (8%). 3% said it needed improvement (understanding of reporting guidance and interpretation of ADR definition) and 3% said it was poor (due to a technical glitch resulting in accessibility which was rectified as soon as we were notified).
- 95% said they would change practice about ADRs as a result with Significant change (48%), Moderate change (30%), Little change (16%). 5% said there would be no change.
- 94% would recommend the e-learning to a colleague

The UK has created a number of free learning modules which all count to CPD points for HCPs. Each are described in high level below.

- E-learning modules for pharmacists

The MHRA in collaboration with Centre for Post-graduate Pharmacy Education (CPPE) has developed a series of three e-learning programmes with the Wales Centre for Pharmacy Professional Education. The programme has been endorsed by the Drug Safety Research Unit. The three e-learning modules aim to help pharmacists understand how to identify, report and prevent ADRs:

[Adverse drug reactions and medicines safety](#)

[Reporting adverse drug reactions](#)

[Patients and adverse drug reactions](#)

- E-learning module for nurses

The MHRA in close collaboration with The Nursing Times have developed an interactive e-learning module for nurses. The module is free once a nurse registers with the Nursing

Times Learning site and upon completion counts for 2 hours continuing professional development (CPD) credits.

For all healthcare professionals and doctors based on the first learning unit created by the MHRA, a BMJ Learning module on pharmacovigilance was developed. Due to the cost of maintenance, this module was archived. The module is still accessible and counts for 1 CPD credit. It is also accredited by a variety of other organisations and countries.

- Other medicines modules

Medicines modules to supplement learning, MHRA has produced a series of free e-learning modules for HCPs based around clinically-relevant aspects of medicines regulation as well as topics on the risks of commonly-prescribed specific classes of medicines. They are written for HCPs responsible for prescribing, supplying or administering medicines. They can be used by: trainees, established clinicians to refresh or update their knowledge, or for clinicians moving from one specialty to another. Questions within the modules test users understanding of the materials. Feedback on the questions are also included. All of these education modules have been accredited for continuing professional development (CPD) points by relevant Royal Colleges:

- Antipsychotics - accredited for 3.5 CPD credits
- Benzodiazepines - 2.5 CPD credits
- Corticosteroids - 2 CPD credits
- Opioids - 2 CPD credits
- Oral anticoagulants - 1.5 CPD credits
- Selective serotonin reuptake inhibitors (SSRIs) - 3 CDP credits

Work is continuing to get these materials introduced into undergraduate training courses for health professionals.

- Regional courses

MHRA regional centres have also developed their own regional ADR modules to increase reporting and awareness through education, all count for CPD credits. The e-learning modules are for the NHS, undergraduates, and there is a safer prescribing course for foundation year doctors that contains information on ADR reporting. Scotland's one is below.

Our regional centre in Scotland, in collaboration with NHS Education for Scotland (NES) launched 6 interactive eLearning modules. NES host the modules on their website and are also accessible via NHS Scotland LearnPro platform to Scottish HCPs and the YCC Scotland website: www.yccscotland.scot.nhs.uk/training/Pages/Educational.aspx

Each interactive module takes 20-30 minutes to complete and they cover:

- Module 1 - Basic principles of ADRs
- Module 2 - Categorisation
- Module 3 - Drug allergy classification
- Module 4 - Diagnosis, interpretation and management of ADRs
- Module 5 - Avoiding ADRs
- Module 6 - Pharmacovigilance

It is difficult to measure effects on reporting from all the above e-learning modules but we capture a field on our webform for reporters to complete one of the options is e-learning/cpd/training - this figure rises steadily each year.

HSA – Singapore

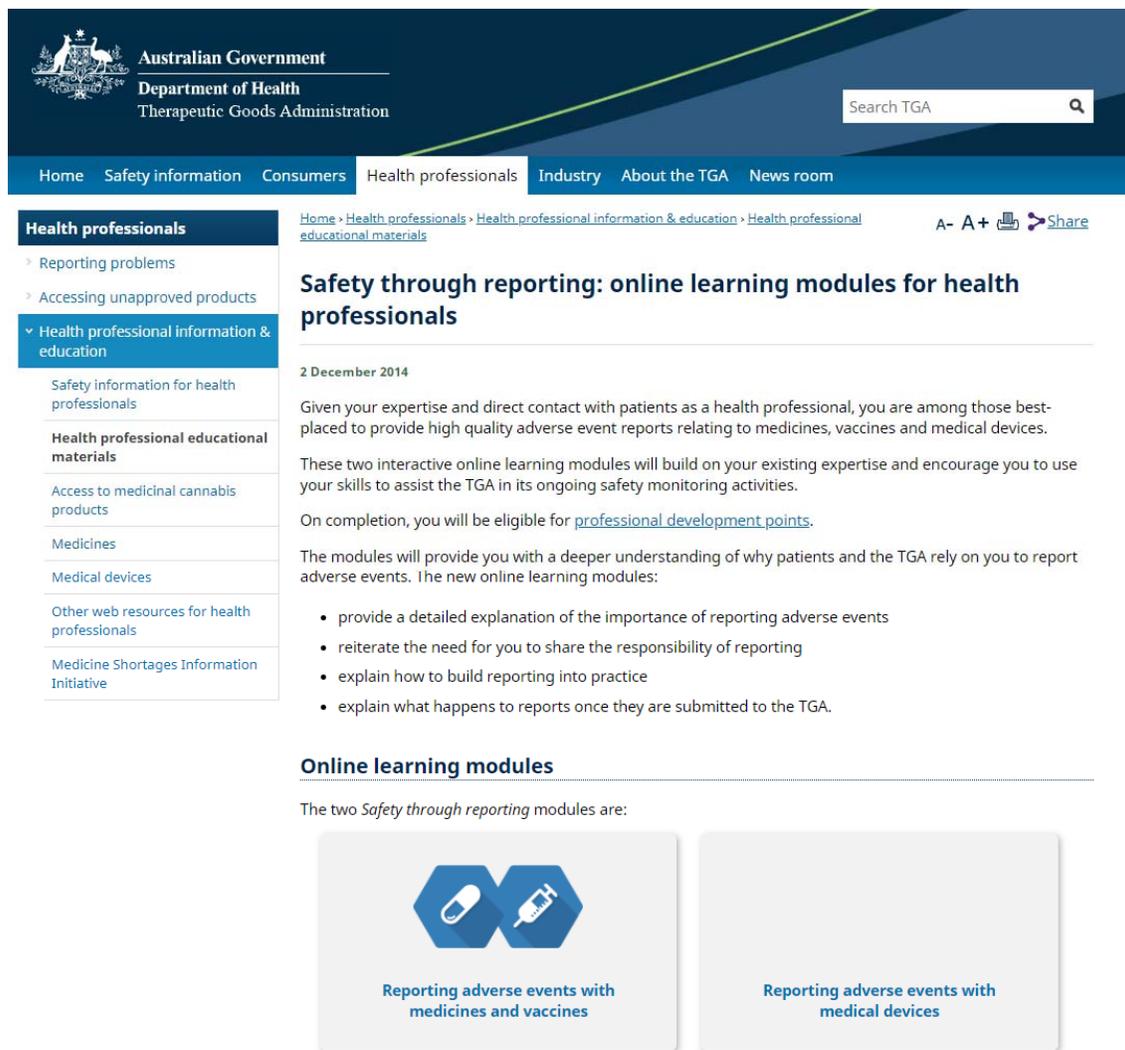
A video presentation on ADR reporting will be published on our HSA website.

TGA – Australia

We developed two modules (one each for medicines and medical devices AE reporting) hosted by NPS Medicinewise. These were initially to run for three years but were reaccredited last year with additional information about our new Black Triangle Scheme.

We have measured the completion rates of the modules but not their effect on reporting behaviour. Participant feedback suggests that they will have a positive effect on reporting behaviour.

<http://www.tga.gov.au/safety-through-reporting-online-learning-modules-health-professionals>



The screenshot shows the Australian Government Department of Health Therapeutic Goods Administration website. The page title is "Safety through reporting: online learning modules for health professionals", dated 2 December 2014. The content includes an introduction stating that health professionals are best-placed to provide high quality adverse event reports, and that two interactive online learning modules will be provided to build on their expertise. The modules will provide a deeper understanding of why patients and the TGA rely on them to report adverse events. A list of four bullet points describes the modules' objectives: provide a detailed explanation of the importance of reporting adverse events, reiterate the need for sharing the responsibility of reporting, explain how to build reporting into practice, and explain what happens to reports once submitted. Below the text, two boxes represent the modules: "Reporting adverse events with medicines and vaccines" and "Reporting adverse events with medical devices".

The importance of reporting adverse events

COFEPRIS – Mexico

A guide has been developed to make the notification online, which is on the page of the ARN of the federal government, accessible to all people.

<https://www.gob.mx/cofepris/documentos/guias-lineamientos-y-requerimientos-de-farmacovigilancia>

https://www.gob.mx/cms/uploads/attachment/file/293842/03_NOM-220_Gu_aSRAMVerFin_2018-01-25.pdf

HC – Canada

All regional centres prepare Power-point presentations and handouts and make them available for educational activities. In addition, as determined by the specific format, mock reports are made available to support discussions on low vs high quality reports. These materials describe Health Canada's post-market ADR surveillance program (Canada Vigilance Program). They also highlight reporting procedures, benefits of reporting, web based tools, interactive scenarios. The target audience includes undergraduate pharmacy and nursing students, and medical residents.

