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Bringing medicines to *life*

One stop shop: Delivering excellence in patient safety across the UK

September 2014

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Preface

On 26 September 2014, the ABPI organised a stakeholder event in London to discuss delivering excellence in medication safety across the UK. This was one of the first occasions where presentations on initiatives concerning medication safety were given by representatives from England, Northern Ireland, Scotland and Wales. The event allowed interested parties the opportunity to understand and discuss the issues surrounding patient safety in terms of 'real world' use of medicines, reporting of adverse drug reactions (ADRs), medication errors and patient engagement tools. The event was organised to ensure regulatory bodies, hospital and community pharmacists, pharmaceutical companies, as well as nurses and patient groups could share knowledge of best practice and identify areas where closer collaboration was required to understand ADRs, improve reporting mechanisms and optimise the safe use of medication. This publication is a summary of this event and includes discussions that took place.

Executive summary

Reporting of ADRs is recognised by all parties as playing a key role in providing data to signal when the risks of an approved medication outweigh the benefits and have the potential to impact patient safety. The Medicines and Healthcare products Regulatory Agency (MHRA) wants to raise awareness amongst healthcare professionals (HCPs) and patients that the definition of an ADR now encompasses medication errors and off-label uses of a drug and reporting these incidents is crucial to safeguarding patients and increasing knowledge.

Although there is a framework for reporting in place the complexity of multiple schemes, which include local reporting via a Local Risk Management Scheme (LRMS), the National Reporting and Learning System (NRLS) and the UK-wide MHRA Yellow Card Scheme, was the subject of much discussion.

Reporting of ADRs is lower in the UK than many other developed countries and although the Yellow Card Scheme is celebrating its 50th anniversary in 2014 there are still issues surrounding its use. Results from an MHRA survey have shown that 15 percent of HCPs are not aware of the scheme and many have never used it. It is clear that additional promotion, education and development of the scheme is still required. The MHRA is developing a 'single reporting portal' to provide access to incident reporting forms. The future of ADR reporting was also detailed with a programme for the development of Europe-wide pharmacovigilance best practice and mobile apps for use with social media.

Angela Carrington (Belfast Health and Social Care Trust)

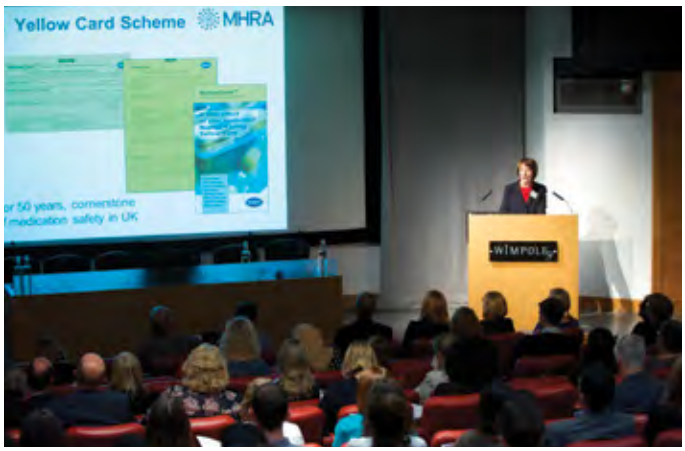
Reporting tools used in the UK primary, secondary and tertiary care settings such as the LRMS and the NRLS were debated. Putting in place, in England, a new National Medical Safety Network of Medical Safety Officers (MSOs) to report ADRs was highlighted as a strategy to streamline reporting by improving how the NRLS in the primary care setting would integrate with MHRA monitoring systems in terms of incident detection and preventing harm.

The NHS and pharmaceutical industry speakers also considered how in actual clinical use many drugs do not have built-in safety with antibiotics, opioids and insulin cited as examples where sub-optimal use of these medications by either the HCP or the patient had caused serious ADRs. Since use of medicines in practice can be sub-optimal, speakers from the Royal Pharmaceutical Society and UK Medicines Information presented strategies and tools which could help to address this issue.

From the NHS throughout the UK many excellent programmes for improving ADR/medication errors reporting from hospital and community pharmacies were presented, as well as patient information materials, all of which are contributing to improving patient safety and it was discussed how to share and implement this best practice expertise across the UK.

