SCOPE Work Package 4
ADR Collection

Increasing Awareness of National Adverse Drug Reaction Reporting Systems: Best Practice Guide

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Acknowledgments

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1. Introduction

1.1 Background

The SCOPE Work Package 4, Topic 3 (WP4.3) is about increasing awareness levels of national adverse drug reaction (ADR) reporting systems. Its aim is to enable and facilitate National Competent Authorities (NCAs) with a set of tools, template methodologies and sharing of knowledge through the establishment of good practice examples across Member States (MS).

A questionnaire aimed at sharing and identifying good practice was circulated to NCAs. A Survey Report (Annex 1) was produced after analysing the findings. Its recommendations were presented to the WP4 leads meeting in June 2015. It was agreed at that meeting that the recommendations informed the need to compile a guidance document covering a number of areas to help NCAs to increase awareness levels of their national spontaneous ADR reporting schemes.

1.2 Purpose of the document

This document provides guidance for consideration by NCAs and their pharmacovigilance centres to increase the number and quality of reports of suspected adverse drug reactions (ADR) entered into their national ADR reporting systems. The guidance refers to example case studies identified and developed from the information supplied by NCAs and pharmacovigilance (PV) centres from the SCOPE Work Package 4, survey on awareness levels (Annex 6).

The purpose of this guidance document is to:

- Complement existing approaches used by NCAs to increase awareness levels

- Highlight extra areas where NCAs can consider adding to their existing strategies

- Highlight good practice from campaigns to increase suspected ADR reporting

- Explore and highlight methods used by NCAs to evaluate their campaigns

- Highlight examples of how regional centres are increasing awareness levels of suspected ADR reporting.

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1.3 Scope

The guidance presents areas where good practice is demonstrated. Such good practice is identified from NCAs that shared information by completing the Work Package 4 survey on raising awareness.

Supported by a document entitled 'Raising awareness of national ADR reporting systems: **case studies by country**', there are two parts that make up this guidance:

• **The SCOPE Strategy for increasing awareness levels of national suspected ADR reporting systems** – a strategy for raising awareness levels, including drivers and referring to example strategies adopted by NCAs and national PV centres. The guidance includes questions that can be used to measure baseline awareness levels for ADR reporting. Such questions can help measure success of any future activity. Examples are shown by various NCAs that have approached benchmarking in this way. It also includes examples of digital initiatives used by NCAs to communicate with stakeholders, in order to increase awareness levels.

• **Raising and measuring awareness levels for ADR reporting systems through campaigns and Regional Monitoring Centres.** The guidance also includes how awareness is measured and refers to specific case studies from NCAs, including examples of the use of social media. It also includes:

   – A 'good practice points to consider guide for developing an effective ADR communications campaign'.

   – A 'checklist to measure campaign success'.

1.4 Limitations/disclaimer

Information used within this guidance is based upon the analysis of the responses to questions from Member States from the SCOPE Work Package 4 survey. It also includes information gathered from further follow-up requested by the author. Follow-up was conducted to gain further insight, documentation and information about responses. If no information was provided at the time of the survey responses or upon subsequent follow-up requests it will not be reflected within the content. As a result case studies vary in the level of detail.

1.5 Definitions and abbreviations

Terminology	Description
ADR(s)	Adverse Drug Reaction(s)
CPD / CPE	Continuous Professional Development / Education
DHPC	Direct Healthcare Professional Communication (DHPC)
EMA	European Medicines Agency

Terminology	Description
GP	General Practitioner
HCP	Healthcare professional
KPI	Key Performance Indicator
MHRA	Medicines and Healthcare products Regulatory Agency (UK)
MAH	Marketing Authorisation Holder
MedDRA	Medical Dictionary for Regulatory Activities
Patient	Members of the Public – includes patients, parents and carers
MS	Member State
NCA	National Competent Authority
NHS	National Health Service (or Systems)
PIL	Patient Information Leaflet
PV	Pharmacovigilance
SCOPE	Strengthening Collaboration for Operating Pharmacovigilance in Europe
SmPC or SPC	Summary of Product Characteristics
WP	Work Package

1.6 List of attachments

Ref No	Document name	Author(s)
Annex 1	Awareness Levels Survey Report	Mitul Jadeja, Paul Barrow
Annex 2	HALMED Strategic Plan 2014-2018	HALMED
Annex 3	Yellow Card Strategy 2011	MHRA – Mitul Jadeja, Paul Barrow
Annex 4	Annex 4 Yellow Card Strategy Update 2013 and a paediatrics communications strategy	MHRA – Mitul Jadeja, Paul Barrow
Annex 6	Raising awareness of national ADR reporting systems: case studies by country	Mitul Jadeja

2. The SCOPE strategy for raising awareness levels of national ADR reporting systems

2.1 What does 'strategy' mean?

For the purposes of the SCOPE Work Package 4 survey 'strategy' was defined as:

'A plan or systematic approach for raising awareness levels, typically over a long period of time'

The reasoning behind this was that it was known that many NCAs do not have a separate strategy to increase awareness of their national adverse drug reaction (ADR) reporting systems, but have conducted some form of awareness-raising activities.

At the minimum, any strategy should address these three elementary questions:

- Where are you now? (section 5)

- Where do you want to be? (section 7)

- How are you going to get there? (section 8)

2.2 The four pillars of the SCOPE strategy

The effectiveness of spontaneous ADR systems in detecting drug safety issues is dependent upon sufficient reporting of high-quality data. As a result, the system is reliant upon the good will and vigilance of healthcare professionals (HCPs) and patients, not only in identifying suspected ADR reports, but also reporting them. Patient reporting includes reporting from patients, parents and carers.

ADR reporting schemes are recognised to be subject to under-reporting [1,2,3]. Efforts to increase numbers of timely and well-completed ADR reports increases the data available to NCAs. This improves their ability to detect, identify, investigate and act on potential drug safety issues, thereby helping to protect public health.

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[1] Moride Y, Haramburu F, Requejo AA, Begaud B. (1997) Under-reporting of adverse drug reactions in general practice. Br J Clin Pharmacol 43: 177-81

[2] Martin MR, Kapoor KV, Wilton LV, and Mann RD. (1998) Underreporting of suspected adverse drug reactions to newly marketed ("black triangle") drugs in general practice: observational study. BMJ Jul 317: 119-120

[3] Hazell L, Shakir SAW. (2006) Under-Reporting of Adverse Drug Reactions A Systematic Review. Drug Safety 29(5): 385-39

The SCOPE strategy presented is:

> *Activities to encourage an increase in the number and quality of suspected ADRs reported to national ADR reporting schemes by healthcare professionals, patients, parents and carers.*

The SCOPE strategy is made up of by four pillars: facilitation, education, motivation and promotion. Activities within each pillar are often based around forming collaborations and partnerships with other organisations. For each pillar there are suggestions for MSs NCAs to consider when developing their own strategy to strengthen their suspected ADR reporting system.
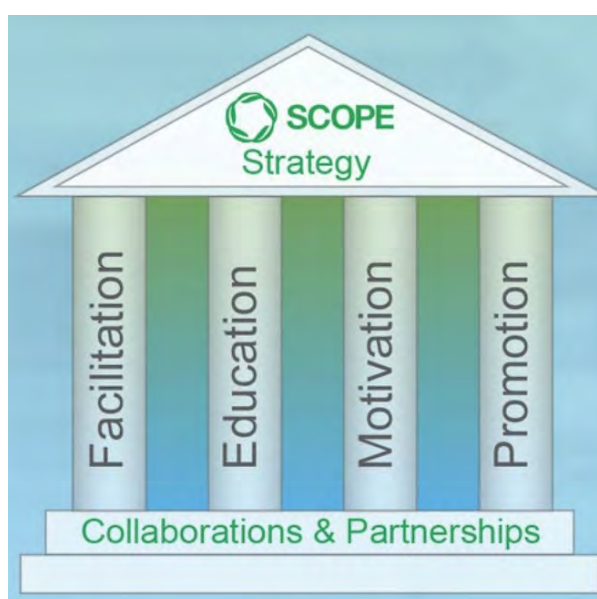

Figure 1. The four pillars of the SCOPE strategy

The four pillars are based on the HMA levers to increase ADR reporting rates and upon the UK's Yellow Card Strategy.

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3. Background and key drivers

3.1 EU Legislation – Directive 2001/83/EC

The new European PV legislation, which came into force in 2013, states that NCAs have an overall responsibility to improve and encourage reporting of ADRs within their respective countries. NCAs are advised in Article 102 of Directive 2010/84/EU amending Directive 2001/83/EC that:

'The Member States shall:

Article 102 (a) – '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;'

'Appropriate measures' to strengthen reporting may be different between Member States. The legislation also gives importance to raising the awareness of the national spontaneous reporting system with patients and their organisations. This guidance aims to help NCAs and their national PV centres consider how they might encourage reporting. It is based around the suggestion of using suspected ADR reporting trends to identify reporting groups or areas where there are low levels of reporting, or where strengthening activities can be focused. A greater understanding of reporter groups, and the health system in which they operate, can help shape strategy direction.

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3.2 HMA strategy

A Strategy for the Heads of Medicines Agencies[4], 2011-15 adopted at the HMA meeting on 25 October 2010, aligns itself to supporting the strengthening of spontaneous ADR reporting systems. It is important that NCAs demonstrate how efforts to develop their ADR reporting systems are seen to respond to the elements of the HMA strategy.

Section 5.8 of the HMA strategy

'Previous work showed wide variations between Member States in spontaneous reporting rates for suspected Adverse Drug Reactions (ADRs).'