Health Canada also collaborated with University of British Columbia (UBC) Continuing Pharmacy Professional Development (UBC CPPD) to develop and deliver an accredited online ADR reporting presentation that is available for pharmacy professionals across the province to access asynchronously according to their own schedules.

<https://cpd.pharmacy.ubc.ca/adverse-drug-reaction-reporting-your-role-patient-safety-free-accredited-online-training-program>



ADVERSE DRUG REACTION REPORTING: YOUR ROLE IN PATIENT SAFETY (FREE, ACCREDITED, ONLINE TRAINING PROGRAM)

ABOUT THIS PROGRAM

UBC Continuing Pharmacy Professional Development is pleased to present the online Adverse Drug Reaction Reporting Program in Collaboration with the Canada Vigilance Program. This program is designed to help BC Pharmacy Professionals develop an awareness and understanding of the importance of Adverse Reaction monitoring and reporting in the provision of safe and effective drug therapy.

TARGET AUDIENCE & ACCREDITATION

This program is designed and accredited for BC Pharmacy Professionals including:

- BC Pharmacists
- BC Pharmacy Technicians

The program is assigned **0.75 CEUs**

BC Accreditation File # **BC-2017-010-ISP**

Accreditation Period: **April 5, 2017 to April 5, 2018**

PROGRAM LEARNING OBJECTIVES

1. Explain the potential impact of adverse reactions (ARs)
2. Explain the importance of monitoring and reporting suspected adverse reactions to health products
3. Describe the process for reporting suspected adverse reactions

CADRM/CFDA – China

A vaccine safety basic knowledge learning manual is available but CADRM has not evaluated the effectiveness.

Education and e-learning – Q27 - In terms of educating HCPs about suspected ADRs, what are the most successful approaches made in your country and why?

MPA – Sweden

The use of regional centres educating HCPs both in academia and at hospitals.

At every opportunity staff from the MPA, Drug Safety will inform about where to find the appropriate forms for ADR reporting.

MHRA - UK

Working with and using:

- regional centres that are tasked with education and promotion, they are based in teaching hospitals and linked to academia.
- incorporating ADR reporting into undergraduate HCP courses
- reporting indicators act as incentives for reporting
- professional networks and champions - allows feedback and confidence to raise potential signals that may have not been reported.
- working with Royal Colleges, trade associations and regulators to add in reporting into their professional codes of conduct to support. It would be good to make this more examinable for all and in annual appraisals to show evidence of it.
- use of professional newsletters, articles, and drug safety update monthly bulletin.

Some of the above are outlined here including the specific wording used.:

The MHRA has worked with regulators of HCPs to add relevant information about suspected ADR reporting into HCPs guides and codes of conduct:

Doctors - The following are competencies included within the UK Foundation Programme Curriculum¹ for doctors produced by the Academy of Medical Royal Colleges (from the Medical Foundation Programme 2012, with August 2015 updates²):

Relationship and communication with patients
Section 2.4 - Complaints:

¹ <http://www.foundationprogramme.nhs.uk/pages/trainers> accessed 14 March 2016

²

http://www.foundationprogramme.nhs.uk/download.asp?file=FP_Curriculum_2012_Updated_for_Aug_2015_-_FINAL.PDF accessed 14 March 2016

- *Understands and addresses common reactions of patients, family and clinical staff when a treatment has been unsuccessful or when there has been a clinical error*

Good clinical care

Section 7.6 - Safe prescribing:

- *Takes an accurate drug history, including self-medication, use of herbal products and enquiry about allergic and other adverse reactions*
- *Notifies regulatory agencies of reportable adverse drug reactions to medicines and blood products*
- *Administers blood products safely and recognises transfusion reactions*
- *Anticipates, prevents and manages adverse drug and transfusion reactions, and understands how and when to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA)*

The above also maps under domain 2 – Safety and Quality of Mapping the Foundation Programme Curriculum 2012 to GMC good medical practice standards: Contribute to and comply with systems to protect patients³:

Contribute to and comply with systems to protect patients

22. You must take part in systems of quality assurance and quality improvement to promote patient safety. This includes:

- a. taking part in regular reviews and audits of your own work and that of your team, responding constructively to the outcomes, taking steps to address any problems and carrying out further training where necessary*
- b. regularly reflecting on your standards of practice and the care you provide*
- c. reviewing patient feedback where it is available.*

23. To help keep patients safe you must:

- a. contribute to confidential inquiries*
- b. contribute to adverse event recognition*
- c. report adverse incidents involving medical devices that put or have the potential to put the safety of a patient, or another person, at risk*
- d. report suspected adverse drug reactions*

This is also mirrored within GMC Good medical practice in relation to guidance on prescribing and managing medicines and devices⁴:

Prescribing guidance: Reporting adverse drug reactions, medical device incidents and other patient safety incidents

46. Early, routine reporting of adverse reactions, incidents and near misses involving medicines and devices can allow performance and systems issues to be investigated, problems rectified and lessons learned. You must make reports in accordance with your employer or contracting body's local clinical governance procedures.

³ http://www.gmc-uk.org/guidance/good_medical_practice/systems_protect.asp. GMC guidance: domain 2: safety and quality. Accessed 14 March 2016

⁴ http://www.gmc-uk.org/guidance/ethical_guidance/14323.asp accessed 14 March 2016

47. You must inform the MHRA about:
- serious suspected adverse reactions to all medicines and all reactions to products marked with a Black Triangle in the BNF and elsewhere using the Yellow Card Scheme.
 - adverse incidents involving medical devices, including those caused by human error that put, or have the potential to put, the safety of patients, healthcare professionals or others at risk.²⁰ These incidents should also be reported to the medical device liaison officer within your organisation.
48. You should provide patients with information about how they can report suspected side effects directly to the MHRA.

Figure 23 – screenshot from GMC website showing prescribing guidance in support of suspected ADR reporting for doctors.



The screenshot shows the GMC website navigation and content. The main heading is "Working with doctors Working for patients". The navigation menu includes "About us", "Education and training", "Registration and licensing", "Good medical practice", "Concerns about doctors", and "Publications". The main content area is titled "Prescribing guidance: Reporting adverse drug reactions, medical device incidents and other patient safety incidents". It contains the following text:

46. Early, routine reporting of adverse reactions, incidents and near misses involving medicines and devices can allow performance and systems issues to be investigated, problems rectified and lessons learned.¹² You must make reports in accordance with your employer or contracting body's local clinical governance procedures.¹⁸

47. You must inform the MHRA about:

- serious suspected adverse reactions to all medicines and all reactions to products marked with a Black Triangle in the BNF and elsewhere using the Yellow Card Scheme.¹⁸
- adverse incidents involving medical devices, including those caused by human error that put, or have the potential to put, the safety of patients, healthcare professionals or others at risk.²⁰ These incidents should also be reported to the medical device liaison officer within your organisation.

48. You should provide patients with information about how they can report suspected side effects directly to the MHRA.

49. You should also:

- check that all serious patient safety incidents are reported to the

On the right side, there is a "Download" section with two PDF files:

- Prescribing Guidance (2013) PDF, 199.89kb
- Arfer da wrth bresgripsiynu a rheoli meddyginiaethau a dyfeisiau (2013) PDF, 227.83kb

Pharmacists - pre-registration training⁵ for pharmacists calls for an understanding of reporting arrangements and within the General Pharmaceutical Council Pre-registration manual⁶ trainees must show that they can under the section:

Managing the dispensing process:

C1.3 Assess the prescription for safety and clinical appropriateness. This will include:

- possible side effects

⁵ <http://www.pharmacyregulation.org/preregmanual> accessed 14 March 2016

⁶ http://www.pharmacyregulation.org/sites/default/files/prm_pdf/pre-registration_manual_version_5.1_march_2016.pdf GPhC pre-registration manual for pharmacists. V5.1 Accessed 14 March 2016

- *risk of adverse drug reactions*

Provide additional clinical and pharmaceutical services:

C2.7 Recognise possible adverse drug reactions, evaluate risks and take action Accordingly*

** this may include advising and informing the patient or their representative, discussions with colleagues and reporting in line with local and national protocols.*

The pre-registration examination can also include questions on reporting suspected ADRs. One such example scenario was when to report a Yellow Card for a patient presenting with a suspected ADR. Feedback from the assessment showed that 86% of candidates selected the correct response. There is some variation depending on the question asked but this is representative of the response seen.

The Royal Pharmaceutical Society's Professional Standards for Public Health Practice for Pharmacy⁷, specifically within Standard 5.0 on Health Protection, shows examples in practice that are applicable to all pharmacists and pharmacy teams working in England and Wales. It states:

In community pharmacy:

- *Encouraging and supporting the appropriate reporting of adverse drug reactions through the Medicines and Healthcare products Regulatory Agency (MHRA) Yellow Card Scheme*

In hospital pharmacy:

- *Encouraging and supporting the appropriate reporting of adverse drug reactions through the MHRA Yellow Card Scheme*

Nurses – the Nursing and Midwifery Council (NMC) has within the Standards for medicine management⁸ a Standard to report suspected ADRs:

Standard 25: Reporting adverse reactions

As a registrant, if a patient experiences an adverse drug reaction to a medication, you must take any action to remedy harm caused by the reaction. You must record this in the patient's notes, notify the prescriber (if you did not prescribe the drug) and notify via the Yellow Card Scheme immediately

Standard 25 is further supported with guidance on reporting and where to find a Yellow Card report.