Background

An adverse drug reaction (ADR), based on Directive 2010/84/EU is defined as a response to a medicinal product which is noxious and unintended[1]. This definition means an ADR can arise as a result of a reaction to off-label use, overdose, misuse, abuse and medication errors and reporting on these types of ADRs is crucial for improving drug safety.



June Raine (MHRA) Conference Chair

There are two routes for reporting an ADR, the Yellow Card Scheme and using the NRLS. The Yellow Card Scheme is one of the longest running reporting system for reporting ADRs and was introduced in 1964 following the thalidomide incident. It originally provided a route for doctors or dentists to fill out a paper-based report to alert the regulatory authorities. The scheme has since expanded to include reporting from pharmacists, nurses, dentists, coroners. In 2003, patients were encouraged to report ADRs via a telephone helpline. In 2002, the Yellow Card became available as an online electronic form and the website was updated in 2008 to provide access to the Yellow Card for patients and professionals to use[2].

To ensure ADR information is analysed and any patient safety issues associated with specific drugs identified, in July 2012, the European Medicines Agency (EMA) set up the Pharmacovigilance Risk Assessment Committee (PRAC)[3]. The PRAC has a broad remit covering all aspects of pharmacovigilance, including risk management planning and post marketing benefit/risk assessment, ensuring the design and evaluation of post-authorisation studies contribute meaningfully to sustainable life cycle benefit/risk management. The PRAC is integral in risk management planning for all new and existing drugs where changes to the risk profile of the drug pose challenges to safe and effective use.

More and better documented spontaneous suspected ADRs, as well as studies, provide key data and information inputs for signal detection and ultimately feed into action in terms of risk management, product information updates and communication to regulators.

The PRAC plays a crucial role in prioritising and evaluating signals identified by regulators and industry to ensure new/changed safety issues can be translated into drug labelling updates, new restrictions on use or advice on optimal use.

The collection of individual reports of ADRs is one of the foundations of a drug surveillance system. To alert HCPs and patients to any medicine that requires additional monitoring and for which any ADR should be reported, the EMA introduced the EU-wide additional monitoring (denoted by a black triangle symbol) in 2013. The black triangle symbol appears on both the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) of all new drugs, any biological product and drugs identified by the PRAC as requiring extra monitoring[4]. Gathering ADR data more intensively for these drugs helps establish the product's risk/benefit profile more rapidly.

A patient safety incident involving a medication error can be reported in the NHS via an LRMS such as Datix or Ulysses to the NRLS – a central database of patient safety incident reports set up in 2003[5]. A patient safety incident is where a patient has been harmed or there is a potential for harm (near miss). All types of incidents are reported including wrong diagnosis, mixed-up test results, medicine and device incidents.

Dr June Raine, from the MHRA, summarised the benefits of reporting ADRs: "Patient safety is paramount for all of us. However, there isn't an effective medicine that is not without risk and clinical trials are limited so it is impossible to see all the side effects of a drug before it is launched. With an estimated 72 percent of the ADRs seen being avoidable this is powerful evidence to strengthen surveillance and depends on active, enthusiastic participation and reporting of incidents by all healthcare professionals."

L>R: June Raine (MHRA) and Lucy Hampshire (Lilly)

Regulatory perspective

According to Mick Foy of the MHRA, from 2006 to 2013 there has been a gradual increase in the numbers of ADRs reported to the MHRA, by both patients and HCPs, from 7,000 to 10,000. In recent years, the MHRA has been actively monitoring the issue of under reporting of ADRs by HCPs and patients. He stated: "Despite the increase in ADR reporting worldwide, we have seen data accessed from the WHO Global Individual Case Safety Reports (ICSR) database, VigiBase[6] (from January 2009-January 2014) that the UK is 17th in the world with 400-500 ADR reports per million people but it is 6th in the world when it comes to reporting serious ADRs."

