Expanding the list of "never events": Policy proposals for engagement.
Royal Pharmaceutical Society Response

The Royal Pharmaceutical Society (RPS) is the new professional body for every pharmacist in Great Britain. We are the only body that represents all sectors of pharmacy in Great Britain and currently have 49,000 members.

The RPS leads and supports the development of the pharmacy profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

Its functions and services include:
Leadership, representation and advocacy: promoting the status of the pharmacy profession and ensuring that pharmacy's voice is heard by governments, the media and the public.

Professional development, education and support: helping pharmacists to advance their careers through professional advancement, career advice and guidance on good practice.

Professional networking and publications: creating a series of communication channels to enable pharmacists to discuss areas of common interest.
The changes for the pharmacy profession, as suggested in this consultation are minimal with many current exemptions being retained.

General comments:
It is disappointing that the Department of Health (DH) did not use the full consultation route for this proposal and we are not sure why the official consultation route was not used in this instance.

Overall we believe that it is extremely difficult to develop a 'never event' that is not attached to a system or a process. Some of the proposed events listed in this consultation appear to be attached to an outcome rather than a system or process.

Whilst we agree with the sentiment and well meaning intentions of the document we are concerned that eight of the total thirteen proposed new events are related to medicines or medical gases. Although medicines are one of the most common clinical interventions in the NHS and research has shown that they are a major risk to patients due to multiple errors, most of the outcomes are minor in nature. We are concerned that the overall balance of this is not right and that unrealistic expectations may be raised and in addition there will be unjustified concerns about the safety of treatment with medicines.

There is also a concern that expanding the list may cause the current sharp focus on 8 events to be lost. The previous 8 events appear to be specific events, whereas some of the proposed new 'never events' appear to be more matters of professional judgement and degree. The extended list of events is largely common interventions used in a wide and varied set of locations including primary and secondary care. These events rely on education and knowledge rather than system changes to deliver the guidance unlike the current list of 'never events'. We believe that what is being sought in many of the medicines proposals is a major change in human behaviour and organisation culture. Using the successful approach

of MRSA and *C.diff* this should not be a binary system of occur or never occurring but a gradual and targeted reduction over time with major financial penalties and rewards to build the barriers and change people's ways of working. These changes in culture, education and behaviour are required not just at provider level, but throughout the healthcare system. The reliance on death and serious unintended injury reflects the lack of robust reporting measures at a national and local level rather than effective patient safety interventions. We should actively, if we want success, be targeting action in terms of process failures not outcomes which rely heavily on many other factors. In principle we do not believe that this approach is the correct approach for medicine related events and the RPS would be happy to enter into dialogue with the Department of Health about how such very serious and rare events can become even rarer.

A couple of the 'never events' relate to labelling errors. In these circumstances computer systems should be designed to make it impossible to produce an inappropriate label. The person providing the label would need to take positive steps to over-ride the system in order to produce an inappropriate label.

In addition, we would query the use of the term 'never events' and the Department of Health itself has calculated that there will be one or two events per Trust per year – therefore these are serious but infrequent events rather than 'never events'. The NPSA guidance is around risk management rather than risk removal and there is always a human element of risk in all systems. There is also a concern within the managed sector that these 'never events' will become targets in the future.

We believe that the main areas that pharmacy has a bearing on are the provision of medicines and medicine-related advice. Other professionals and patients need to expect to be asked questions and be reminded that these questions are part of the safety assurance undertaken by pharmacists

These 'never events' mainly relate to the correct procedures being put in place by management and owners, and thereby, the cost of putting right any mistakes would fall on the original care setting. In pharmacy we have recently had the introduction of Responsible Pharmacist regulations which could potentially lay the cost of putting right the mistake at the feet of the Responsible Pharmacist (RP) rather than the pharmacy owner or superintendent pharmacist. There would need to be clear guidance on how this would work in practice.

In terms of picking up subsequent cost recovery, we consider this to be a very complex area and we do not believe that the DH has given this enough thought. A number of issues need to be addressed in more detail:

- Liability. Attribution of costs will require clear attribution of blame. For a medicines related event this could involve the prescriber, the dispenser and the patient to varying degrees. This could result in more legal challenges and break down of working relationships. In this system, any pharmacist, even the supervising pharmacist for the transaction rather than the responsible pharmacist could end up facing patient relatives explaining that never events do occur albeit infrequently.
- Individuals: A significant amount of dispensing is now undertaken by employees working as part of the pharmacy team within corporate bodies. Although a threat of additional costs might motivate organisations, this issue is already high on their minds because of existing legal liabilities so it is not clear how these proposals will alter the behaviours of individual employees.
- Limit of liability: It is not clear to what extent the cost recovery will apply. It could be just for any immediate treatment and / or corrective procedures or it could extend beyond this; if so, for how long and to what extent? Does it only cover treatment related to the event and its consequences, or would it be for all other treatments the patient may be receiving at the same time?