⁷ <http://www.rpharms.com/support-pdfs/professional-standards-for-public-health.pdf> RPS, Professional Standards for Public Health Practice for Pharmacy. Accessed 14 March 2016

⁸ NMC - Standards for medicines management:
<https://www.nmc.org.uk/globalassets/sitedocuments/standards/nmc-standards-for-medicines-management.pdf> accessed 14 March 2016, pages 10 and 38.

HSA – Singapore

Lectures with focus on ADR reporting to undergraduate HCP students to lay the foundation for a good ADR reporting culture by future HCPs

ANVISA – Brazil

Despite the modesty strategies, we realize the increase of the awareness in ADR Reporting in actions like the structuring of The Sentinel Network and the obligations of Hospitals reporting 2013 (RDC 36/2013). Currently, the Sentinel Network is composed by 240 services, and corresponds to approximately 50% of all adverse events reports received for medicines. Regarding the Pharmacovigilance, besides receiving reports, the Network is a constant tool for information exchange, such as the reinforcement signal in searching for changes in the benefit-risk medication profile.

COFEPRIS - Mexico

Knowing the international guidelines and including them in national standard (NOM-220-SSA1-2016 for installation and operation of the PV), has helped to increase the number of notifications, as well as the quality of the information.

HC – Canada

Regional lectures/workshops with students appear to be the most successful approach. These are hands- on interactive approaches engaging input by course instructors to tie the topic into other sections of their curriculum. Showing an individual and allowing them to actively participate improves their attention, allows for a safe environment to "practice" and ask questions, receive immediate feedback to improve reporting skills and to ensure they are familiar with the resource/reporting tools and how to use them

[See also first paragraph in Q14 \(What approaches have worked well and why\)](#)

CADRM/CFDA – China

The training materials are standardised by the National Centre, and trainings for HCP are carried by provincial centers.

Education and e-learning – Q28 - In terms of educating HCPs about suspected ADRs, what are the least successful approaches made in your country and why?

MPA – Sweden

Only to publish information e.g. the forms on the web site without any additional contacts will not be successful.

MHRA - UK

At first, we attended lots of conferences and had stalls, although we still do when appropriate according to a business case, speaking opportunities are more welcomed as an opportunity to influence stakeholders attending an event.

ANVISA – Brazil

The least successful approaches are periodically lectures.

COFEPRIS - Mexico

Making audiences understand and the use of MedDRA terminology. For that reason, there has been training to national institutes which pharmaceutical industry also do.

HC – Canada

Remote learning opportunities such as webinars are often the only means to educate, but this is very disconnected, impersonal and one sided. As a presenter it is more challenging to encourage interaction and to know if the participants are actually present.

CADRM/CFDA – China

It's difficult to cover very well because of the big area of China and large numbers of HCP with varied background.

Education and e-learning – Q29 - How do you engage more experienced HCPs at advanced stages in their careers? How can this be made more effective?

MPA – Sweden

Educational activities are performed through our regional centre at advanced levels. Also, the hospital management e.g. the medical directors are being approached in different ways with information about ADR reporting.

MHRA - UK

see q before. can be made more effective through further testing with HCP curriculum, e-learning, CPD, and inspections and audit on issues and evidence of proactive reporting of HCPs and organisations (MHRA are planning to take this forward) with transparency of reporting rates in HCP organisations and settings.

Liverpool Health Partners Yellow Card Working Group case study:

In the UK, there is a national drive to improve patient safety, reporting of adverse drug reactions (ADRs) to the Yellow Card Scheme is seen as an important marker of patient safety and the quality of patient care. In May 2014, a new initiative was introduced within the North West of England, this was a collaboration between the Liverpool Health Partners (LHP) and one of the regional Yellow Card Centres North West. LHP is a combination of twelve hospitals and healthcare organisations, scientific, academic and innovation institutions in Liverpool and Merseyside. A working group, named YCWG was set up and comprises doctors, pharmacists and researchers who meet quarterly to share good practice and provide a networking forum to explore ideas and initiatives and lend support. Five meetings have been held up to the end of 2015.

The objectives of the YCWG are to:

- Improve patient safety
- Improve quality of care of patients
- Improve education and training in drug safety for HCPs
- Develop Liverpool as a centre of excellence for improving drug safety by use of innovative approaches.

Initiatives identified and shared within the group so far include:

- A designated “Champions” within organisations to increase ADR reporting. Several sites identified a motivated individual and saw a substantial rise in reporting from LHP organisations increased from 298 reports in 2013/14 to 488 in 2014/15 a 64% increase. This experience has stimulated all member Trusts to identify a Champion. Support from LHP Chief Executives has reinforced the importance of this approach.
- The opportunity for LHP Champions to network and share ideas leading to raised awareness, improved engagement and increased ADR reporting has stimulated the development of a North West-wide network of YC Champions.
- The inclusion of ADR reporting in a proposed PGCert module for foundation medics is under discussion as part of the educational focus of the LHP.
- A short audit on current practice in ADR reporting in an Acute Medical Admissions unit was conducted in one Trust. Prior to the audit ADR reporting via the YCS was extremely low reporting was not considered unless the reaction was serious and unusual. Over the eight-week audit period 12 suspected ADRs were identified and reported. The findings showed that improved awareness alongside a designated reporting pathway results increased YC submissions.

HSA – Singapore

We seek their inputs on our bulletin articles or invite them to co-author articles on safety issues. We also tap on their experience by seeking their inputs on safety signals that we have detected.

TGA – Australia

So far, we have engaged them through the e-learning and conferences.

We are currently in the process of developing and deploying internet advertising resources to heighten awareness of the new Black Triangle Scheme and, depending on the success of this, we may look at widening these activities to promote AE reporting more generally.

COFEPRIS – Mexico

It could be more effective if HCPs in Mexico had more pharmacovigilance subjects during their university studies.

HC - Canada

In order to reinforce the information delivered through the undergraduate curriculum, Regional centres target students along different points of their learning career by collaborating with continuing professional development programs to create ADR modules that are accredited to support practicing HCPs maintain the skills and knowledge to report ADRs. One region also engages with HCP associations and regulatory bodies in cross promotion of the accredited e-learning to improve uptake by members.

<http://www.bcparmacists.org/readlinks/guest-post-adverse-drug-reaction-reporting-your-responsibility>

The most important criteria for developing Continuing Education (CE) programs include flexibility in order that all HCP can participate and for that participation to be recognised in the context of their professional practice (i.e., access should be free and the CE activity should be accredited). The internet offers an increasing number of options for the delivery of continuing education, especially to health care professionals working in remote locations. An on-line module can be utilized to overcome access- and cost-related problems.

Experienced HCPs often have some basic awareness of the existence of AR reporting. This audience is often interested in what is done with the information once submitted. It is important at this stage to incorporate case scenarios along with some background workup information that has resulted in the identification of a signal and the development of a risk communication. This audience is curious about the process. They wish to be able to have their voice heard to provide suggestions of what works and what does not, how to facilitate the reporting processes to make them more efficient, less cumbersome. They are often interested in the various tools available for reporting, garnering information on safety and information submitted.

Time constraints are challenging factor with HCPs. Being flexible and enabling them to access learning modules when convenient for them is important. HCPs also want to ensure they receive continuing education credits for learning activities.

CADRM/CFDA – China

Through holding forum and expert consultation.

Education and e-learning – Q30 - What impact has education made on reporting? How is this measured?

MPA – Sweden

This is currently not measured.

MHRA - UK

- [see question before](#)
- difficult to measure effects on reporting but we capture a field on our webform for reporters to complete one of the options is e-learning/cpd/training - this figure has risen steadily each year.
- surveys on effectiveness of the modules
- signals from sources of collaborative networks for HCPs and safety officers
- enquiries
- increase in numbers of reports - where did you hear about us
- quality of reports - in progress from sources

TGA – Australia

We haven't measured the impact beyond the participant feedback, which was very positive.

COFEPRIS – Mexico

Proper training allows the HCPs to collect accurate information for the correct analysis of the notification. This can only be measured until the evaluation of the ADRs is carried out.

CADRM/CFDA – China

Education has good influence, but its effect is not evaluated.

Education and e-learning – Q32 - Do you have experience with education toolkits or therapeutic toolkits for patients and their organisations? This includes any specific education materials or training. Please describe them.

MPA – Sweden

We have a special form for consumers to use when reporting ADRs. The form will explain what to add in different fields or boxes.

MHRA - UK

Regional centres have objectives to educate patient organisations.

Training for patient organisations - information day on PV for EURODIS rare disease patient organisations in EU.

Valproate and of risk of abnormal pregnancy outcomes case study for toolkit

In January 2015 a Drug Safety Update (DSU) article by the MHRA advised healthcare professionals that children exposed to valproate in utero are at high risk of developmental disorders and congenital malformations. The EU agreed Risk Minimisation Materials were distributed with the letter and links to both contained in the DSU article. In the subsequent 12 months the MHRA colleagues from pharmacovigilance and also communications divisions worked collaboratively with the MAH concerned and through major consultation with patient groups and professionals produced a final communications toolkit which was released on 8 February 2016. The toolkit consisted of a: patient card, patient guide, checklist and booklet for HCPs and the packaging label-ling which the MAH are now rolling out globally.