Mick Foy (MHRA)

To try to improve reporting rates in the UK, the MHRA has begun introducing the electronic Yellow Card Scheme into the primary care setting via GP System of Choice (GPSoC) and SystmOne GP clinical computer systems. To make reporting easier, the MHRA is also developing a 'single reporting portal' to provide access to incident reporting forms. He commented: "Our research showed that 85 percent of HCPs recognise the Yellow Card as the system for ADR reporting but because there are four different cards they are sometimes confused as to which one to complete. The majority of HCPs, patients, carers, pharmaceutical and device industry stakeholders we polled believe using the Yellow Card brand for incident reporting would increase reporting of ADRs. A new website providing access to incident reporting will be launched later in 2014."

The MHRA is also working closely with NHS England to integrate data capture and avoid duplication from LRMS and NRLS into the MHRA database.

On a European level, the MHRA is involved in the Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) project which is running from 2013 until 2016[7]. This programme will gather information and expertise on how regulators in member states run their national pharmacovigilance systems. Using this information, SCOPE will develop and deliver guidance, training in key aspects of pharmacovigilance and tools and templates to support best practice.

The MHRA also recognises that data on ADRs can be gathered via social media and is leading a consortium of organisations including European medicines regulators, academics and the pharmaceutical industry in a WEB-RADR (Recognising Adverse Drug Reactions) consortium which will run from 2014 to 2017 to develop a mobile app for HCPs and the public to report ADRs[8].

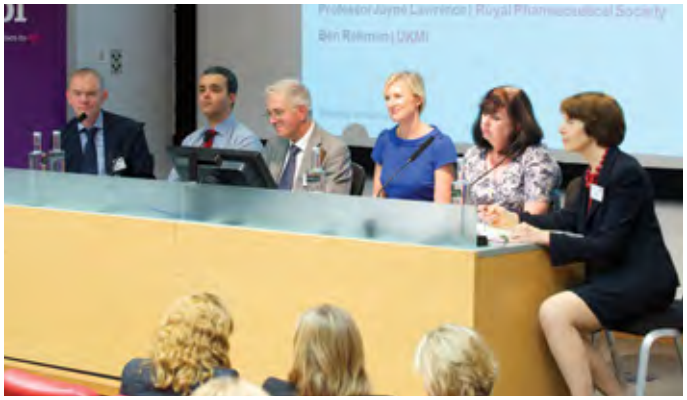
Mick Foy concluded: "We need to maintain all methods of reporting ADRs to make it easy to gather as much data as possible. When ADR reports are compared in the USA from the FDA reporting system and Twitter, the numbers and types of data reported are very similar. This means potentially social media could help with obtaining ADR information but it needs to be underpinned by a framework, which is why we are developing tools for its use."

Industry perspective

The pharmaceutical industry views ADR reporting outside the clinical trial setting as a vital method for evaluating drugs in larger populations than are possible with clinical trials. Dr Sarah Hall of Takeda UK stated: "Published literature[9] shows that from 2002 to 2011, 19 drugs were withdrawn in the EU for pharmacovigilance reasons and that in 18 of the 19 withdrawals the majority of the pharmacovigilance evidence used to support withdrawal was from drug safety case information; this is how important ADR reporting is."

Dr Jenny Lean of Pfizer went on to say that the industry would like to see drug safety reports which include more than just what has been traditionally considered an ADR as this additional reporting can identify areas for risk minimisation. Therefore, it requires more reporting on exposure during pregnancy and breast feeding and off-label uses of drugs in children as these patient populations are often underrepresented in clinical trials for ethical and safety reasons. It would like information on lack of efficacy, particularly with vaccines and antibiotics, as this will provide a clearer picture of antibiotic resistance, for example. It would also need additional reporting of medication errors, near misses and accidental exposure as this can provide valuable feedback on where labelling or patient information leaflets need to be written more clearly or where a product needs to be modified.

L>R: Jenny Lean (Pfizer) and Sarah Hall (Takeda)



Panel Discussion (AM)
L>R: Mick Foy, Ben Rehman, David Cousins, Lucy Hampshire, Jayne Lawrence and June Raine (Chair)

Dr Hall provided an example of risk minimisation in action, citing how patients incorrectly sticking on and inappropriately disposing of clear transdermal fentanyl patches contributed to a number of cases of accidental exposure in young children and how reporting of these incidents led to implementation of a number of PRAC recommendations in 2014. These include distribution of a letter to all HCPs in the UK, an MHRA Drug Safety Update[10], an opioid learning update on the MHRA website and discussions on possible changes to increase the patch's visibility.