'Levers to improve such rates include:

- *__education__ – of healthcare professionals, patients and the public.*

- *__motivation__ – using incentives for reporting, such as prompt feedback.*

- *__facilitation__ – maximising the use of Information Technology.*

- *__promotion__ – general awareness raising on the importance of pharmacovigilance for public health protection.'*

Section 5.9 HMA strategy

'HMA will seek to promote consistently high standards of spontaneous reporting throughout the Network, using the forthcoming pharmacovigilance legislation and the opportunities for spreading best practice through the existing scientific contacts among the NCAs and at the EMA.'

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[4] A Strategy for the Heads of Medicines Agencies, 2011-15. http://www.hma.eu/fileadmin/dateien/HMA_joint/02-_HMA_Strategy_Annual_Reports/02-HMA_Strategy_Paper/2010_12_HMA_StrategyPaperII.pdf - Accessed 29 October 2015

4. Strategies used by Member States

NCAs were asked if they had a strategy for raising awareness levels of their national suspected ADR reporting system. Eighteen NCAs (64%) responded indicating they had a strategy based on the definition set out in section 2.1. Nine (32%) did not and one stated they are not responsible for creating a strategy. Free-text responses from 17 NCAs described their own strategies on raising awareness (including links to information if publicly available). Analysis of these showed only 11 were considered to be some form of strategy. Most were not documented in any great detail.

Many respondents presented information or links in their national language(s) and were then translated. Common themes were education through publication and lectures, with concern for raising the number of ADR reports.

4.1 Documented strategies from NCAs and an example of good practice

Only five NCAs suggested or referred to a documented strategy. Upon follow-up, the number increased to six. These strategies are outlined within the case studies for raising awareness levels of national ADR reporting systems by country for:

- Croatia (Annex 2 contains HALMED's Strategic Plan 2014-2018)

- Greece

- Malta

- Netherlands

- Romania

- United Kingdom. Although none of the Yellow Card strategy papers are formally published, the MHRA has shared the latest (at the time of this report) two documents of its updated Yellow Card strategy:

  – Annex 3. Yellow Card Strategy 2011

  – Annex 4. Yellow Card Strategy Update 2013 and a paediatrics communications strategy

5. Where are you now? (analysing ADR trends and reporter groups)

It is important to know where you are before developing your own strategy to increase awareness levels and improve reporting, in order to focus resources and efforts. This can be achieved through an analysis of current ADR trends by reporter group, previous years, and types of data, which can help identify areas to focus on.

5.1 ADR trends to analyse current reporting rates

A good place to start is to analyse the overall numbers of suspected ADR reports over a five year period. One can take a high level analysis looking at the numbers, types and proportion of reports received.

The total number of reports submitted directly to the NCA compared to those received via the pharmaceutical industry gives a good benchmark of 'direct reporting' from HCPs and patients. This can be further analysed to look at the numbers and proportions of serious and fatal reactions, the numbers of direct reports from HCPs and patients, the numbers and proportions of electronic reports from these sources, numbers of direct paediatric (>18) and elderly reports (65+), numbers of medication errors, reports of additional monitored drugs, herbal and vaccine products.

An example format for this can be found in Annex 5, Table 2.

A trend analysis is recommended for a minimum of two years up to five years to establish the numbers of suspected ADR reports received directly by different reporter groups. At the minimum, for smaller PV resources this could be restricted to the main reporter groups, which are usually: members of public, pharmacists, nurses and doctors as shown in Annex 5, Table 3.

One could also do a more detailed analysis of more reporter groups over time, adapted and expanded from E2B (R2) ISCR specification standard, A.2.1.4 [5]. This can help identify changes in reporting numbers and the areas where efforts should be focused. An example can be found in Annex 6, Table 4.

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[5] http://www.ich.org/products/electronic-standards.html

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Clustered column chart graphs in Microsoft Excel are a useful way of displaying such information. An example is shown in **Figure 2** below adapted from the 2014 annual report of the UK's Human Medicines Regulations 2012 Advisory Bodies[6].
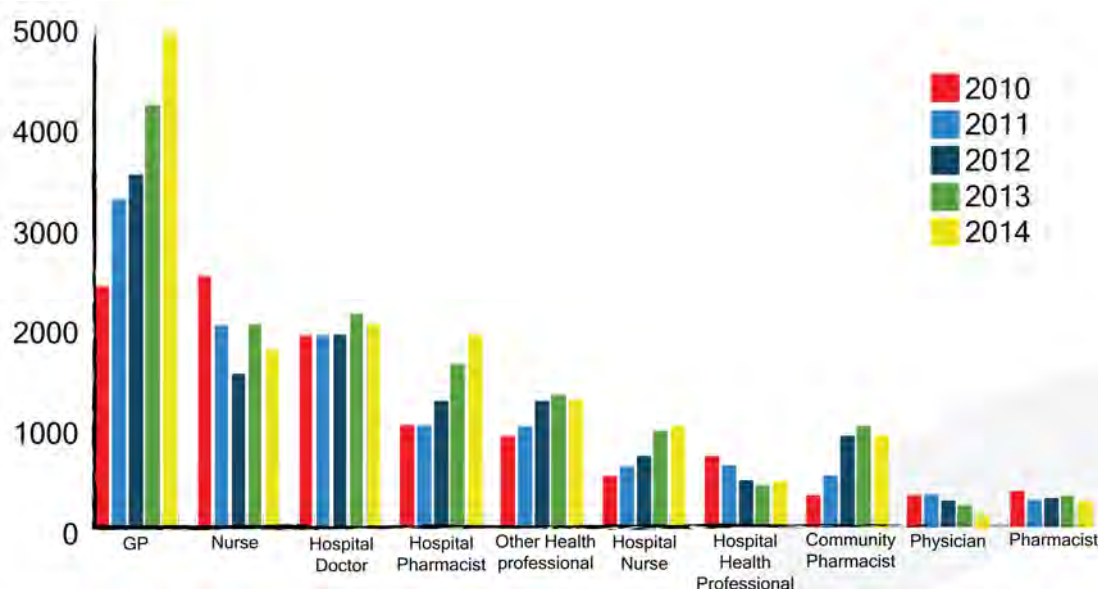

Figure 2. Number of direct UK spontaneous suspected ADR reports received by the Yellow Card Scheme between 2010 and 2014, broken down by reporter qualification

Other health professionals include: dentists, optometrists, coroners, healthcare assistants, paramedics, chiropodists, medical students and other non-specified health professionals

Trends such as large falls or low levels of ADR reporting can be used to prioritise where to focus efforts. Trends can be also used to identify and further investigate why reporting might have increased for certain periods of time in a particular reporter group – for example, due to efforts to raise awareness, safety issues, media, general publicity about a particular ADR and medicine, or a particular campaign. One may also see potential correlations between related reporter groups, e.g. increase in nurse reporting and decline in GP reporting.

Some activities to increase awareness levels are difficult to measure. The easiest to measure is changes in ADR reporting rates over a specific period of time.

It is not absolutely essential to identify all of the specific factors underlying the trends in reporting before progress is made to develop or implement a strategy, but it may be useful to gain an understanding of the situation.

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[6] https://www.gov.uk/government/publications/human-medicines-regulations-2012-advisory-bodies-annual-report-2014, reporting of suspected adverse drug reactions, Pg 34, Figure 2: accessed 28 January 2016

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5.2 Identifying your stakeholders and knowing your audience

NCAs interact with stakeholders on numerous levels in order to increase awareness, as detailed within the WP4 Awareness levels Survey Report. The majority of this occurs through interaction with HCPs and trainees (24, 89%), followed by professional bodies (19, 73%) and national health services (18, 67%) to encourage reporting.

Gaining an understanding of the factors influencing the reporting of stakeholders can be valuable. Such work could highlight specific issues, enabling NCAs to focus efforts on strengthening reporting from these groups. It may also be useful to look more widely and include groups of HCPs where reporting levels are stable or increasing. It may be worth exploring to establish any key factors which motivate, demotivate or stimulate these groups to report. One can consider the relevance of these findings to drive efforts to stimulate reporting either generally or from specific reporting groups.

Understanding reasons behind patient reporting is valuable for an NCA to encourage reporting and increase awareness. A useful independent study from the UK highlighted the importance and value of patient reporting, including examining the issues and barriers to reporting through questionnaires and ADR data from the NCA[7]. There have also been other studies examining existing practices in consumer and patient reporting conducted globally.[8]

Most stakeholder analysis and identification is conducted at an NCA level, often from improving a customer service point of view. A detailed stakeholder analysis can help shape both messages and responses. There are many methods to do this. An example from the UK is a stakeholder matrix model, which looks at current behaviours and attitudes moving to future and desired behaviour and attitudes. An example related to patients is shown below. This matrix model can be tailored for each stakeholder and can help inform strategy implementation or communication tasks. In this example, by answering the four questions within each quadrant, one can start to produce messages that are specific to patients. For example, it helps to formulate specific messages.

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[7] Avery AJ, Anderson C, Bond CM, Fortnum H, Gifford A, Hannaford PC, et al. Evaluation of patient reporting of adverse drug reactions to the UK 'Yellow Card Scheme': literature review, descriptive and qualitative analyses, and questionnaire surveys. Health Technol Assess 2011;15(20).
http://aura.abdn.ac.uk/bitstream/2164/2957/1/mon1520_YCS.pdf accessed 29 January 2016

[8] Van Hunsel F Härmark L, Pal S, Olsson S, van Grootheest K. Experiences with adverse drug reaction reporting by patients: an 11-country survey. Drug Saf. 2012 Jan 1;35(1):45-60. doi: 10.2165/11594320

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For example from the matrix in **Figure 3** below, key messages were extrapolated which included: report side effects online, the Agency monitors the safety of medicines, the reporting of their side effects matters and helps to contribute to patient safety.

Target: Public (general)   Aim: Increase patient reporting

Spell out what your audience does now

- Report just 6% of all reports
- Report established medicines
- Not aware of YC
- Lack understanding of what happens with reports
- Quality of reports are good
- Mainly find out through web searches/ website
- Mixed whether side effect is reported to HCP

What do you want them to do in future?