The MHRA developed these new communication materials for utilisation by organisations and healthcare professionals to discuss risks and benefits with patients. With the MAH the development of the materials involved continuous partnership with stakeholder group meetings, phone calls and written communications. The process also involved meetings with Royal Colleges, voluntary organisations, the Minister and senior members of the MHRA team to explore ways for professional bodies to support the messages. Several members of the Royal Colleges and voluntary groups from across various disciplines also attended stakeholder meetings with patients.

These new communication materials were published in the MHRA's February 2016 Drug Safety Update: <https://www.gov.uk/drug-safety-update/valproate-and-of-risk-of-abnormal-pregnancy-outcomes-new-communication-materials>

The following groups specifically support the release of the toolkit on their respective websites. These include Epilepsy Action, Epilepsy Research UK, Epilepsy Society, Young Epilepsy, Bipolar UK, FPA - the sexual health charity, Organisation for Anti-Convulsant Syndrome (OACS), INFACT, Migraine Action, FACS-Aware, Royal College of Midwives, and the Royal College of Pharmacists.

Work is ongoing to publicise this.

CADRM/CFDA – China

Distributing the propaganda materials to the public extensively.

Stakeholder interaction – Q36 - Please briefly describe what interaction there is with each of the above stakeholders specific to increasing levels of awareness or improve quality of ADRs. Please also describe what's been the most successful and why including any challenges of your approaches.

MPA – Sweden

Education of and dedicated staff with enough time available at the mentioned stakeholders is very important.

The yearly pharmacovigilance day for the HCPs will also give an opportunity to improve quality and quantity of reporting.

MHRA - UK

There are many levels of engagement with different and varied stakeholders. Mainly due to campaign work (some outlined below to give a high level idea of different stakeholders and outputs) others due to adding information online and to organisations to promote reporting through their own channels.

Phases 1 and 2 campaigns - GP, community pharmacists and patients

- A public awareness campaign, focussing on pharmacies and GP surgeries was launched in February 2013. Highlights of the campaign included:
- Support by GPs and pharmacy bodies such as the: National Pharmacy Association, the Royal Pharmaceutical Society, the Company Chemists Association, the Association of Independent Pharmacies and the Royal College of General Practitioners
- The five regional Yellow Card Centres also helped promote the scheme
- General press and media coverage
- National distribution of HCP and patient Yellow Card forms to pharmacies
- The development of case studies showing the value and importance of reporting
- Training materials for pharmacists
- The use of social media to raise awareness with the public,
- Interactive online case studies for doctors
- The production of an updated video about Yellow Card reporting which was displayed for patients in 339 pharmacies across the UK through collaboration with a pharmacy multiple chain.

Phase 3 - Paediatrics campaign highlights

- Benchmarking before and after the campaign to measure success
- Stakeholder workshop to facilitate situation analysis and tailor messages for the campaign

- Polls utilised to develop media attention to the campaign regionally and nationally
- General communications to parents and carers (articles, social media, press activity)
- The NHS patient facing website paediatric content was updated
- Partnership with the UK's biggest pharmacy chain for various items of promotional work - articles, adverts, online information

- A new video developed to promote ADR reporting in children
- Promotion via social media
- Yellow Card information was added into the Personal Child Health Record (the red book) - given to parents of new-borns
- Partnership with the Royal College of Paediatrics and Child Health (RCPCH)
- New paediatric reporting guidance produced for reporting suspected ADRs for HCPs
- A Drug Safety Update article on the new reporting guidelines alongside a RCPCH bulletin to their registered members - mainly paediatricians
- Press release issued which was picked up by media on regional reporting
- 2,500 forms distributed via partnership with National Pharmacy Association to independent pharmacies
- Guidelines and awareness was raise through Medication Safety Network and MHRAs 5 Yellow Card Centres.

Phase 3 - Parents and carers

Some specific output examples included:

- Omnibus survey to gauge awareness levels amongst parents - Nov 2013
- Advert in mumsnet e-newsletter - Dec 2013
- Coverage in parenting magazines including Prima Baby and Pregnancy Magazine, and My Family Magazine - Jan 2014
- Coverage in The Times
- News article on Family Lives website (familylives.org.uk) - Jan to Feb 2014
- Social media activity:
- Twitter -MHRA and NHS Choices
- Facebook - Posts on 7 parent/carer focused pages (resulting in Gentle Parenting website posting Yellow Card article - over 8,000 subscribers) - over 60,000 parents/carers reached
- Tweeting by Public Health England, NHS Choices, and other relevant groups
- News flash item in the UK's biggest pharmacy multiple magazine for patients (Apr Jul edition)
- Various forms of media coverage (March 2014) - some examples are:
- <http://www.standard.co.uk/panewsfeeds/call-to-report-drug-sideeffects-9164279.html>
- <http://www.itv.com/news/update/2014-03-03/one-in-five-fail-to-tell-gp-about-childs-reaction-to-medicine/>
- <http://www.nursingtimes.net/nursing-practice/clinical-zones/childrens-nursing/call-to-report-drug-side-effects/5068511.article?blocktitle=News&contentID=4385>
- Yellow Card graphic in children's health sections on pharmacy chains website
- NHS Choices - Content update under Children and Medicines page - <http://www.nhs.uk/conditions/pregnancy-and-baby/pages/childrens-medicines.aspx>
- Media coverage for HCPs:
- http://www.chemistanddruggist.co.uk/news-content/-/article_display_list/17471068/pharmacy-failing-to-win-parental-confidence-in-medicine-advice

- <https://www.pharmaceutical-journal.com/news-and-analysis/news/parents-in-london-less-likely-than-those-in-wales-to-tell-a-pharmacist-about-medicine-side-effects/11135406.article>
- Yellow card video developed and posted on YouTube - April 2014: <https://www.youtube.com/watch?v=ZEHAG3D2NJg> A social media campaign to promote this Yellow Card video received 24 retweets meaning an audience reach of around 349,000 people
- In collaboration with ADRIC study colleagues and the RCPCH, a leaflet was developed for the Medicines for Children website on 'side effects from children's medicines' aimed at parents: <http://www.medicinesforchildren.org.uk/search-for-a-leaflet/side-effects-from-childrens-medicines/>

Phase 3 - Paediatricians and allied healthcare professionals

- Some specific output examples included collaborative partnerships to strengthen and embed reporting of suspected ADRs with Royal Colleges and professional bodies. A particularly emphasis to strengthen reporting in children and young people from parents and paediatric healthcare professionals continued in 2015/16 as follow up work. This was enabled via a continued partnership with the Royal College of Paediatrics and Child Health (RCPCH) and three separate strands of project work. Through the MedsIQ initiative, the Paediatric Care Online UK (PCO UK) project, and the Personal Child Health Record (the 'red book').
- All three now contain sustainable information and champion reporting to the Yellow Card Scheme. PCO UK contains information about the Scheme under each and every product and MedsIQ information about reporting including Drug Safety Update as a tool for safe prescribing. The Red book, given to all parents when a child is born, now contains a page for parents high-lighting the Yellow Card Scheme and the importance of reporting suspected side effects.
- Further partnerships were established with 'Medicines for Children' a programme run by RCPCH, Neonatal and Paediatric Pharmacists (NPPG) and WellChild to provide information on children's medicines that can be trusted by any parent. Supported by the ADRIC (Adverse Drug Reactions in Children) study and the impetus of the new pharmacovigilance legislation, the MHRA has worked together to add new information about side effects and links to Yellow Card reporting is now integrated into each medicines information leaflet on the Medicines for Children website. This is further reinforced by a readily accessible stand-alone information leaflet for parents about side effects.

Other outputs included:

- Stakeholder workshop - Sep 2013 to help shape the campaign and partner with participants
- Royal College of Paediatrics and Child Health collaboration. Quote from president and article agreed - this was used to do a press release and formulate articles for wider publishing and launch of the campaign.
- New BNF, BNFC guidelines for reporting suspected ADRs in children following a stakeholder workshop and liaison with experts and the RCPCH
- Various professional articles
- Article on Yellow Card in Professional Association for Childcare and Early years (PACEY)
- Survey for pharmacists on reporting suspected ADRs via the biggest pharmacy multiple
- Various promotion about reporting suspected ADRs via pharmacy multiples

- National Pharmacy Association collaboration and communication to their members (May/June edition), including 2,500 HCP and patient forms distribution.

HSA – Singapore

- HCPs- Roadshows are conducted
- Trainee HCPs- Lectures are given
- Professional bodies or organisations, and their invited speakers

ANVISA – Brazil

NOTIVISA is the post-market surveillance electronic system that collects and assesses reports of suspected adverse reactions to health products (medications; natural health products; biologics [biotechnology products, vaccines, fractionated blood products, human blood and blood components, as well as human cells, tissues and organs]; radiopharmaceuticals; cosmetics; medical devices; and disinfectants and sanitizers with disinfectant claims) marketed in Brazil.

The Brazil Vigilance Electronic System has collected reports of suspected adverse reactions since 2007. Adverse reaction reports are submitted by health professionals and consumers on a voluntary basis either directly to Anvisa or via Market Authorization Holders (MAHs).

In Brazil, the approach of signal detection from spontaneous reporting has been the manual review of individual case safety reports followed by formulation of hypotheses, leading to further investigations which sometimes result in regulatory warnings and changes of the product monographs and in some instances withdrawals of marketing authorizations.

Development of data mining capacity in Brazil Vigilance database is being explored. Besides, ANVISA is planning to purchase a new system which includes data mining tools and open the expectation to link this new system to public systems available in the country.