Dr Lean also provided an example of how ADR reporting of severe and fatal cardiac adverse events of an off-label bolus injection (IV push) of erythromycin, a licensed product for more than 50 years, led to the use of bolus injection (IV push) being issued as a contra-indication.

She summarised: "Benefit and risk analysis should occur throughout the lifecycle of a drug to keep patients safe. As we have seen with erythromycin, even an antibiotic with a well-established safety profile can cause harm when wrongly administered. ADR reporting is how we discover the true safety profile of a drug and we need to encourage more as current voluntary reporting vastly under-estimates ADRs due to low report rates. It is mainly through ADR reporting that we can help keep patients safe so the pharma industry believes we should be encouraging HCPs and patients to report even potential safety risks. The system is only as good as the information reported into us and if patients and HCPs are in doubt about something being not quite right with a drug they should give us a shout."

Strategies for optimising use of medicines

As well as improving ADR reporting, strategies for optimising the use of medicines are required and these were discussed as an essential part of improving patient safety. The Royal Pharmaceutical Society (RPS) Expert Advisory Panel of 16 experts from across the whole of pharmaceutical science has consulted and introduced a document in 2014, entitled *New Medicines, Better Medicines, Better Use of Medicines*[11]. This highlights major challenges surrounding the use of medicines in practice.

Professor Jayne Lawrence of the Royal Pharmaceutical Society stated: "This report makes seven recommendations all of which have safety aspects. Our first recommendation is to ensure the safe use of medicines and we will work to promote research into the causes of medication errors in patients and research into interventions to reduce those errors. We will also help improve patient understanding of the risks and benefits of their medication and pharmacovigilance and reporting of suspected ADRs by HCPs and patients."

Jayne Lawrence (RPS)

According to Professor Lawrence ADRs account for 6.5 percent of hospital admissions with more than 70 percent of these being avoidable. There were an estimated 1.7 million prescribing errors in general practice in England in 2010. Professor Lawrence commented: "We heard of a case of a 92 year old patient who was being prescribed 19 different drugs and after a full medication review when the amount she was prescribed was reduced to four drugs all her side-effects and problems ceased."

Since this published and anecdotal evidence suggests that the use of medicines is "sub- optimal", the RPS is developing principles to support medicines optimisation in collaboration with patients, the NHS and the pharmaceutical industry. This has resulted in the introduction of a publication by the RPS of a guidance document, *Medicines Optimisation: Helping patients to make the most of medicines*[12] and from NHS England *Medicines Optimisation Prototype Dashboard*[13] which Clinical Commissioning Groups (CCGs) that are trialling the dashboard can access via PINCER software.

Ben Rehman (UKMi)

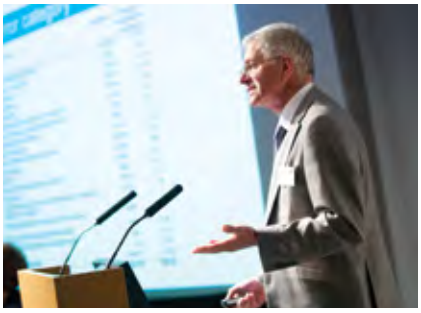
Another strategy for optimising use of drugs was presented by Ben Rehman of UK Medicines Information (UKMi). According to Ben Rehman, the NLRS database can provide a retrospective guide to the safety of medicines in use but to determine the safety profile of medicines before they are procured or contracted for use by the NHS, an assessment tool was not available. This led in 2013 to UKMi developing, validating and testing a new 'in-use product safety assessment' tool which is available as either a PDF checklist or Excel spreadsheet[14]. He stated: "The tool is available and has been used to assess the safety of eight different products and is going to be used to assess six other new medicines and devices. There has been a positive response to the tool from the pharmaceutical industry as it recognises the tool could contribute to better in-use safety design prior to marketing authorisation."

Professor Lawrence concluded: "We need to be giving the right medication to the right person at the right time and this is why we all have to work collaboratively to develop strategies and tools to ensure patients are getting the best outcomes from what they are being prescribed."