- Report side effects (ALL/more/specific?)
- Report online rather than by paper where possible

What are there current attitudes & beliefs? Why do they do what they do now?

- They don't know who looks after medicines
- They don't know about Yellow Card
- They don't get told that they can report by HCPs

What response do you want them to have to communication – What must they think/feel/believe to change behaviour

- That their side effects matter
- That it's important to report any suspected side effects
- That medicines are being looked after
- The YC scheme is open for all to report their side effects

Figure 3. UK example of a basic stakeholder analysis matrix for patients

6. Benchmarking – a formal assessment of awareness levels

Benchmarking through reporter surveys is identified as good practice, as it can provide useful quantitative results and qualitative analysis, which allows an NCA to gain a further understanding of the maturity levels of awareness for its reporters and potential reporters.

Benchmarking through qualitative survey methods can help focus messages and campaign efforts. It can help to tailor the complexity of messages and educational methods that may be used to raise awareness levels. Although a snapshot in time, it should be an effective tool available to an NCA to focus and measure the effectiveness of strategy efforts before and after implementation.

6.1 Results from survey

NCAs were asked if they had conducted any formal assessment of awareness levels and if so, with which target group.

Only few NCAs have estimated how well known their Agency is with HCPs (11) and public (6). Even less have estimated their ADR reporting scheme awareness with HCPs (8) and public (5).

A detailed analysis of this can be found within the survey report (Annex 1).

Case studies of good practice

Although some respondents in the survey confused an awareness level survey with a customer service or satisfaction survey. The 11 NCAs that described their formal assessment of awareness levels used a range of tools, techniques and varying audiences: telephone interviews, workshops with HCPs, questionnaires allied to other campaigns, quantitative polls of small numbers of selected HCPs from various settings, patient user groups, non-governmental organisations and industry, and large national omnibus surveys of the general public and HCPs.

Examples of benchmarking, to raise awareness of national ADR reporting systems and understand stakeholders, are shown from:

- Bulgaria
- Ireland
- Malta
- Portugal (with Netherlands)
- UK

6.2 Sharing best practice – a template of questions to ask and methodology

A robust survey method is to use an unbiased third party professional company to conduct national polls. Online survey tools such as SurveyMonkey[9] can also be useful. There are limitations to using online survey tools. Sometimes face to face stakeholder engagement brings added value to developing messages and gaining a greater understanding of the audience.

When asking questions it can be beneficial to understand what is known about medicines already, including their personal experience and concerns about medicines.[10]

Below is a set of questions that NCAs can use to benchmark awareness about ADR reporting. These have been adapted from the UK surveys[11,12, 13].

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[9] https://www.surveymonkey.com/ - accessed on 29 January 2016

[10] http://webarchive.nationalarchives.gov.uk/20150121113625/http://www.mhra.gov.uk/home/groups/comms-sp/documents/websiteresources/con2025477.pdf accessed 29 January 2016

[11] http://webarchive.nationalarchives.gov.uk/20150121113625/http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con052027.pdf - accessed 29 January 2016

[12] http://webarchive.nationalarchives.gov.uk/20150121113625/http://www.mhra.gov.uk/home/groups/comms-sp/documents/websiteresources/con2025479.pdf - accessed 29 January 2016
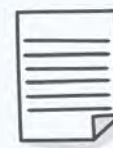
[13] http://webarchive.nationalarchives.gov.uk/20150121113625/http://www.mhra.gov.uk/home/groups/comms-sp/documents/websiteresources/con2025477.pdf - patient - accessed 29 January 2016

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Medicines Regulation

Who, or which organisation, if any, do you think regulates medicines to make sure they work and are safe enough to use?

Example answers can be:

- Healthcare professional regulators
- Healthcare professional bodies
- NHS
- Pharmaceutical companies
- The government
- Quango/department/agency
- (insert name of) NCA
- Don't know
- Other (please specify).

How much, if anything, would you say you know about the way medicines are regulated?

How much confidence, if any, do you have in the way medicines are regulated?

For both of the above questions example answers can be:

- A great deal
- A fair amount
- Not very much
- Nothing at all
- Don't know

The ADR reporting system

Who or which organisation, if any, would you contact if you wished to report an unexpected side effect with a medicine (or ADR if aimed at HCPs)?

Example answers can be:

- Doctor/GP
- Hospital
- The NHS
- List national professional organisations and organisations that regulate HCPs
- Pharmaceutical company
- Friend/relative/work colleague,
- Nurse
- Pharmacist
- (insert name of) NCA

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- None – I would not know who to contact
- None – I would not report it
- Don't know

If a patient reports an ADR to you, to whom or to which organisation would you report it, if anyone?

Example answers can be:

- Doctor
- Nurse
- Pharmacist
- National ADR reporting system
- (insert name of) NCA
- Local authority/trusts
- The patient's doctor
- Professional regulators
- Escalate with a superior
- The manufacturer/pharmaceutical/drug company, surgery/hospital/place where patient received treatment.

Barriers to reporting

Which, if any, of the following things would help you to report suspected ADRs?

Example answers can be:

- Online reporting
- Clearer reporting guidelines
- A mobile app
- Easier/faster access to reporting forms
- Feedback on reports
- Telephone reporting
- Paper supplies of reporting forms
- Nothing
- Other (specify)
- Don't know / can't recall

Tip: it is good have estimated awareness levels for the different types of HCPs for the above questions, for example for doctors, nurses and pharmacists. It can also help to gain insight for each groups perceptions and attitudes to the NCA and also to suspected ADR reporting. Which-ever questions NCAs choose to use, should be asked again at later dates to enable effective measurement and helps to identify any changes over time.

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7. Where do you want to be? (identifying, evaluating and planning your strategic options)

Using the information from benchmarking, trends and stakeholder engagement, the following are a set of recommended questions to ask for horizon scanning and when considering your strategy objectives:

- **Focus** - Across the national healthcare system, where will you choose to raise awareness levels and where will you not focus efforts? Why?

- **Stakeholders** - What about patients and their organisations? What sustainable actions or partnerships can you form to raise ADR reporting in these groups? How will you go about doing this?

- **Interactions** - How is your work linked to other national organisations, professional regulators and the national healthcare system in relation to patient safety?

- **Partnerships** - Have you explored the opportunity for collaboration?

- **Implementation** - What do you need to implement your strategy? What are the needs of your stakeholders?

- **Measuring success** - In each particular area of focus, how will you measure your goals to increase awareness levels and reporting? What does success look like? How can you measure this before and after implementing efforts?

- **Sustainable efforts** - How can strategy efforts be sustainable?

8. How you are going to get there? (based on SCOPE strategy – section 2.2)

The four pillars of the SCOPE strategy are: facilitation, education, motivation and promotion.

These can be looked at in turn with the aim of increasing the volume and quality of suspected ADR reports, ideally in a long-term, self-sufficient and sustainable way, identifying what is needed to maintain any key capabilities.

From this point onwards, the following sections contain a series of suggestions under each pillar for NCAs to consider. Each suggestion can be adapted to suit the national context. A good way of doing this could be the use of SMART[14] objectives. When tailoring a suggestion into an objective, it is important to think about what is necessary to build, maintain and sustain them into the planning process.

Each suggestion is accompanied, where possible, with case studies from NCAs that were identified from the responses to the WP4 survey and subsequent follow-up. The case studies intend to highlight where current practice is, and include identified good practice.

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[14] SMART: Specific – target a specific area for improvement, Measurable – quantify or at least suggest an indicator of progress, Assignable – specify who will do it, Realistic – state what results can realistically be achieved given available resources, Time-related – specify when the result(s) can be achieved.
https://en.wikipedia.org/wiki/SMART_criteria accessed 12 February 2016

9. Facilitation – making reporting easy and accessible

This pillar is about making reporting easy and accessible to meet the needs of reporters using a range of methods, including information technology (IT).
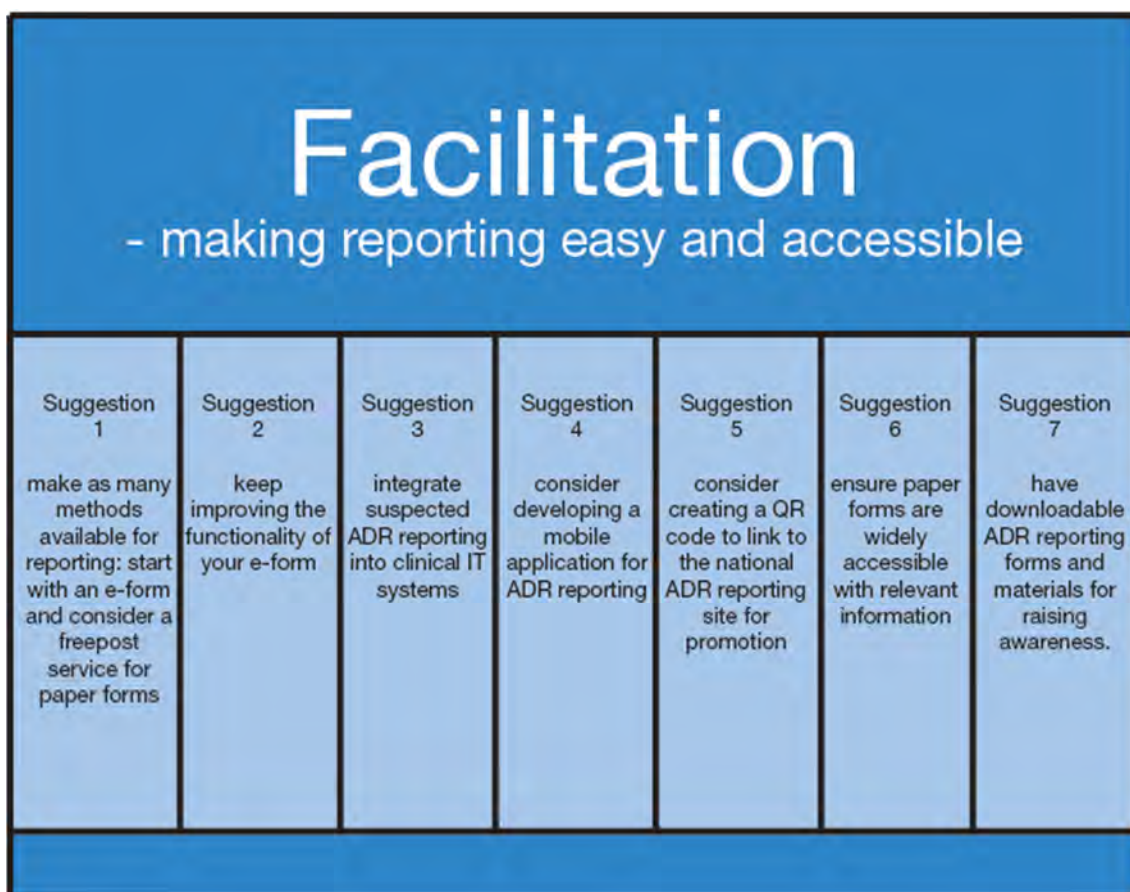
Figure 4. Suggestions for NCAs to consider incorporating within their strategy under facilitation