By doing that, we expect to be able to offer a better system and reporting forms in order to stimulate and have more adherence to reporting.

TGA – Australia

- The relevant interactions have been listed in the campaigns section.

COFEPRIS – Mexico

- HCP: workshops and courses on the NOM-220-SSA-2016 for installation and operation of the PV standard and the new reporting system.
- Professionals bodies or organizations: participation as members of the PV working group and updating of national standards.
- Other parts of National Health Systems: receive training from the National Pharmacovigilance Centre and are responsible for replicating it to the HCPs of each federal entity.

HC - Canada

- Lectures to undergraduate HCPs and trainee HCPs. Presentations to practicing HCPs, institutions. These lectures include program overview; who, what, where, when, why, how to report; minimum essential information, value of quality information; overview of evaluation process; case scenarios for examples and audience participation; workshops to include mock patient interviews to assist in gathering information; how to document information; review of online resource/reporting tools.

- Dissemination of Pharmacovigilance program brochures, information sheets, reporting forms and contact information for additional information.
- Collaboration with professional bodies/organizations, health authorities, researchers, academia, patient safety and quality councils and provincial/regional ministries of health on projects or articles to increase awareness of the importance of ADR reporting.
- Lectures, presentations and workshop formats would appear to be the least challenging and the most successful approaches as they involve face-to-face interaction, participant interaction, hands on experience with web based reporting and resource tools. They facilitate open dialogue and interaction in a safe environment (see Q27).
- Challenges arise when roles and responsibilities are unclear.

CADRM/CFDA – China

We have a monitoring system with stable staff covering every province. Training to HCPs can be carried by provincial centres.

Mandatory reporting – Q40 - HCPs mandatory reporting requirements

MPA – Sweden

All suspected ADRs should be reported to the NCA

MHLW/PMDA – Japan

The Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical devices

Article 68-10

2) Proprietors of pharmacies; proprietors of hospitals or clinics for human beings or human-reared animals; or physicians, dentists, pharmacists, registered sales clerk, veterinarians and other medical professionals shall, in the case where they learn of the occurrence of any disease, disability or death suspected to be caused by the side effects use of the pharmaceuticals, medical devices or regenerative medicine products, or the occurrence of any infectious disease suspected to be caused by the use of such items, and when it is found to be necessary in order to prevent the occurrence or spread of hazards to public health and hygiene, report the same to the Minister of Health, Labour and Welfare.

HSA – Singapore

Under the Health Products Act and the Health Products (Therapeutic Products) Regulations, manufacturers, importers, suppliers or registrants of a therapeutic product (western pharmaceuticals) are mandated to report serious adverse reactions (no later than 15 days after first awareness). Hence, healthcare professionals who supply therapeutic products are legally mandated to report. Enforcement of the reporting requirements focused on the companies. For healthcare professionals, we take an educational approach to remind them to report ADRs instead.

COFEPRIS – Mexico

The HCPs have the obligation to:

- Report to the National Pharmacovigilance Centre (CNFV) all suspicions of adverse drug reactions (SRAM), both expected and unexpected.
- Use the MedDRA dictionary for ADR coding.

CADRM/CFDA – China

Drug Administration Law of the People's Republic of China: The State applies a system of report on adverse drug reaction. Drug manufacturers, drug distributors and medical institutions shall make constant investigations into quality, therapeutic efficacy and reactions of the drugs produced, distributed and used by them. When serious adverse drug reactions possibly induced by drug use are discovered, they shall, without delay, report the matter to the local drug regulatory departments and administrative departments for health of the people's governments of provinces, autonomous regions and municipalities directly under the Central Government.

Provisions for Adverse Drug Reaction Reporting and Monitoring: The State applies a system of report on adverse drug reaction. Drug manufacturers, drug distributors and medical institutions (applicable to Q41 below) shall report adverse drug reactions.

Mandatory reporting – Q41 – Healthcare institutions (HCIs) mandatory reporting requirements

MPA – Sweden

All suspected ADRs should be reported to the NCA

MHLW/PMDA – Japan

The Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical devices: Article 68-10

2) Proprietors of pharmacies; proprietors of hospitals or clinics for human beings or human-reared animals; or physicians, dentists, pharmacists, registered sales clerk, veterinarians and other medical professionals shall, in the case where they learn of the occurrence of any disease, disability or death suspected to be caused by the side effects use of the pharmaceuticals, medical devices or regenerative medicine products, or the occurrence of any infectious disease suspected to be caused by the use of such items, and when it is found to be necessary in order to prevent the occurrence or spread of hazards to public health and hygiene, report the same to the Minister of Health, Labour and Welfare.

ANVISA – Brazil

The serious adverse events reports are mandatory for all hospitals since 2013 (RDC 36/2013). Despite this, there has been no audit yet.

COFEPRIS – Mexico

The HCPs have the obligation to:

- Report to the National Pharmacovigilance Center (CNFV) all suspicions of adverse drug reactions (SRAM), both expected and unexpected.
- Use the MedDRA dictionary for ADR coding.

8. Improving quality – Q45 – Please describe how the quality of ADR reports is measured

MPA – Sweden

There is an automatic quality check built-in for registered reports. There is also a quality check in relation to the validity of incoming reports

MHRA - UK

Electronic reporting and validations help keep quality high without need for much human intervention including use of pre-populated drop-down fields.

Through assessment and follow up for completeness – this can be difficult to measure, other methods include internal audits on quality of reports put onto the system, queries, duplicate management.

Plans are to introduce a study of the quality of reports received using Clinical Documentation tool (ClinDoc) and our own tools developed for the purpose, we are considering both the completeness of the case in terms of the information provided and the strength of the case in terms of signal management. As a control, we are comparing how the quality of cases from other clinical systems differs from the quality of electronic cases reported via the Yellow Card website.

HSA – Singapore

WHO sends to HSA our VigiGrade Completeness score for the ICSRs reported in our database. The VigiGrade Completeness Score was developed by Uppsala Monitoring Centre to measure the amount of clinically relevant information in a structured format.

COFEPRIS – Mexico

The quality of the ADR reports information is described in the current regulatory framework. However, through the training, compliance with the maximum degree of quality of the report has been encouraged. Additionally, if the information is not sufficient, the online system does not allow the notification to be sent.

HC – Canada

Health Canada has an algorithm for measuring quality. The completeness of reports is measured on a scale from 1 to 5 based on the existence of data in certain key fields. For a report to receive a certain score, it must have data in all fields: (see below).

Score Required Fields

1	Patient Sex and Age
2	All of Therapy start & Duration + Reaction Onset for at least one reaction
3	Outcome
4	All of Therapy unit dose and time unit for at least one suspect product
5	Therapy route admin for at least one (same) suspect product

In addition, Health Canada's quarterly submissions of AR data to the WHO are assessed through their completeness algorithms and a report is provided to us. Unfortunately, there are limitations to this as we remove data fields which may contain personal information before submitting, which negatively affects the completeness score.

CADRM/CFDA – China

Formulate the report's completion criteria; establish the standards for report quality evaluation; conduct a random inspection of case reports regularly.

Improving quality – Q46 – Reporting and guidance

MPA - Sweden

Guidance on homepage and in the web forms.

MHRA - UK

For HCPs: <https://www.gov.uk/guidance/the-yellow-card-scheme-guidance-for-healthcare-professionals>

Statements are present for HCPs within in their key codes of practice for suspected ADR reporting. Supporting guidance is present in their reference materials such as drug formularies such as the BNF with a reporting form at the back of them, drug directories, on online websites and professional bodies and regulator websites. The MHRA has worked with various organisations to facilitate reporting forms into HCP publication resources alongside supporting information on: the importance of reporting suspected ADRs, reporting guidance, information about additional monitoring, special populations, preventing ADRs, regional centres and links to report online.

Through campaigns we have produced crib sheets on what to report and why including various fields. e.g. importance of batch numbers, information to help assess the case, concomitant medication etc.

Guidelines for HCPs are:

Yellow Cards can be used for reporting suspected adverse drug reactions to medicines, vaccines, herbal or complementary products, whether self-medicated or prescribed. This includes suspected adverse drug reactions associated with misuse, overdose, medication errors or from use of unlicensed and off-label medicines.

Report all suspected adverse drug reactions that are:

- serious, medically significant or result in harm. Serious events are fatal, life-threatening, a congenital abnormality, disabling or incapacitating, or resulting in hospitalisation.
- associated with newer drugs and vaccines (¾); the most up-to-date list of black triangle medicines is available at: www.mhra.gov.uk/blacktriangle

If in doubt whether to report a suspected adverse drug reaction, please complete a Yellow Card. HCPs are not asked to establish causality just to report their suspicions of an ADR that might be occurring.

We have also strengthened areas to report with guidance available on our website. Also reporting in children, for example:

The identification and reporting of adverse reactions to drugs in children and neonates is especially important because:

- the action of the drug and its pharmacokinetics in children (especially in the very young) may be different from that in adults;
- drugs may not have been extensively tested in children;
- many drugs are not specifically licensed for use in children and are used either off-label or as unlicensed products;
- drugs may affect the way a child grows and develops or may cause delayed adverse reactions which do not occur in adults;
- suitable formulations may not be available to allow precise dosing in children or they may contain excipients that should be used with caution in children;
- the nature and course of illnesses and adverse drug reactions may differ between adults and children.