NHS perspective

ADR reporting

According to Dr David Cousins of NHS England from 2005-2010, almost 5.5 million patient safety incidents were reported in NHS England and Wales via the NRLS and of these around 10 percent were medication related. The top three causes of medication incidence, which account for 40 percent of the reports: were omitted or delayed medication; the wrong dose, strength or frequency administered[15]. Dr Cousins said: "The number one cause of death or serious harm, which is submitted to the NRLS arises from the unsafe use of opioid medicines."



David Cousins (NHS England)

Since the new Directive 2010/84/EU now includes ADRs arising from medication errors, the NHS needs a system to report these errors to the MHRA. Dr Cousins commented: "The need to report more has meant the NHS and MHRA having a shared agenda to improve reporting systems. Currently, with the NRLS database, the quality of the data we receive can be poor and can take anything up to six months to reach the database."

The MHRA and NHS England are working together to improve methods for reporting and learning of medication errors. A jointly issued Patient Safety Alert in March 2014 recommended improving governance arrangements in healthcare provider organisations in England with an identified board-level director, medication safety officer and medication safety committee to ensure improvements in reporting and learning of patient safety incidents involving medicines.

Incidents involving medicines causing actual harm reported to the NRLS will be shared with the MHRA. A National Medication Safety Network has been established to provide additional support and communication. A similar initiative has also been taken to improving reporting and learning of medical devices.

According to Professor Matt Griffiths of the Royal College of Nursing there are around 67,000 nurse prescribers across the UK (around 10 percent of the entire profession). Many nurses are overloaded with emails so reporting of ADRs is often less of a priority than ensuring patients experiencing ADRs are treated. He commented: "Many nurses are not aware of the significance of the black triangle symbol for example and as we have heard only 85 percent of healthcare professionals are aware of Yellow Card reporting. It would therefore be good if the pharmaceutical industry reps could come and explain to this nurse group on either a one-to-one basis or in lunchtime seminars that they have to be more vigilant when they are using a drug with the black triangle symbol, note any ADRs and report them promptly."

These reporting issues have led to NHS England setting up a National Medication Safety Network in 2014[16] within large primary care settings and to recruiting Medical Safety Officers (MSOs) tasked to support medication error reporting. Cousins concluded: "To date we have recruited 310 MSOs and they meet monthly online via Webex to discuss any new risks identified and best practice to minimise these risks, as well as improve timeliness and quality of reports. This will ensure we have a bottom up and top down approach to reporting. However, there does need to be a 'Good Pharmacovigilance Practice' for HCPs and as yet this is not formalised."

ADR reporting in practice

To show how reporting ADRs by hospital pharmacists can improve patient safety, Janet Thomas of Wales' Betsi Cadwaladr University Health Board presented a snapshot of how North East Wales has been learning from suspected medication-related admissions since 2006. The scheme involves data collection, follow up and feedback to the various origins, be they primary, secondary or tertiary care and other agencies. To support accurate medicines reconciliation, the All Wales Green Medicines 'Bag for Life' is centrally available to all healthcare providers, including the ambulance trust. Clarifying and checking the drugs being used, helps to determine if medication errors have caused the hospital admission.

Janet Thomas (Wales Betsi Cadwaladr University Health Board)

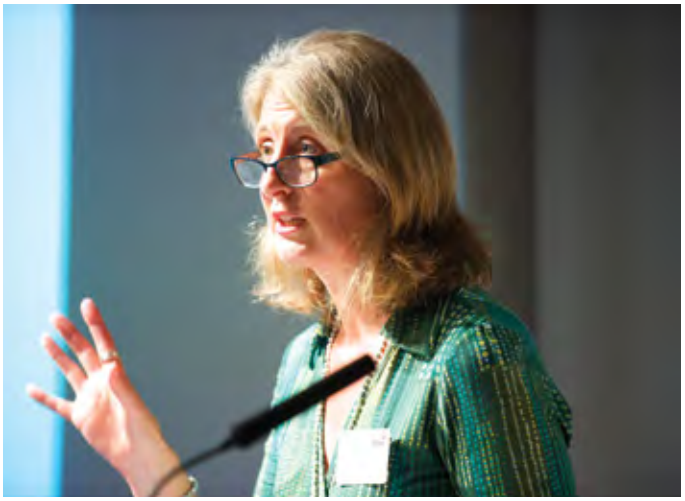
To date this programme has helped identify root causes such as wrong drug/dose or choice; labelling deficiencies in the additional labels number six and seven; conflicting reference sources, as well as a lack of awareness regarding generic/brand names and contra-indication or drug interaction. The similarity between drug names and prescribing /selection or dispensing of incorrect drugs was also highlighted as an issue. It was emphasised that other organisations need to do similar work to maximise the learning as medication-related admissions are acknowledged to occur across the UK and beyond.