Overall we are not convinced that imposing cost recovery would actually change individual practice in such a way that would reduce the occurrence of 'never events' but would instead merely create additional burdens and bureaucracy. Any sort of punitive approach has a big risk of discouraging accident reporting and openness.

We believe that in order to make the aspiration of 'never events' more robust certain systems would need to be established. If all relevant healthcare professionals had access to patient's records this would enable them to have up to date and accurate information at the time when they are interacting with the patient. It would also enable them to input their actions into a shared record.

Comments on specific events, current and proposed:

Never event 3: Wrong route of administration of chemotherapy.

If this event refers to the wrong route of cytotoxic (i.e. cancer) chemotherapy then that should be stated. If this event is intended to refer specifically to intrathecal administration of vincristine, as the supporting information suggests, a better definition would read 'Administration of chemotherapy by the wrong route, such as vincristine prescribed for IV administration accidentally administered into the intrathecal space'. However, if the intention is to make it wider , an alternative definition would be 'Administration of medicines by the wrong route, such as intrathecal injection of anticancer chemotherapy prescribed for intravenous administration, intravenous injection of a liquid prescribed for oral administration or of a local anaesthetic prescribed for epidural infusion'.

Never event 8: Intravenous administration of mis-selected concentrated potassium chloride

We do not agree with the current event or the proposed amendment as it is unclear what is meant by 'over infusion of concentrated potassium chloride' as it is the rate and overall dose of infusion rather than the concentration of the product itself that is the key risk factor. However, it is impossible to specify an 'ideal' rate or one which is 'safe' in all circumstances as this will vary depending on; the patient, the care environment and monitoring and administration equipment.

We would suggest an alternative of 'Sudden death or serious harm associated with maladministration of potassium chloride resulting from inappropriate selection or inadequate dilution of Strong Potassium Chloride Injection or other concentrated potassium containing product, or infusion of a diluted solution at a clinically inappropriate rate.'

Never event 11: Death or serious injury as a result of a healthcare professional's prescribing, preparing or administration of insulin in overdose, or his or her failure to prescribe or administer insulin when clinically indicated in a healthcare setting.

A better definition would also include the statement that 'The most commonly identified sources of insulin specific error are failure by prescribers to write "units" in full and / or to specify exactly the intended product and failure by care professionals to select the appropriate product, to measure the correct dose and / or calculate and set the correct infusion rate.'

Never event 12: Death or serious injury arising from failure to recognise and act on critical oxygen saturation levels in a patient undergoing general anaesthesia.

We would suggest the following alternative, 'Death or serious injury arising from failure to monitor and / or recognise and act on critical oxygen saturation levels in a patient being prepared for or undergoing general anaesthesia or requiring or receiving ventilator support in an operating theatre, intensive care or similar environment'.

Never event 13: Death or serious injury associated with the use of wrongly prepared high risk injectable medication, including dose when the error occurs in the healthcare facility preparing and administering medication.

We believe that this is too broad to be useful. Much of this is already covered in the specific never events referring to accidental wrong-route chemotherapy, potassium add insulin. We would suggest that this event is not included.

Never event 16: Death or severe injury as a result of the administration of the wrong gas or failure to administer the correct gas at all through a line designated for oxygen in a healthcare facility
We would suggest that this event is linked to the proposed new 'never event' for oxygen treatment (never event 12) and that a better definition would be 'Death or serious injury as a result of the accidental administration of air or any other unintended medical gas through a line designated for oxygen, or failure to administer the correct gas.'

Never event 17: Daily administration of oral methotrexate for non-cancer treatment or provision of oral methotrexate for non-cancer treatment with the instruction to take daily.
We would suggest that a better definition would be 'Prescription, supply or administration of daily oral methotrexate when weekly treatment is indicated or intended, usually for non-cancer treatment'

Never event 18: Death or serious injury arising from overdose with opioid medicines where the dose of opioid given was inappropriate to the pateint's condition and needs.
Currently pharmacists working in the community do not have access to patient's records so it would be difficult for them to make a professional judgement and to ascertain previous opioid doses. If this was to become a 'never event' it would need to be supported by the correct infrastructure such as access to patient's records to ensure safe and consistent practice.

Never event 19: Death or serious injury arising from overdose of midazolam injection.
This event would also be pertinent to pharmacy and we believe it is similar to the existing never events in that it is specialised and amenable to system changes.

Never event 22: Death or serious injury caused by administration of oral / enteral medication, feed or flush intravenously or intrathecally; or caused by intravenous medication administered intrathecally or vice versa.
If this event is specifically for enteral / parenteral administration, rather than an overall never event on 'wrong route' errors then we would suggest the following 'Death or serious injury due to parenteral administration of any oral liquid medicine, enteral feeding product or other liquid intended for oral or enteral administration'.

An additional never event that could be included is 'Death or serious injury as a result of a healthcare professional's prescribing, dispensing or administration of anticoagulant therapy'. The supply of anticoagulant therapy has many issues similar to other suggested 'never events' for example prescribing and supply of known interacting medication.

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