Patients - there is no guidance except to make them aware of the reporting scheme and encouraging them to report.

As a result, over 80% of all ADR reports are serious in 2017.

There are reporting statements in the SmPC and PILs for medicines too which has had a good effect on reporting as we ask online how they heard about us. The roll out of standard wording within patient information leaflets to report any suspected side effects to medicines also contributes to raising awareness of the Scheme. Data taken from our Yellow Card website, 'where did you hear about us', suggests an increase of 58% (1,174 reports in 2015 increasing to 1,855 reports in 2016) in those selecting the 'Patient Information Leaflet' category as the source of information. This builds upon the foundations of previous campaign and strategy work to have reporting messages and information about reporting in trusted places such as patient organisations and information health websites such as NHS Choices.

There are a number of tailored step by step guides on how to report too depending on the method of reporting including pregnancy.

[MHLW/PMDA - Japan](#)

Reporting Guidance is under production. Basic ideas were published in July 2017.

[HSA - Singapore](#)

We are in the midst of producing a video on ADR reporting and to raise awareness on submitting a good quality report that will be published on our website.

[TGA - Australia](#)

This has been described earlier.

[HC - Canada](#)

This topic is also covered during Health Canada's regional workshops. We provide various examples, case scenarios in order to touch on added value elements to support evaluation/assessment practices. Low vs high quality report examples along with reviewing the rationale for completing the various sections of a report (e.g., medical history, concomitant medications). Cover designated medical events, reports of interest (e.g., serious, newly marketed drugs). Identifying "trigger tools" for flagging reports (e.g., drug/antidote for treatment, laboratory tests, patient complaint/clinical triggers).

CADRM/CFDA – China

Improve the accuracy of structural content in electronic reports by means of standardized selection, using standard drug names, adverse reaction name terms.

Improving quality – Q46 - IT/technical solutions

MHRA - UK

Electronic reporting has been used by the MHRA as a means to facilitate reporting. This reduces the amount of resource needed for manual entry of ADR data, whilst also making data available for signal detection more quickly as the data can be loaded automatically into the MHRAs pharmacovigilance database. Use of E2B fields via XML with validations enables high quality reports to come onto the database from EHR/clinical systems.

Reporting directly from clinical systems has a number of benefits. It improves access to Yellow Card reporting and reduces the effort required to complete the form through automatic population of information from the patient record. Reporters can be prompted to complete a Yellow Card within the system when specific tasks are completed, such as a medication being withdrawn i.e. triggers for reporting -e.g. fatals or withdrawal of medicine. more info on this is detailed within SCOPE Document 3. Raising awareness of national ADR reporting systems: case studies by country -

<http://www.scopejointaction.eu/outputsandresults/adr-collection/awareness-levels/>

As a result MHRA has developed an electronic Yellow Card reporting information standard for the English National Health Service (NHS) based around the ICH E2B(R2) standard. It defined the electronic Yellow Card message, standard requirements and a number of triggers for a user to prompt completion of an electronic Yellow Card. Primary care systems are the main target for the standard, however IT systems across healthcare are also able to implement the standard, such as pharmacy electronic prescription service (EPS) systems, patient medical record (PMR) systems, and secondary care local risk management systems (LRMS).

These are coupled with smart drop down fields for medicines and reactions which are predictive as the user types. MHRA has produced a mapping with SNOMED CT as MedDRA is not used in NHS systems.

As part of a review to improve existing functionality and quality, the MHRA worked with NHS Digital to develop the Data Coordination Board standard, DCB 1582 Electronic Yellow Card Reporting Standard which replaces the old ISB 1582 Electronic Yellow Card Reporting information standard. This standard can be used by IT providers to better integrate Yellow Card reporting into their systems.

App uses similar E2B fields.Key features enables users to:

- Have a convenient alternative to using paper forms or using the website
- Use the app for free on iOS and Android systems
- Easily report side effects directly to the Yellow Card Scheme
- Create a ‘watch list’ of medications to receive official news and alerts on
- View numbers of Yellow Cards received by MHRA for medicines of interest
- See an immediate response that shows Yellow Card has been accepted
- Submit updates to Yellow Cards already submitted
- View previous Yellow Cards submitted through the app

HSA – Singapore

There are certain fields in our online ADR reporting forms that are made mandatory and auto-population of patient's details will be present in our form.

TGA – Australia

This has been described earlier.

Improving quality – Q46 - Developing easier to use reporting forms

MPA – Sweden

Specific forms for consumers

MHRA - UK

Use of E2B fields via XML with validations enables high quality reports to come onto the database from the webform.

These are coupled with smart drop down fields for medicines and reactions which are sensitive and predictive as one types in values.

We have also strengthened areas of report through question bubbles, making it easier to report medication errors, ADRs in pregnancy.

Initially user tested through a specific patient user group, since launching the online Yellow Card reporting site for collecting suspected ADR reports the MHRA has strengthened and enhanced it as a result of various interactions with stakeholders and internal recommendations by the PV team. The aim is to develop a seamless reporting experience for the reporter. The Yellow Card reporting site for suspected ADRs has the added functionality of smart dropdowns from existing dictionaries for suspected drugs and MedDRA Lower Level Terms for ADRs which are auto populated as the user types - it also includes the option to add free text for both fields. The site also includes smart fields to request additional information depending upon previous answers. We have now implemented patient friendly MedDRA terms.

Some improvements were based on considered feedback and interaction with patient organisations to enable reporting of different scenarios such as in pregnancy, and to capture changes in legislation requirements (medication errors and biological traceability of batch numbers and corresponding help information). This improvement work has occurred through planned and scheduled periodic review for IT enhancements. There is also a feedback box for reporters to contact the MHRA on such matters and general PV queries. There have also been changes as a result of recommendations from the independent review to harmonise reporting discrepancies between HCPs and patient forms

TGA – Australia

We have refined our forms over time and will shortly be introducing new forms as part of a new Adverse Events Management System.

HC – Canada

As noted in answer to Q56, Health Canada currently has a one page reporting form which is available for both the public and HCPs. The form use plain language for ease of use for the

general public (https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/medeff/report-declaration/ser-des_form-eng.pdf).

In one region additional options for reporting are provided: <http://bcpslscentral.ca/online-adr-reporting-is-coming/>

Improving quality – Q46 - Educational activities for HCPs post and pre-graduate

MPA – Sweden

Educations activities through regional centres

E-learning available on web site

MHRA - UK

We engage with group HCPs, academia, undergraduate and postgraduate programmes which we talk to, we organize summer university placements schemes, talk at conferences and various courses.

The Scheme is in the main reporter groups curricula.

Education is supported by YCCs mainly based in teaching hospitals, they often do outreach to HCPs advanced in their careers.

MHLW/PMDA – Japan

Meetings/lectures are used to educate HCPs on reporting.

HSA – Singapore

Lectures are given during their curriculum to educate post and pre-graduate HCPs on how to submit a good quality ADR report in future.

TGA – Australia

This has been described earlier.

HC – Canada

Health Canada offers lectures and presentations for HCPs highlighting the importance of providing quality reports - minimum data elements and additional elements for completeness and assessment. We also use cases to review the information that should be provided on the ADR reporting form. Details provided in Q 26, Q27, and Q36

One region provides an accredited online ADR training program (described under Q26) highlighting the importance of providing quality reports - minimum data elements and additional elements for completeness and assessment

(<https://cpd.pharmacy.ubc.ca/adverse-drug-reaction-reporting-your-role-patient-safety-free-accredited-online-training-program>)

Improving quality – Q46 - E-learning and feedback

MPA – Sweden

E-learning available on web site

MHRA - UK

e-learning already covered previously - using questions and answers with learning about situations to report and fields to include and why.

MHRA has created a document published on their reporting site as well as their general web-site. Case studies are used in campaigns and also have been linked digitally through partnership organisations to promote ADR reporting and show the value of reporting and also improve quality. The document outlines the value of the Yellow Card Scheme through demonstrating the numerous important safety issues that reporting has helped to identify - many of which were not recognised as being related to a particular medicine until information was received via Yellow Cards. The document shows a table of safety issues.

Feedback through drug safety news via the app.

TGA – Australia

This has been described earlier.

COFEPRIS – Mexico

They are used in the face-to-face workshops that are carried out periodically, answering and resolving the doubts of the participants. It is very useful and didactic to work with real cases and on the online platform.

HC – Canada

Regional Online training programs highlighting the importance of providing quality reports - minimum data elements and additional elements for completeness and assessment.
(Described under Q26)

Feedback: if required, we call the reporter for additional information/clarification and at that time, remind the reporter that Health Canada's ability to detect health product safety issues depends on the quality, accuracy and completeness of the reports we receive. It's an opportunity for us to remind reporters that complete reports help us with the evaluation process.

This is also an opportunity to discuss the program, value of reporting and rationale for such requests for assessment purposes. Reporters are often very pleased to hear that a regulatory body is actually looking at the information they have and gathering additional details. These personal interactions also can result in identifying new stakeholders and education opportunities.

The national and the regional offices also receive inquiries via phone, e-mail and mail which result in additional information being provided to stakeholders about Health Canada's post-market surveillance program (Canada Vigilance Program). Responses to professional stakeholders foster and strengthen our working relationships

Improving quality – Q46 - Focussed training

MHRA - UK

Regional events and courses e.g. med errors.