Additionally, this programme has provided opportunities for multi-disciplinary collaboration. For instance, Acute Kidney Injury (AKI) admissions involving medicines and acute illness, have led to cross-sector implementation of an AKI Medicines Risk Reduction patient information leaflet along with healthcare professionals' education and an information letter about this. This will contribute to reducing the risk and severity of any AKI in the future given the vast prescribing of the many common medicines involved.

Angela Carrington, lead pharmacist for the Northern Ireland Medicines Governance Team focused on how their work to help improve patient safety in Northern Ireland, which includes incident reporting; medication incident data management; regional medication incident trend analyses; regional best practice policies; audits and medication safety toolkits, as well as undergraduate and postgraduate medication safety training.

Cathy Harrison of Department of Health, Social Services and Public Safety (DHSSPS - NI) discussed the development of the medicine optimisation framework in Northern Ireland and where medicines governance fits with this.

Cathy Harrison (Northern Ireland DHSSPS)



Laura McIver (HIS)

Harrison presented and Carrington touched on the view that working with community pharmacists to encourage their ADR reporting can improve drug safety. According to Harrison, around 1.8 million people are prescribed 38 million medicines and medical devices per year in Northern Ireland and the majority of these prescriptions are fulfilled by community pharmacies, therefore their input can be essential in maintaining patient safety. This has led to the publication of the five year strategy document, *Making it better through pharmacy in the community*[17].

As part of this focus on drug safety, community pharmacists in Northern Ireland will, in the future, be able to access the Northern Ireland Electronic Care Record (NIECR) to check what a patient has been prescribed is correct. They will also be able to access and send an anonymous electronic adverse incident form (the system is currently paper based) to report their dispensing errors and 'near misses'[18].

Carrington stated: "Community pharmacists can be prosecuted so anonymous forms are helping us to capture safety data we would not otherwise obtain. This data is used to produce two types of quarterly medicines safety matters newsletters[19], one to GPs and community pharmacists, covering medicine safety issues pertinent to both professions and another to community pharmacists relating to dispensing incidents and other relevant issues. This is helping disseminate learning and good practice points."

Improving patient information

In addition to reporting ADRs, there have to be plans in place to address issues that have been reported to ensure patients and HCPs do not repeat poor practice. Mary Baker, MBE of the European Brain Council and a patient advocate commented: "We have to get society on board and help people to take responsibility for their own health because now many in the UK are dealing with comorbidity and the NHS was not set up to deal with it on this scale. Since the average reading age in the UK is 10 years old, patient safety information has to be simple to read and understand if patients are to correctly and safely take their medication. Also the community pharmacist is where many patients get their drugs so pharmacists could also be provided with tools to help patients understand what their medication is for and why they are taking it."

Laura McIver of Healthcare Improvement Scotland (HIS) presented how in NHS Scotland the 'Safer Use of Medicines, a Scottish Patient Safety Programme (SPSP)'[20] is being implemented to fulfil this need.