Suggestion 1 – make many methods available for reporting: start with an e-form, and consider a freepost service for paper forms

It is recognised that access to a variety of reporting modalities is important to provide convenient methods of reporting for HCPs and patients. **Figure 5** shows how NCAs facilitate improving the ease of reporting through their efforts.

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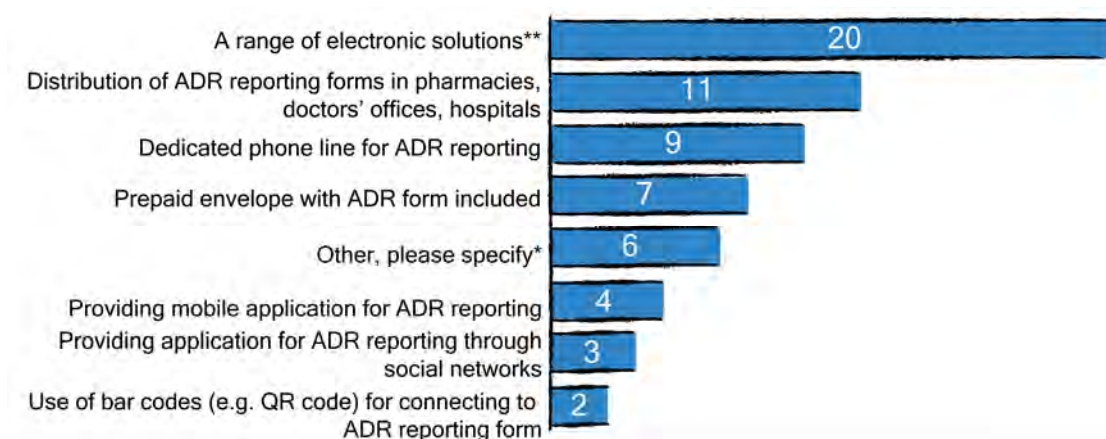**Figure 5. Responses to Q31 of the survey by NCAs(If you focus efforts on improving ease of ADR reporting, please indicate how)**

**A range of electronic solutions means the provision of technical solutions that minimises effort in ADR reporting; for example, pre-filled sections of ADR reporting form, e.g. deriving from electronic healthcare records or web application for ADR reporting. BG, LT, LV, MT, NO indicate that they do not focus on this element.

Q30 and **Q31** of the survey report at Annex 1 discuss this in more detail.

The easiest way to facilitate reporting is to have accessible forms. This can be achieved through a variety of methods:

- Electronically – some include:
    - An NCA's online reporting portal
    - Links from other websites and web-based applications
    - Clinical IT systems and local risk management systems, e.g. from hospitals
    - Bar or QR codes
    - SMS
    - email
    - Mobile applications
    - Social media

- Paper
    - NCA individual paper forms
    - Paper forms integrated into HCP guides, compendiums and national formularies
    - Postcards
    - Fax

- Telephone
    - Directly to NCA
    - Reported via NHS helplines
    - Complaints service

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More information on ADR collection and how forms are made available can be found in WP4.1 and WP4.4 survey reports. For example:
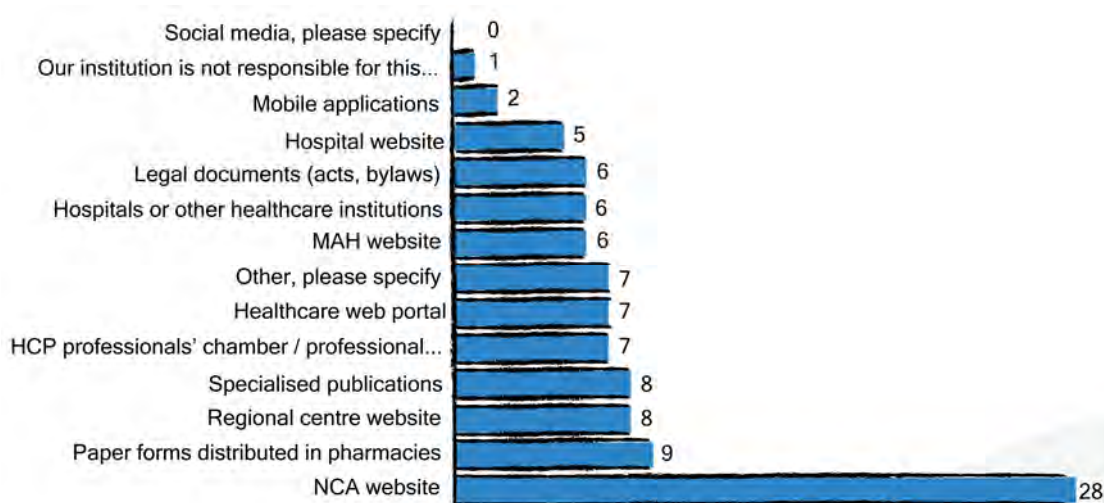

Figure 6. Responses to Q24 of the WP4.1 survey report show how ADR reporting forms are made available to reporters by NCAs

There is also underlying regulation, which supports and enables the facilitation pillar, in particular the e-form and having other methods of reporting as outlined below:

Legislation requires the development of web-reporting for HCPs and patients:

> *"Regulation 1235/2010…Article 25*
>
> *The Agency [EMA], in collaboration with the Member States, shall develop standard web-based structured forms for the reporting of suspected adverse reactions by health-care professionals and patients…"*

Further support is also provided for patient reporting through provision of alternative reporting methods:

> *"Directive 2010/84/EU… Article 102. The Member States shall… [continued]*
>
> *(b) facilitate patient reporting through the provision of alternative reporting formats in addition to web-based formats."*

The above legislation drivers were also highlighted within the UK's Yellow Card Strategy document.

Although electronic reporting is a vital channel, as mandated above, paper reporting is still necessary. It is important to remove any other barriers of ADR reports being submitted to the NCA. It is suggested that NCAs consider using a freepost service for reporters to send in completed paper ADR forms. A freepost service means the postal charge to send in a paper ADR form is paid by the NCA and not the reporter.

Nine NCAs (33.3%) indicated that a prepaid mail for reporting exists for their national ADR reporting systems. One example is the MHRA's paper forms, which all have a freepost address on the back of their forms. 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.
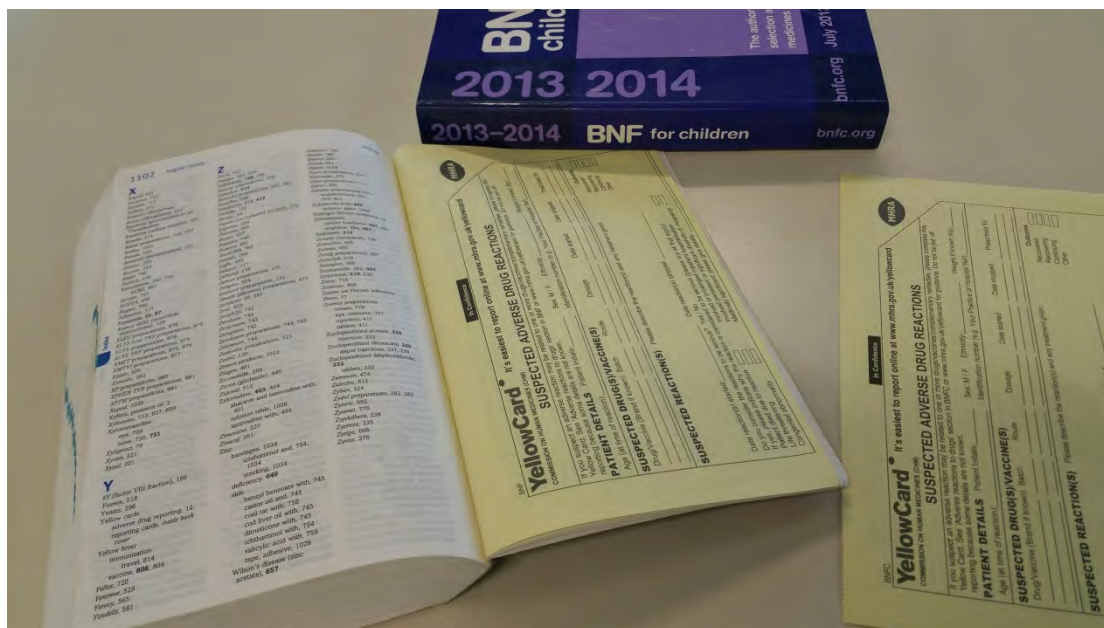

Figure 7. An example of a detachable free post Yellow Card reporting form, with free postage to the MHRA, is at the back of each British National Formulary; it is also within the BNF for children and Nurses Prescribers' Formulary (NPF)

Suggestion 2 – keep improving the functionality of your e-form

It is important to continuously improve and enhance the functionality of your existing online national ADR reporting site to make it easier to report suspected ADRs for all reporters and scenarios. This might be achieved in a number of ways:

By enabling it to be a 'mobile friendly' reporting site

- Making sure it is on the 'white list' of organisations sites so that it can be accessed by reporters within their organisational IT networks and systems by enabling relevant firewall and security settings

- Through focus groups of reporters, make it easier to be use in various situations and increase the quality of reports

- Design it towards E2B(R3) functionality

Case study of good practice

This can be identified from the United Kingdom.