Recently training was given with IT suppliers Furthermore, in a bid to continue to support the integration of the Yellow Card into GP systems and improve reporting quality a meeting between the MHRA and SystmOne trainers was arranged in Newcastle. Further conversations and opportunities for engagement from this meeting will be pursued throughout 2018. MHRA would look to continue this collaboration with other clinical system suppliers

TGA – Australia

This has been described earlier.

HC – Canada

The regional centres conduct workshops with pharmacy students to give them the opportunity to find the ADR reporting form on the Health Canada website and to learn how to fill out the form accurately. We also use cases to review the information that should be provided on the ADR reporting form.

These workshops are focused learning activities (details provided in Q26, Q27, and Q36). Tell me and I'll forget. Show me and I'll remember. Involve me and I'll understand. - Confucius. This is the basis of these activities. Mock patient interviews, completing mock reports, receiving feedback on mock reports, searching and using web based resource tools, signing up for e-notifications, searching for risk communications, on-site to answer questions while completing a report. Such interactions also serve to identify previously encountered challenges real life situations.

CADRM/CFDA – China

The National Centre trains provincial centres, and provincial centres train medical institutions.

Improving quality – Q46 - Specific networks

MHRA - UK

Raising awareness about reporting and quality through networks and champions. One example is below:

The NHS Improvement & National Medication Safety Network:

In March 2014, a significant piece of partnership work was undertaken by the MHRA in conjunction with the patient safety team at NHS England, which function has now moved to NHS Improvement. Jointly, two patient safety alerts were issued to help healthcare providers increase incident reporting for medication errors and medical devices explaining this work and to emphasize the importance of reporting. The alerts also instructed providers to take specific steps such as board level director (medical or nursing supported by the chief pharmacist) oversight, the establishment of safety officers to improve local reporting and increase data quality; and the establishment of national networks to maximize learning and provide guidance on minimizing harm relating to these two incident types.

As of 2018 there are approximately 500 Medication Safety Officers (MSOs) and 360 Medical Device Safety Officers within the network in England. These officers are mainly based in hospitals in England. In addition to increasing reporting and data quality, they act as safety contacts to allow better communication between local and national levels.

The two networks act as a forum for discussing potential and recognised safety issues, identifying trends and actions to improve the safe use of medicines and medical devices, much of which takes place via monthly webinars. A new online forum for MSOs and MDSOs was also developed to share information and promote discussion on important safety topics. The network has also seen the creation of smaller networks, discussion groups and online information forums in specific regions, clinical specialities and some healthcare settings. Devolved Administrations and independent healthcare organisations are also guest participants of the networks to increase transparency and encourage greater coherent vigilance activities across the UK.

Supporting the networks are annual run conferences and local meetings organized by MSOs themselves. The network has shown to be an important new route for healthcare professionals to raise potential safety signals which have resulted in regulatory action for both medicines and medical device incidents and an increase in reporting and quality. The MHRA also published a paper on this topic.

This will be synergistic and will be aligned with the World Health Organisation Global Patient Safety Challenge on Medication Safety that was launched in March 2017 through a patient safety conference to reduce severe, avoidable medication-associated harm. In addition to improving the quality of reporting, the MSOs serve as the essential link between the identification and implementation of (local and national) medication safety initiatives and the daily operations to improve patient safety with the use of medicines. Monthly web conferences take place with approximately 100 attendees on each occasion where there is an incident review, topic focus and round up of all safety information.

The National Reporting and Learning System (NRLS) is the English NHS system for reporting incidents within the NHS. These may include ADRs and have historically included incidents of medication error. MHRA and NHS England have been working together to improve data ex-change so that both parties get the data they need to investigate issues within their respective remits. NRLS is to be redeveloped in the coming years and the MHRA will be a key partner to help ensure the format and quality of reports for suspected ADRs meet the needs of the MHRA. This will include working with suppliers of local risk management systems where many cases of interest are initially recorded before transfer into NRLS so they can be sent directly to the MHRA. Since the Scheme covers the whole of the UK and whilst many of the collaborative links mentioned above are for the English health system, parallel discussions continue to be held with the other governments to ensure the benefits of such collaborations can be mirrored across the UK.

TGA – Australia

We liaise with a range of HCP professional groups through standing committees and at other times as required.

Improving quality – Q46 - Local outreach (e.g. hospitals or regional monitoring centres)

MPA – Sweden

Regional centres

MHRA - UK

Covered by networks and education. In addition, the five regional Yellow Card Centres (YCCs) perform an important role in supporting the Yellow Card Scheme through delivering local training, education, communication, feedback, including strategic and promotional activities. Such activities help the MHRA strengthen surveillance locally and nationally to stimulate an increase in suspected ADR reporting and general awareness of the Yellow Card Scheme. Their stakeholders include devolved administrations (for the Welsh and Scottish YCCs), HCPs and their representative organisations both at primary and secondary care level. Educational elements also include training of post graduates and undergraduates. Over recent years YCCs have also interacted with patients, their organisations and charities to raise awareness and increase suspected ADR reporting.

Overall SMART objectives are set out and agreed for all YCCs which align with the MHRAs Yellow Card Strategy to increase reporting and quality of suspected ADRs. They are mainly in teaching hospitals and provide a valuable resource for providing advice and direction for educational activities so that ADR reporting is on the agenda of student HCPs and those HCPs that are practicing. To this effect, YCCs have developed their own e-learning modules available on their website which are used further to motivate and educate regional reporters. One YCC has worked with a national provider to input into a national e-learning module consisting of 3 units on PV and suspected ADRs.

The MHRA provides quarterly trending data for YCCs to analyse, including reporter qualifications, age, sex, suspected ADR numbers, geographical locations, types of medicines and suspected ADRs. This enables YCCs to focus their strategy and efforts on areas where a drive or campaign is needed locally.

YCCs often run their own campaigns to distribute materials they develop, approved by the MHRA, so there is flexibility for creativity and tailoring to the appetite of local reporters. YCCs also organise and attend workshops, lectures, meetings, write publications, conduct studies that add value to PV and ADR reporting, and organise event days for local HCPs to encourage suspected ADR reporting and educate them. All YCCs attend and are invited to speak at local conferences and congresses to represent the Yellow Card Scheme and encourage reporting for HCPs and patients related topics. YCCs often share their campaign collateral with each other.

Over recent years, YCCs interact more with patients as they seek to collaborate with patient organisations and specific disease areas to promote reporting through campaigns and mini-projects as per their objectives. Within devolved administration government areas they also coordinate with Expert Patient Programme, supplying leaflets, forms and packs when required.

The contact details for YCCs are promoted within the British National Formulary (BNF) and where possible in Agency communications relating to Yellow Card Scheme.

Generic templates for presentations were also issued to YCCs to enable stakeholders to acknowledge and relate that YCCs are commissioned by the MHRA in a formal capacity. This also aids with the gravitas of messages about suspected ADRs and affiliation to a national approach. A new way of working and collaboration now takes place through quarterly telephone conferences with all 5 YCCs and the MHRA to facilitate greater lines of communication, more harmonisation, sharing of good practice and ideas to promote suspected ADR work so more of an efficient focus can be put into campaign efforts. It also allows a multi-pronged feedback system between the MHRA, YCCs and HCPs within the healthcare system. YCCs submit annual reports to the MHRA to reflect on progress and report on their promotional work and future activities.

YCC Wales set up local champions in health boards in Wales which has been adopted by other regional centres. The role specification for the Hospital Champion Scheme was agreed to:

- Act as an information resource, provide guidance and to deal with local queries on PV and Yellow Card reporting
- Proactively assist other colleagues in the completion of Yellow Cards as a result of suspected ADRs
- Provide education and training sessions on PV and Yellow Card reporting to hospital staff
- Increase local publicity of the Yellow Card Scheme
- Keep up to date with legislative changes at the MHRA and EMA and communicate these and other drug safety issues to the relevant parties
- Attend a training session at YCC Wales
- Provide YCC Wales details of all training sessions undertaken.

HSA – Singapore

Roadshows are conducted to educate HCPs on how to submit a good quality ADR report.

HC – Canada

See Q27 (In terms of educating HCPs about suspected ADRs, what are the most successful approaches made in your country and why) and Q80 (Educational activities for HCPs, post and pre-graduate)

Improving quality – Q46 - Provide examples of good quality reports

MHRA - UK

Case studies, example reports in presentations, and monthly incident review with safety officers to highlight areas of concern/issues.

COFEPRIS – Mexico

They are used in the face-to-face workshops that are carried out periodically, answering and resolving the doubts of the participants. It is very useful and didactic to work with real cases and on the online platform.

HC – Canada

As a learning tool, a case scenario is presented accompanied by a low-quality report. Students/HCPs are tasked to identify how to improve the quality of information taking into consideration the clinical skills of patient assessment to assist them in understanding the

importance of providing relevant information such as, concomitant medications, medical history etc. to facilitate the identification of new potential safety signals.

Improving quality – Q46 - Specific tools and template methodologies

MHRA - UK

We have our own internal quality audit to improve internal classification to improve quality.

There is also QA audit on reports from Industry was feedback.

See below future plans for tools and template methodologies being developed.