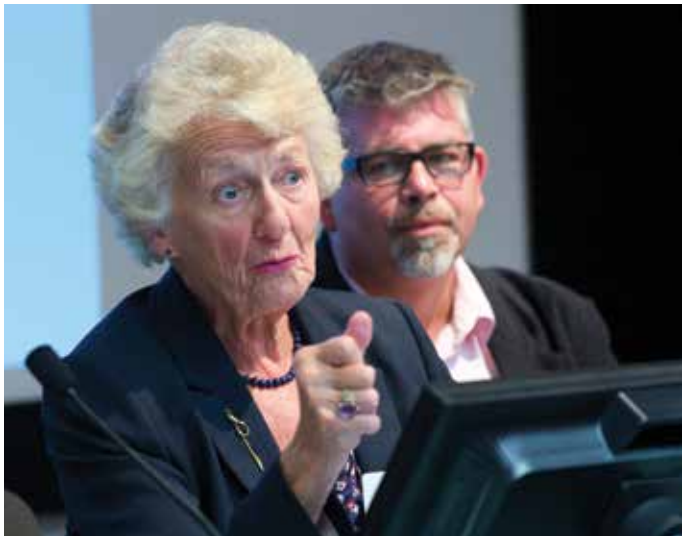
According to McIver in NHS Greater Glasgow and Clyde following an NHS rapid response report, which identified that syringes being marked in ml and not insulin units was causing patients to over or under dose their insulin, an education programme was put in place for patients, carers and HCPs. McIver stated: "The programme showed how to check which insulin you were using and how to give it in the right dose at the right time. Implementing this programme has resulted in us seeing a 50 percent reduction in insulin-related dosing errors in the clinical areas it has been tested."

McIver also described how NHS Grampian is developing resources via their 'Safe to ask' programme. These include a patient information leaflet which explains what questions patients should ask an HCP, alongside credit card-sized information with a simple check list for HCPs on all questions required before prescribing and administering medicines. She also detailed how NHS Tayside developed a similar scheme called 'Safe Prescribing Tayside' which, as well as patient information, includes a checklist guide for HCPs on medicines reconciliation to be used on admission and discharge from hospital.

McIver concluded: "In Scotland we are developing patient information leaflets and short, sharp information in credit card-size that can be stored in a purse or wallet because many patients do not know what questions to ask before they take their medication or which drugs to stop taking when they are ill. The benefit of the SPSP is that we can develop and test interventions locally and then spread those that work throughout Scotland. We have ideas of some national interventions such as the development of one New Oral Anti-Coagulants (NOAC) reference booklet and we're keen to work with the industry on this to facilitate the spread of good practice."

Future challenges

The event identified several challenges which include slow or delayed ADR reporting and lack of access to near miss data. This could be addressed in future with the development of 'good vigilance practices' for the NHS and use of new technology to facilitate integrated reporting and using social media to deliver real-time risk identification and management. The question of how to marry up the expertise on ADR reporting and patient safety information being initiated and utilised in pockets of the NHS was also flagged up as an issue. This could be tackled with conferences and forums to share information and the initiation of a programme similar to the European SCOPE project for the UK to harmonise and build up on best practice. The implementation of a common, single drug chart used across the NHS was highlighted as a simple step that could be taken to harmonise and promote drug reconciliation and documentation.



Mary Baker (EBC) and Matt Griffiths (RCN)

Other challenges identified were insufficient numbers of patient decision tools and under utilising community pharmacists in helping spread some key drug safety messages. To address these issues it was suggested that the industry could help by collaborating to produce single guides for the use of high-risk medicines, starting with one for NOACs, as a case study and better communication tools for community pharmacists to provide to patients, such as inhaler pictorials. There was also a consensus that there is a need for education on understanding risk minimisation efforts and streamlined communications on patient safety by implementing a single alerting system.

Lucy Hampshire of Lilly summarised: "ADR reporting and developing key learnings from that feedback are crucial processes in ensuring drugs are used safely. It is extremely important and commendable that major bodies such as the MHRA and NHS England are working together to make ADR reporting simpler, as well as more integrated and timely as this will provide information on 'real-world' use of drugs and devices. Therefore, we need to commit to bringing the diverse stakeholders at this event together again to ensure that new tools for optimising the use of medicines and best practice for ADR reporting can be shared and successfully implemented and this event marks the beginning of a UK patient safety culture change."

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We represent innovative research-based biopharmaceutical companies, both large and small, leading an exciting new era of biosciences in the UK.

Our industry, a major contributor to the economy of the UK, brings life-saving and life-enhancing medicines to patients. Our members supply 90per cent of all medicines used by the NHS, and are researching anddeveloping over two-thirds of the current medicines pipeline, ensuring that the UK remains at the forefront of helping patients prevent and overcome diseases.

The ABPI is recognised by government as the industry body negotiating on behalf of the branded pharmaceutical industry, for statutory consultation requirements including the pricing scheme for medicines in the UK.

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