Suggestion 3 – integrate suspected ADR reporting into clinical IT systems

Electronic reporting increases the speed at which reports are sent to the NCA, reduces the burden of data entry and can speed up subsequent signal detection processes, especially if automated. It is evident that this is the preferred option of reporting and the most sustainable way in which to embed suspected ADR reporting into the healthcare system.
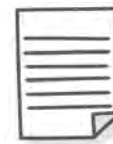
Case studies of good practice can be identified from:

- The Netherlands

- Spain

- United Kingdom (example of best practice)

Suggestion 4 – consider developing a mobile application for ADR reporting

A mobile phone app will help NCAs monitor the safety of medicines, providing a platform for direct and instant ADR reporting for patients and HCPs on the move. Apps could provide additional functionality for NCAs to provide instant feedback through acknowledgement and for them to communicate the latest PV safety information back to reporters.
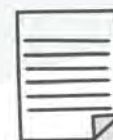
At the time of the survey report, Germany, Greece, Italy and the United Kingdom provide a mobile application for ADR reporting.

Mobile technologies offer an interesting opportunity to increase engagement between NCAs and HCPs and patients. They can create the opportunity for NCAs to improve the information they make available to stakeholders, which may have knock on improvements to reporting in the future.

SCOPE hasn't specifically studied the utility of mobile apps, as these are being explored by the Innovative Medicines Initiative's WEB-RADR project[15]. One work stream of this three year project, is to deliver a mobile app reporting platform, evaluate barriers and facilitators for its use and assess its utility for pharmacovigilance. To enable this evaluation, the project is delivering apps to the United Kingdom, Netherlands and Croatia, which are being developed and enhanced through the project based on user feedback. By the end of the project, a mobile app package will be made available for any NCAs to adopt if they wish, with provision for local translations and branding as appropriate. A number of options will be available for technical connection of the app to national PV databases, including use of local APIs, and the WHO Vigiflow system.

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[15] http://web-radr.eu/work-packages/wp3a/ accessed 9 March 2016

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WEB-RADR intends to conduct a scientific evaluation of the value of mobile app reporting, which will be used to make policy recommendations on wider adoption, use and principles for communication. Results will be shared widely within the EU network, and on the WEB-RADR website, with the aim of providing sufficiently mature recommendations, which can be taken into account when updating GVP guidelines.

The WEB-RADR project will publicise details about options for adoption of their mobile app platform developed through the project in due course, but the research elements of the project are intended to be generalizable to any PV mobile platform. In the context of WP4.3's focus on awareness levels, the following case study is around the evaluation of the barriers and facilitators for use of a mobile app for NCAs to consider.

Case study of good practice

As part of the mobile app work stream of WEB-RADR, a team led by the University of Groningen designed a study to evaluate the barriers and facilitators for use of an app in different populations. It included patients of differing background and a range of different HCPs in different NCAs.

The qualitative analysis included focus group discussions, and face to face interviews in the Netherlands, Spain and the United Kingdom. Participants were asked general questions, followed by specific questions based upon a prototype app. The data collected was analysed and arranged according to the themes of the Unified Theory of Acceptance and Use of Technology: performance expectancy, effort expectancy, social influence and facilitating conditions[16]. Nine focus groups were conducted, and 13 individual interviews, including both those already knowledgeable about PV and others considered naïve about PV. An important factor in the setup of the project was that the user evaluation activities feed directly into the development cycle for later versions of the app.

The majority of participants expressed an expectation that an app should facilitate 2-way communication, either between an HCP/patient and a regulator, or directly between a patient and a HCP. Security, ease of use and the language used in an app (specifically differences in terminology for patients and HCPs) were considered influencing factors, as were layout, operating system and cost.

Although some of the findings were predicted, there were interesting nuances between different reporter groups, such as adolescents and their parents and the importance of flexibility, since requirements will differ significantly within groups. The research conducted has already influenced a number of design decisions within the app, and is a critical part of the process of implementation of such a tool.

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[16] De Vries S, presented at the DIA Euromeeting, Hamburg. Paper, Barriers and facilitators to using a mobile app [publication pending]

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Case studies of good practice

An important aspect when considering the launch of an app is the associated communication strategy. Good practice has been identified from:

- United Kingdom

- The Netherlands

- Croatia

Suggestion 5 – consider creating a QR code to link to the national ADR reporting site for promotion

NCAs can generate their own QR code[17] online[18]. In order to do so, simply insert the URL for the respective reporting site, or any other specific URL, and the site will create a QR code that can be saved as an image for use in promotional material. It is intended that the resulting QR code on the promotional material can be scanned by a smartphone which directs one to the webpage or allows the webpage to be saved for viewing later. In this way, it is a useful method to provide easy access bridging the link between short messages on paper or posters to websites that may contain a lot more information.

Croatia and the United Kingdom are the only NCAs that have indicated use of this to raise awareness levels within the survey.

Case study of best practice

This can be identified from Croatia.

Suggestion 6 – ensure paper forms are widely accessible with relevant information

By making forms widely accessible, or the information about reporting and how to access forms is an important part of enabling an increase in awareness and reporting. One can gain an understanding through engaging with audiences as to where to focus such activities.

Some places to introduce paper forms and supporting information (for education and promotion elements of strategy) for HCPs can be through their respective guides, compendiums, national formularies, and prescription pads. This should be mirrored in any online versions also.

Case study of good practice

This can be identified from United Kingdom.

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[17] https://en.wikipedia.org/wiki/QR_code Information about what a QR code is. Accessed 9 March 2016
[18] http://www.qr-code-generator.com/ - accessed 17 January 2016

Suggestion 7 – have downloadable ADR reporting forms and materials for raising awareness

Many NCAs do have downloadable forms to report suspected ADRs including materials for raising awareness this on their reporting site or on their NCAs website. A few examples are outlined below from Croatia, Ireland, Sweden and the United Kingdom.

Case studies of good practice

This can be identified from:

- Croatia
- Sweden
- Ireland
- United Kingdom

10. Education – raise understanding of the purpose and value of reporting

The education pillar of the strategy to raise the understanding of the purpose and value of reporting is in line with BEMA[19] IV, Key Performance Indicator (KPI) 3.5:

> *'Education of stakeholders regarding reporting of safety, quality and efficacy issues improves reporting rates and provides a good basis for timely and appropriate regulatory action.'*

More detail regarding how NCAs educate reporters can be found within the respective responses received from Q37, Q38 and Q46 of the survey. In summary, approximately half of NCAs use case studies of communicated signals, regulatory actions and their outcomes in order to show the importance of ADR reporting. Sixteen NCAs that indicated they have developed or contributed to learning packages about ADR reporting.

The education of HCPs about ADR reporting is a common method used by NCAs to increase awareness levels. This is conducted through research and academic institutions that are allied to teaching universities for HCPs, and via e-learning packages, publications and books. Undergraduate HCP interaction occurs through training, lectures, course syllabuses and workshops. Many NCAs have phone-lines for HCPs to report and through conversation educate reporters about reporting. HCPs are targeted directly through regional centres, their professional bodies, congresses, queries, workshops and lectures. It is suggested for NCAs to consider using as many of these approaches as suitable to educate reporters.

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[19] http://www.hma.eu/bema.html BEMA accessed 15 March 2016

Figure 8.Suggestions for NCAs to consider incorporating within their strategy under education

Suggestion 8 – develop case studies that show the importance of reporting

Explaining the impact of reporting through case studies can be a good method of breaking down complex regulations into a real-life scenario that reporters can relate to. It also enables regulators to showcase example outcomes of regulatory action and communicated signals to show the importance of ADR reporting for HCPs and patients, using them as tools to promote and educate reporters.

Many NCAs use case studies to explain examples of regulatory action during lectures, congresses, workshops and presentations. The format is usually a presentation slide showing a list of regulatory action taken for a handful of specific drug event combinations.

Case studies of good practice

This can be identified from United Kingdom and Croatia.

Suggestion 9 – develop an e-learning module on ADR reporting for HCPs or use the SCOPE package

One of the main deliverables of WP4.3 is to develop an e-learning module for ADR reporting specifically aimed at educating HCPs. It is suggested that NCAs consider using this e-learning unit or consider translating it or developing their own to educate HCPs within their respective countries. Once developed the tool can be promoted in messages and interactions with HCPs. As an incentive, the unit could be accredited for Continuous Professional Development (CPD) or equivalent through HCP bodies.

Case studies of good practice

This can be identified from:

- Sweden

- Ireland

- Croatia

- United Kingdom

Suggestion 10 – aim to introduce ADR reporting in examinable undergraduate courses

The majority of spontaneous suspected ADR reporting systems are reliant upon the goodwill of HCPs reporting suspected ADRs. To sustain this, to increase the contribution and to provide the attitude, knowledge and skills necessary, it is important to educate future HCPs. This can be achieved in a number of ways. NCAs can consider incorporating relevant information into HCPs' curricula, for example, what the pharmacovigilance system is, how it works, including the importance and impact of reporting suspected ADRs. Another method could be to incorporate reporting into current HCPs' codes of practice, for example by including it within their respective professional duty and guidance documents. Both can provide impetus to encourage education and examination, as considered appropriate.