Improving quality – Q46 - Future plans

MPA – Sweden

Electronic reporting directly from the medical record systems

MHRA - UK

With the number of reports received through integrated clinical systems increasing, the MHRA is undertaking the development of a pilot study of the quality of reports received via these integrated channels. As part of this, we are using the learnings from the Clinical Documentation tool (ClinDoc), developed by the Netherlands Pharmacovigilance Centre Lareb for the WEB-RADR project, to consider how best to evaluate the quality of our cases. Using both ClinDoc and our own tools developed for the purpose, we are considering both the completeness of the case in terms of the information provided and the strength of the case in terms of signal management. As a control, we are comparing how the quality of cases from clinical systems differs from the quality of electronic cases reported via the Yellow Card website. We are also looking at the tool in Oosterhuis et al.

There will be future feedback to reporters about on their reports that result in a signal and regulatory action. This is being developed and to be piloted.

Future plans to produce APIs for reporting which has many applications.

HSA - Singapore

IT enhancement of electronic reporting forms.

TGA – Australia

Currently in the process of developing a long-running survey that will provide a "Baseline" for awareness of AE reporting, both via HCPs and consumers and then we can track changes over time in subsequent years.

Through working to integrate AE reporting into HCP software.

Refining and improving our electronic forms to better integrate into our systems.

Improving quality – Q48 – Most successful efforts to improve quality of ADR reports

MPA – Sweden

E-forms with mandatory fields and guidance

Secure line to report electronically from the HCPs using the web form

MHRA - UK

electronic methods, IT solutions coupled with guidance, the use of HCP networks, educational activities and e-learning

internal audit functions - MHRA runs a QMS system

MHLW/PMDA – Japan

Efforts for improvement is underway.

HSA - Singapore

IT/Technical solutions: Provides rapid and seamless reporting as HCPs manage their patients during consultations

ANVISA – Brazil

Those efforts are depending on the acquisition of the new IT solution.

COFEPRIS - Mexico

The most successful effort has been to review and update the standard (NOM-220-SSA1) for the Installation and Operation of Pharmacovigilance, since in addition to standardizing criteria with international standards, the role and activities of each one of the participants in the PV are clearly specified. Additionally, the notification system can code the minimum degree of report, which does not allow the sending of incomplete or unnecessary information.

CADRM/CFDA – China

Realise online reports, reduce errors in the free entry of standardised content through the Selection (of fields), and increase the level of completion through training.

9. Improving quality – Q49 – Least successful efforts to improve quality of ADR reports

MHRA - UK

Difficult to measure least effective ways to improve quality

MHLW/PMDA – Japan

Efforts for improvement is underway.

COFEPRIS – Mexico

The least successful effort has been to try to include the topic of Pharmacovigilance as a subject in some universities.

Improving quality – Q50 – How have you improved the quality of suspected ADR reporting through electronic methods? Which are the most and least successful and why

MPA – Sweden

See above

MHRA - UK

Already covered within previous answers

MHLW/PMDA - Japan

HSA – Singapore

Consideration has been given to making some fields of the electronic AE report mandatory for HCPs fill in (to fulfill the VigiGrade completeness score). However, this is not a good solution as it makes reporting burdensome for HCPs. This may also compromise the volume of reports if HCPs find it too challenging to submit a simple AE report.

COFEPRIS – Mexico

During the use of the electronic platform in the workshops, user comments are emerging. One of the improvements has been to distinguish which are the obligatory questions for the sending of the notification and which are the necessary questions for the correct evaluation.

HC – Canada

The Online Form on Health Canada Drug and Health Product Register (DHPR) page (<https://hpr-rps.hres.ca/?lang=en>) guides the user to fill in key data fields. The use of drop down codes helps ensure we receive standardized data. The form on DHPR is assigned a few key fields that are categorized as mandatory in order for the report to be accepted (<https://hpr-rps.hres.ca/static/content/form-formule.php>).

A minority of reports which are not e-reported are entered into the system manually.

Reports submitted via the DHPR do have higher completeness scores than non-DHPR reports.

Health Canada is in the process of updating its infrastructure to automate uploading into a standard format.

CADRM/CFDA – China

Realise online reporting, reduce errors in the free entry of standardised content through the selection of fields.

Feedback – Q52 - What's been the most successful approaches and why?

MPA – Sweden

No measurement performed

MHRA - UK

- Through Networks e.g. healthcare professionals
- iDAPs (<https://yellowcard.mhra.gov.uk/iDAP/>)
- the app – medicines of interest, safety bulletins and access to iDAPs
- case studies used in promotion and information about regulatory action taken, information on leaflets about value of reporting outcomes and messages in campaigns.
- through enquiries, acknowledgement letters, via DHPCs
- case studies/contribution to PV example:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/607628/Contribution_of_Yellow_Cards_to_identifying_safety_issues.pdf
- ADRIC study and Avery independent reviews reinforced Agency view that people want to know about the value of their reports.

HSA – Singapore

The most successful approach would be to engage the reporters directly regarding the reports they have submitted to obtain follow up information and inform them that their reports have contributed to positive regulatory outcome.

COFEPRIS – Mexico

The e-mail of submitted reports provides at the end of the questionnaire, a message to the user with a code number for the follow-up, and a copy of the questionnaire.

HC - Canada

Continuous engagement is key

CADRM/CFDA – China

Publish information on adverse drug reactions and provide safety information to the public.

Feedback – Q53 - What's been the least successful approaches and why?

MPA – Sweden

No measurement performed

MHRA - UK

Being able to get back to reporters to feedback about signals due to regulatory timelines which might take months.

HSA – Singapore

Through the website as HCPs are required to be aware of information published.

ANVISA - Brazil

Speaking opportunities, because of the absence of a specific feedback

COFEPRIS – Mexico

At this moment, we are under implementation of a new standard. We realise that, it has had good acceptance, despite this, there are some difficulties using the new technological tools.

Feedback – Q54 - Future plans to strengthen feedback to improve reporting and quality?

MPA – Sweden

Individual feedback to reporters in relation to detected suspected signals, more specific information on the web site.

MHRA - UK

As mentioned, a pilot to feedback on contribution of their reports to risk mitigation, signals and regulatory actions to reporters, ongoing work with CPRD and PV outcomes.

HSA – Singapore

More engagement with the reporters.

ANVISA – Brazil

We are studying the best way. We hope to learn more in ICMRA group

COFEPRIS – Mexico

It is planned to periodically publish on the federal government's website, reports received at the national pharmacovigilance centre, such as the number of ADR, quality of information, severity and possible actions carried out by the authority.

Facilitation – Q55 - What solutions have you implemented to improve the ease of reporting? Which are the most and least successful and why?

MPA - Sweden

"E-forms for HCPs and Consumers.

A pilot planned during 2018 to have direct electronic reporting of ADRs from the HCPs medical record system."

MHRA - UK

Making as many methods available to report as possible, ensuring forms are widely accessible with relevant information at the right places.

For paper forms, all have a freepost address on the back. The HCP forms are designed so they can be folded and sealed, and the patient form has a detachable pre-paid envelope that the form can be inserted into. Both types have the address pre-printed on the front side of the envelope. Forms can be downloaded too or sent out. There is a dedicated telephone line for reporting.

Electronic methods - webform, app, integration into clinical systems are the most successful and popular methods of reporting.

HSA - Singapore

In 2006, HSA implemented the Critical Medication Information Store (CMIS), a national electronic platform in all public healthcare institutions in Singapore. CMIS allows HCPs to record, access adverse drug reactions in the patients' medical records online and submit these reports directly to HSA.

The CMIS allows HCPs to enter allergies and ADRs into the hospital electronic medical records system during routine clinical management of each patient. This information flows seamlessly to HSA on a daily basis, removing the need for HCPs to submit a separate report. There are two forms: the Quick Report which contains fewer fields and can be completed quickly, and the Full Report which allows more information to be entered.

Since the implementation of CMIS, the number of reports received has increased from around 1,000 per year to 20,000 per year. While the quantity has increased, the types of ADRs reported via CMIS typically lean towards allergies (e.g. angioedema, rash), and often contain limited information.

Each CMIS report is reviewed by two officers before they are accepted into the ADR database. To streamline the review process, the system has been designed to (1) filter away ADR reports which are invalid (e.g. reports of drug classes, non-drugs or unknown drugs/reaction), (2) automatically code commonly reported ADRs, and (3) highlight possible duplicate reports.

ANVISA - Brazil

IT solutions to simplify the reporting form and make easier

TGA - Australia

As mentioned earlier, we have been reworking our online forms and working towards integrating AE reporting in clinical software.

COFEPRIS - Mexico

The most successful solution to improve the ease of reporting has been the standardization of the reporting format with international instances such as ICH E2B, and the implementation of MedDRA terminology.

HC - Canada

Health Canada offers multiple methods of reporting, including an online form, enterable PDF, postage paid form, etc.

The most successful method is the online reporting form (<https://hpr-rps.hres.ca/static/content/form-formule.php>) see Q50

The least successful is the postage paid form as it is not a straight forward process. This method is being discontinued.

As already stated in Q23 in one region, Health Canada collaborated with the provincial patient safety database to leverage existing patient safety reporting mechanisms to optimize the transfer of information without presenting a cumbersome process to institutions. While there was no formal assessment of the success/failure of the launch, the number of ADR reports submitted by the regional health authority was monitored for the first 6 months after launch. In the first health authority to come on board, there was a quadrupling of reporting

over the previous four months prior to the launch date. We also noticed a trend towards a range of different reporters (not just the traditional reporters from pharmacy, medicine or nursing). (<http://bcpslcentral.ca/online-adr-reporting-is-coming/>)

CADRM/CFDA – China

Realise online reports; Electronic Health Records and clinical software integration are future plans.