Patient safety can be improved by changing the reporting culture and it helps if professional bodies fully support the reporting of suspected ADRs and consider both reporting and the discussion of side effects with patients to be responsibilities of HCPs.

Case studies of good practice

This can be identified from the Netherlands and the United Kingdom.

Suggestion 11 – educate reporters locally – consider using regional centres

Local education about suspected ADRs can be organised in a more familiar setting for HCPs, patients, and their respective organisations. It can also allow more engagement, direct feedback and an opportunity to dispel misconceptions and some of the barriers to reporting suspected ADRs. Many NCAs do this through workshops, academia, local congresses and visiting healthcare settings. Alternatively, some NCAs use regional centres to do this.

Case studies of good practice

This can be identified from Croatia.

Please refer to Annex 6 Raising Awareness of National ADR Reporting Systems: Case Studies by Country for illustrations of how Regional Monitoring Centres in Italy, France and the UK raise awareness levels specifically in relation to suspected ADR reporting.

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11. Motivation – making reporters more likely to report

This pillar is about making reporters more likely to report. There are many barriers to ADR reporting and reasons behind underreporting, which have been highlighted through numerous studies. Such studies have shown common observations and interesting cultural issues, together with knowledge and attitudes, lack of time and accessibility of forms, which were discussed within the WP4.3 survey report. The barriers are similar to the 'seven deadly sins' presented by Dr Inman on why prescribers do not report[20].

It is suggested that higher reporting rates for suspected ADRs correspond to a better patient safety culture. NCAs may wish to consider how best to transform or enhance their own healthcare systems to reinforce a positive reporting culture when it comes to suspected ADR reporting.

The most common methods indicated by NCAs to motivate reporters are: written feedback (21, 75%), answers to enquiries (19, 70%) and speaking opportunities (18, 67%). Further information on this can be found within the survey report.

Figure 9. Responses to Q48, which asked how NCAs encourage and motivate HCPs to report suspected ADRs

Four NCAs chose the 'Other' category. They described a dedicated email address; a call for reporting incorporated into press releases; by an ADR bulletin and educational materials; conferences, articles, case studies, showing the impact and importance of reporting; explaining the importance of reporting in educational material and DHPC, mailings; monthly newsletter including analysis of ADRs and statistics on the number of ADRs from each region quarterly.

NCAs can consider as many of the above methods to increase motivation of reporters as they wish. Four are suggested below:

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[20] [20] Inman WH. Attitudes to adverse drug-reaction reporting. Br. J. Clin. Pharmacol. 1996 May, 41: 433-5

Figure 10. Suggestions for NCAs to consider incorporating within their strategy under motivation

Suggestion 12 – consider adding suspected ADR reporting into part of a HCP's revalidation and appraisal process

To further embed reporting into the heart of their healthcare systems, NCAs may wish to consider influencing professional bodies and regulators to ensure HCPs are motivated by including suspected ADR reporting within the professional revalidation and appraisal processes. This can promote good practice and embed a safety reporting culture for suspected ADRs into the system.

Another area for consideration is how ADR reporting data can be used to inform audits for patient safety purposes. This could be in collaboration with other regulators that performed them, or as intelligence prior to a planned audit. Any process and ADR information used in this way should be transparent for local and national learning.

NCAs may also consider supporting HCPs use of the national ADR reporting and staying up-to-date with the latest safety information for revalidation and appraisals by providing e-learning modules. This can further be supported by relevant training and examinations on recognising and managing ADRs, active suspected ADR reporting, and the prevention of ADRs from medication. This can be considered at the various stages of a HCPs career, for example, including this at undergraduate level, in postgraduate education curricula, and as part of various CPD learning levels.

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From the WP4 survey, there was no identifiable information to elaborate further or give specific examples of this best practice for this strategy guidance. However, the UK has made efforts to explore work in this area with the Care Quality Commission (CQC), the independent regulator of all health and social care services in England. The MHRA plans to work with them in future to share reporting data from NHS organisations to help inform CQC audits for improving patient safety. It is recognised by the CQC that Yellow Card reporting can potentially be an important indicator of the reporting culture of a Trust. Reporting rates can help when viewed alongside other data sources to inform the CQC on where to audit, and where previously audited organisations have improved their reporting rates.

Suggestion 13 – using ADR reporting as a quality indicator for HCPs

Reporting suspected ADRs is part of a HCPs duty. Although no financial incentives are given in EU for reporting, a HCP can be motivated to report through various quality indicators.

Case study of good practice

This can be identified from the United Kingdom.

Suggestion 14 – set up a national network of ADR reporting champions
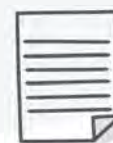
Designated 'champions' can help increase awareness of suspected ADR reporting through local education and reporting. They can also build a rapport locally with networks to disseminate safety information and act as a channel to motivate and educate reporters to encourage reporting.

Case study of good practice

This can be identified from Malta and the United Kingdom.

Suggestion 15 – recognise and reward reporting

It is considered good practice to acknowledge suspected ADR reports received via an acknowledgement upon receipt of an ADR – NCAs can refer to WP4.2 which focuses on this practice.

Other methods that NCAs may wish to consider include: positive feedback to encourage reporting when following up a suspected ADR report for further information, recognising the contribution of reporters at congresses and speaking opportunities, through telephone queries, and via general query responses.

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When exploring reward (not financial), one method might be to consider proportions of CPD/CPE credits for each spontaneous ADR report that is submitted by a HCP. It is acknowledged there may be reservations about stimulating reporting in this manner and the possibility of increasing false positives. However, one NCA indicated this method is used as a way of increasing awareness amongst HCPs and motivating them to report.

From the WP4.3 survey, two NCAs indicated they reward HCPs for reporting. Upon follow-up, this number increased to three NCAs that show the only practice in this area.

Case studies of good practice

This can be identified from:

- Croatia – CPE points for medics and pharmacists

- Latvia – Rewards to HCPs that report the highest number of reported ADRs

- Denmark – Competition for medics

- United Kingdom – Sir Derrick Dunlop Award

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12. Promotion – developing and maintaining promotion and communication strategies

This pillar of the strategy is focused on the various methods that can be considered by NCAs to promote their national ADR reporting schemes.

Promotion
- developing and maintaining promotion and communication strategies

Suggestion 16	Suggestion 17	Suggestion 18	Suggestion 19	Suggestion 20	Suggestion 21	Suggestion 22	Suggestion 23
create a brand	include a set of key messages to patients	identify trusted websites to publicise ADR reporting	form partner-ships	distribute forms to where they can be accessed	publish ADR trending data and encourage promotion and research	use social media channels regularly	insert statements to encourage reporting in relevant Agency comms

Figure 11. Suggestions for NCAs to consider incorporating within their strategy under promotion

12.1 Results from survey

The WP4.3 survey report, specifically analysis of Q6 and Q7, provides detail about the types of methods used by NCAs to promote suspected ADR reporting. Nearly all promote their respective national ADR reporting systems to HCPs (28) and patients (27). It is clear that a range of tools are used for promoting ADR reporting.

The following graph shows a summary of how NCAs promote ADR reporting, including the types of activities that are conducted. Further analysis of this information provided can be found within the survey report.

NCAs may wish to consider using as many activities as possible from the following graph to promote ADR reporting.
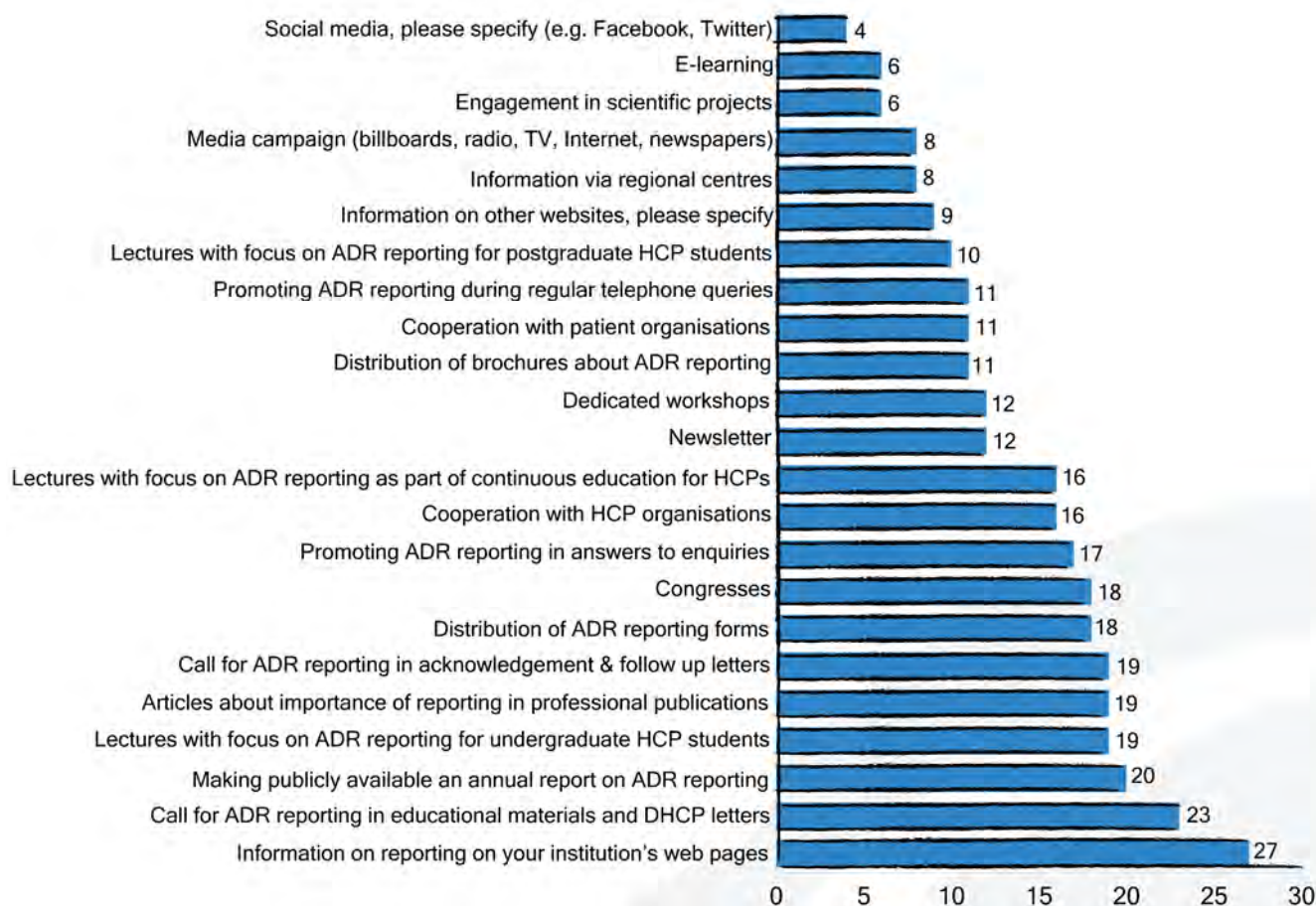
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Figure 12. How NCAs promote suspected ADR reporting

Although not considered 'active' promotion, the highest responses for how NCAs promote ADR reporting is through their institution's webpages (27), a call for ADR reporting in educational materials and DHCP letters (23) and through annual reports on ADR reporting (20). There is little use of social media and e-learning to promote ADR reporting. As expected, probably due to the associated costs, media and television campaigns are tools that are less utilised by NCAs to promote ADR reporting.

Case study of practice

This can be identified from Croatia – information on NCA's websites.

Suggestion 16 – create a brand

NCAs may wish to consider creating a brand by naming their national ADR reporting scheme and creating a logo that is easily recognisable and associated with their agency. If this is not possible, NCAs should consider using the organisation's logo.

When using a logo or branding image it is good practice to hyperlink it. This allows users to be directed to the relevant pages to promote awareness and reporting.

A logo can be used in almost any official correspondence from letterheads and signatures to PowerPoint presentation headers and templates. It can also be used digitally to promote the national suspected ADR reporting system.

Case study of good practice

This can be identified from the United Kingdom.

Suggestion 17 – include a set of key messages to patients and parents

Case study of good practice can be identified by the United Kingdom.

Based on this case study, NCAs may wish to consider using the following set of key messages for developing basic patient messages for promotion purposes:

Key messages

- Your report is important to help make medicines safer.

- Only a suspicion is needed to report.

- How to report.

- Always read the Patient Information Leaflet supplied with your medicine for more information on side effects.

- Speak to your HCP for further advice.

Depending on the length of the message and format, NCAs may also consider adding information about regulatory action taken as a result of suspected ADR reporting to show the value of reporting (see the use of case studies in suggestion 8). This is particularly important if the safety issue was unrecognised until suspected ADR reports were received.

The ADRIC study suggested that the following messages are important, which NCAs may also wish to consider when developing promotional messages aimed at parents:

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Key messages

- Reports from parents like you are very useful. Parents know their child better than anyone and can tell us about things that healthcare professionals can't.

- We want parents to send reports even if they only have slight concerns about a medicine – you don't need to be certain that a medicine has actually caused a side effect to send a report.

- Reports are confidential. We won't share the information on your report with your child's doctor if you don't want us to.
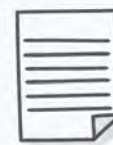
It is also important to include why it is important to report ADRs in children, where possible, to encourage paediatric reporting of suspected ADRs.

Suggestion 18 – identify trusted websites to publicise ADR reporting

NCAs may wish to consider identifying the top 10 trusted websites used by HCPs and patients. Once identified one could develop a plan to make contact with each so that the information about the importance of suspected ADR reporting, including relevant URL hyperlinks and logos, are added, linking HCPs and patients to national suspected ADR reporting sites.

Case studies of practice

Nine NCAs indicated that they use information on other websites to promote suspected ADR reporting.

Table 1. Websites indicated by NCAs that are used to promote suspected ADR reporting

Member State	Examples of which websites and the types of websites used to promote ADR reporting through
Spain	OCU (Spanish Consumers and Users Organization), SiNASP (the system of notification and registration of incidents and events developed by the Ministry of Health) and The Spanish Association of Paediatricians
Czech Republic	Referring to the EMA website
Iceland	Through MAHs websites
Ireland	MIMS (Ireland), IMF, MAHs, Pharmaceutical Society of Ireland (PSI), Irish Academy of Continuing Medical Education (IaCME)
France	Patient associations' websites
Netherlands	Patient organisations
United Kingdom	Professional websites, Royal Colleges, Medicines Information websites, NHS websites, patient organisations including their associations and charities, sources of trusted patient information websites, parenting websites, child-minders website, national formularies, some large pharmacy organisations including their respective intranets
Croatia	patients' organisations' websites
Norway	www.helsenorge.no (a patient website that allows access to services to monitor their own health and health information)

Suggestion 19 – form partnerships with relevant organisations and bodies

NCAs may wish to consider their potential stakeholders with view to approaching them for partnerships to promote suspected ADR reporting. This can be done by identifying all HCP bodies and their regulators, patient organisations and charities they might choose to work with. For patients, identifying the top disease areas and respective patient charities that are considered trusted sources for patient information is a useful approach.

A plan could be developed for establishing contact to explore possibilities of joint working and use of both organisations' communications channels to promote suspected ADR reporting, e.g. through social media, newsletters, member communications, articles, the internet, form distribution, etc. A sustainable output could be for information about the importance of ADR reporting, including URL hyperlinks are signposted to the national ADR reporting site, including brand logos and promotional materials to raise awareness and strengthen patient safety.

Case study of good practice

This can be identified from the United Kingdom.

## Suggestion 20 – distribute forms to where they can be accessed

Although the strategy focuses upon electronic reporting, it is recognised that paper forms are needed. It can also often be a reminder for HCPs to report suspected ADRs and an aid to discuss self-reporting with a patient and raise awareness in general.

From the SCOPE WP4.3 survey report, 20 NCAs (71%) distribute suspected ADR reporting forms. Q32 and Q33 examine this in further detail, including how forms are distributed. The main ways identified for distribution are via:

- Workshops, congresses and conferences

- Active distribution to healthcare institutions and via their bodies

- Active distribution to patient organisations and via their charities

- Regional Monitoring centres

- Downloadable forms which can be printed out by anyone

- The NCA upon request

- Campaigns

Suggestion 21 – publish ADR trending data to encourage promotion and research
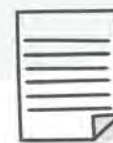
Publishing information about ADR trending data within annual reports and wider journals is an indirect method of proactive promotion.

NCAs may wish to consider adding relevant information about their strategic activities and reporting trends to their NCA's published annual reports, for publishing within scientific and clinical peer-reviewed journals, and presenting through posters at conferences. Such methods can have a positive impact both internally, in recognising individual and team efforts in these areas, and externally in raising awareness of the NCA and PV. In certain instances, it may also be time-efficient to refer queries to annual report data.

NCAs might also consider how best to encourage the use of spontaneous ADR data for research and support researchers in this way.

Case studies of good practice

This can be identified from the Netherlands and Denmark.

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Suggestion 22 – use social media channels regularly

There are a multitude of social media tools available online[21], as well as information on suggested approaches to growing a social media presence online[22] and ways to measure social media success[23]. Based on these and current practice, NCAs may consider creating accounts, if they have not already done so, for the following main social media platforms:

- Twitter – a social service that enables users to send and read short 140-character messages called "tweets"

- Facebook – a social networking service

- LinkedIn – a business oriented social networking service

- YouTube – a video-sharing website

- Storify – a social network service allowing users to create timelines using social media (e.g. Facebook, Twitter, Instagram etc.)

In general, social media is a widely under-used resource for raising awareness in PV. From the SCOPE WP4.3 survey, five NCAs indicated they use social media to raise awareness of suspected ADR reporting. It is suggested therefore NCAs consider more regular use to promote, make announcements, and encourage suspected ADR reporting and general PV activities.

Social media and other digital channels can allow a much wider reach for messages, as well as the targeting of specific audiences (for example via LinkedIn groups). It can also help create and develop opportunities for a two-way discussion with stakeholders through direct feedback. Digital channels such as these can amplify a message, for example, through coordinating a particular message about ADR trends and a call for reporting supported by another organisation the message to report can be reposted, retweeted or shared so the message reaches different organisations and their followers/friends/members. In this way the message is also targeted.

NCAs may consider using a number of hashtags[24] that mark keywords or topics related to suspected ADRs. One isn't limited to any particular hashtag, but hashtags can help to build a story based on a brand and theme. Hashtags can be used at the end of social media posts such as on Twitter or Facebook to raise awareness levels and extend the reach of the message to report suspected ADRs to as many people as possible.

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[21] http://www.inc.com/jeff-haden/60-awesome-social-media-tools-for-entrepreneurs.html; Accessed 4 April 2016

[22] http://www.forbes.com/sites/johnrampton/2014/09/29/25-ways-to-grow-your-social-media-presence/ Accessed 4 April 2016

[23] https://www.themuse.com/advice/4-ways-to-measure-your-social-media-success; Accessed 4 April 2016

[24] https://en.wikipedia.org/wiki/Hashtag; Accessed 3 June 2016

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Some example hashtags are below:

#ReportSideEffects, #SideEffects, #PatientSafety, #Patients, #Medicines,
#ReportingMakesMedicinesSafer, #Safermedicines, #ProtectingPublicHealth, #ADRs
#AdverseDrugReactions, #MedicinesSafety, #ThinkPatientSafety #MakingMedicinesSafer,
#Pharmacovigilance, #RaisingAwareness, #your national ADR reporting scheme name,
#your NCA name, or similar according to national languages

If aimed at particular HCPs or audiences add appropriate hashtags to target messages, for example, #doctors, #pharmacy, #children, #KeepingChildrenSafe etc.

Try to be creative, personal and relevant to the post.

Suggested good practice to raise awareness levels of suspected ADR reporting:

- Use URLs to your NCA website or national ADR reporting site (these can be shortened by using a URL shortener online)

- Explain what the national ADR reporting site is and what it does

- Give examples of regulatory action to show the significance of reporting

- Use digital images, posters and videos to raise awareness

- Use pre-agreed quotes from stakeholders at congresses

- Tag other relevant organisations

- Liaise with other organisations to coordinate posts and reposts

- Post often and be creative

- Consider a blog[25]

- 'Retweet' and 'share' other appropriate messages about PV and patient safety or drug safety issues

- Consider use of social media for consultations, surveys, announcements and general promotion

- Consider creation of policy, or follow existing organisational policy, on how to respond to comments on social media.

NCAs may also wish to consider leveraging content across different platforms to boost social media efficiency and to avoid posting identical content on every single social media platform.

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[25] https://en.wikipedia.org/wiki/Blog accessed 3 June 2016

For example, one could:

- Write a blog about the importance of reporting suspected ADRs

- Use a shortened URL link on Twitter with a comment to signpost to it and consider using a hashtag

- Consider tagging other organisations who might repost or be relevant

- Alongside this, a related picture can be posted on Facebook including a link to the blog, consider using relevant hashtags in the post

- Consider tagging other organisations who might repost or be relevant

- Monitor ADR reports and build a story showcasing any changes, tweets, posts on Storify

This is an example of how to make better use of the various platforms, instead of having to create four separate pieces of social media content.

Case studies of current practice

The five NCAs that indicated use of social media to promote suspected ADR reporting were

- France
- Latvia
- Norway
- Italy
- United Kingdom

Suggestion 23 – insert statements to encourage reporting in relevant agency communications

NCAs may wish to consider adding sustainable statements to encourage the reporting of suspected ADRs within agency communications, where appropriate. This may include the URL of the reporting site and a link to the safety bulletin, if applicable. Example communications that this could be incorporated into include: drug alerts, DHPCs, newsletters, press releases, media queries, email signatures, and general queries.

For example, in January 2016, letters were sent to HCPs regarding erlotinib (Tarceva)[26] and fingolimod (Gilenya ▼)[27]. Both contain a call for reporting.

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[26] https://assets.digital.cabinet-office.gov.uk/media/56c239d2e5274a036600001d/Tarceva_DHPC_sent_14_Jan_2016.pdf accessed 8 April 2016

[27] https://assets.digital.cabinet-office.gov.uk/media/56c239a9e5274a036900002b/Gilenya_DHPC_sent_22_Jan_2016.pdf accessed 11 April 2016

13. Collaboration

Questions 44 to 48 within the SCOPE WP4.3 survey focused upon how NCAs engage with stakeholders to increase awareness levels of their respective ADR reporting schemes. Responses indicated that most often engagement with stakeholders is done directly with HCPs or trainees (24, 89%), followed by professional bodies (19, 73%) and national health systems (18, 67%). Academia and commercial stakeholders follow closely with 17 (63%) and 16 (59%) respectively. The least frequently reported stakeholder engagement was with charities (3, 14%) and patient associations, patient organisations and MAHs (Other) with 2 NCAs (12%). It is recognised that this figure on working with patient organisations differs (is significantly lower) from other responses provided by NCAs within the SCOPE surveys and that the questions may have been interpreted differently. The main focus of these questions were engagement with HCPs and their related institutions. For further analysis and detail, please refer to the SCOPE WP4.3 survey report.

Campaigns often involve collaboration with organisations to raise the profile of ADR reporting. More on these examples can be found in the Campaign section of the guidance document.

Suggestion 24: explore and maximise any promotional opportunities for joint collaborations and partnerships: aim to promote through low/no cost outward facing communication channels

When making contact with organisations it is suggested that NCAs consider exploring and maximising any promotional opportunities for joint collaboration.

NCAs may opt to consider the outward facing communication channels of the organisation and the various low or no cost channels to reach the other organisations members and stakeholders. For example, through a range of activities including: joint articles, a video of people advocating and encouraging the reporting of suspected ADRs from different organisations, form distribution, blogs, training, presidents newsletters, making use of local networks, and promotion via digital media channels.

Some of the 'named engagement' collaborations and interactions indicated by NCAs within the SCOPE WP4.3 survey are:

- Latvia
- Lithuania
- Iceland
- Denmark
- Romania
- Ireland
- Portugal

Case studies of good practice

This can be identified from the Netherlands through collaboration with patient organisations to increase knowledge about drug use and side effects via the ADHD network, and Ireland.

Suggestion 25: collaborate with other organisations to capture reports of all types of harm from medicines

The expanded definition of an ADR includes all reactions in a patient that are "noxious and unintended". This means that where an adverse effect was suspected as a result of a medication error, misuse, or abuse, it is a suspected ADR. This also includes reports where a medicine is used outside its licensed condition, i.e. off-label use. This opens up more opportunities to collect data that might be collected by different NHS organisations. Collaboration and integration of reporting can be a good way to collect this information.

Case studies of best practice

This can be identified from Spain and the United Kingdom

14. Resource

Suggestion 26: allocate a dedicated resource to strategy activities
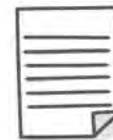
The SCOPE survey report shows that 19 NCAs (68%) do not have a specific budget and make the case for finances as required for raising awareness levels. The majority of resource for strategy work (65%) and campaigns (54%) comes from existing resource available within PV departments.

NCAs may wish to consider this guidance report to allocate a resource to such activities to strengthen national ADR surveillance systems and increase awareness levels of the systems in place to safeguard patient safety.

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15. Next steps and adapting to change

Suggestion 27: consider using 'the golden thread' principle

NCAs may consider developing some of the strategic activities into personal objectives and business plans for strengthening surveillance, and thereby patient safety, through the suggestions outlined in this strategy. This can be the difference between simply having an organisational purpose and having a sense of purpose shared by all employees working for the organisation and often beyond, including external stakeholders. An organisation's shared sense of purpose is its identity and 'the golden thread' to which its strategy can be aligned.[28]

It is suggested that PV staff consider influencing the top management of their respective NCAs to incorporate the overall aims of a strategy to raise awareness levels of spontaneous national ADR reporting systems into the NCA strategies and plans. Projects that stem out of the strategy can be also incorporated at the various departmental levels within the organisation's objectives and into staff objectives. For example, how the project relates to the divisional business plan for vigilance activities, and also corporate communications objectives at a departmental level, further strengthened by individual staff objectives.

When implementing strategic activities NCAs may consider using a project management approach. This can help bring clarity to identifying and logging potential risks, reviewing budget, allocating resources, and roles and responsibilities for each objective set.

15.1 The importance of regular audit and review

It is suggested that any strategy to raise awareness of spontaneous ADR reporting is subject to regular reporting to senior management through audit and planned as part of good business planning. Any overall strategy should be reviewed at least every two years to ensure it continues to be fit for purpose.

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[28] http://www.cipd.co.uk/NR/rdonlyres/BD7289E3-5AA5-44E3-9C22-4ED1EAACB40C/0/5048_Sharedpurposesurvey.pdf 'the golden thread' principle. Accessed 11 April 2016

Annexes

Annex 1. Raising Awareness of Adverse Drug Reaction Reporting Systems: Survey Report

WP4-3 Survey
Report layout draft

Annex 2. HALMED Strategic Plan 2014-2018

Strategic plan
HALMED.pdf

Annex 3. Yellow Card Strategy 2011

Yellow Card
Strategy 2011.pdf

Annex 4 Yellow Card Strategy Update 2013 and a paediatrics communications strategy

Yellow Card
Strategy 2013 updat

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Annex 5. Analysing current suspected ADR reporting rates

Table 2. Five year trending analysis to target strategy efforts

High level category	2011	2012	2013	2014	2015	N and% change between 2014 & 2015
Total number of suspected ADR reports (N)						
N* and % serious reactions						
N and % fatal reactions						
N and % electronic reports						
N and % pharmaceutical industry reports						
N and % direct reports						
N and % direct HCP reports						
N and % direct electronic HCP reports						
N and % direct patient reports						
N and % direct electronic patient reports						
N and % children reports (>18)						
N and % elderly reports (65+)						
N and % ADR medication errors						
N and % number of additional monitored drugs						
N and % herbal products						
N and % vaccines reports						

*N = numbers of suspected ADR reports

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Table 3. A minimum trending analysis for direct reports

Combined reporter group category	2011	2012	2013	2014	2015	% change between 2014 & 2015
Doctors						
Nurses						
Pharmacy						
Members of public*						

*Members of public include patients, carers and parents

Table 4. Detailed analysis showing the numbers of direct ADR reports broken down by reporter groups

Reporter group category	2011	2012	2013	2014	2015	% change between 2014 & 2015
Community pharmacist						
Dentist						
GP						
Healthcare assistant						
Hospital doctor						
Hospital HCP						
Hospital nurse						
Hospital pharmacist						
Midwife						
Nurse						
Other HCPs*						
Pharmacist						
Physician						
Carer**						
Parent**						
Patient**						

*Other HCPs: dentists, optometrists, coroners, healthcare assistants, paramedics, chiropodists, medical students, Pharmacy technician, Pharmacy assistant, Pre-reg pharmacist, Radiographers, and other non-specified health professionals

**Members of public include patients, carers and parents

Annex 6. Raising Awareness of National ADR Reporting Systems: Case Studies by Country

Raising Awareness
of National ADR Rep