National Patient Safety Alert Committee (NaPSAC)

Notes from 15:30-17:00 Tuesday 14th August 2018

Attended	On behalf of (name)	On behalf of (organisation or alert-issuing body/team)
Aidan Fowler	-	Chair/ NHS Improvement
Ted Baker	-	Deputy Chair/CQC
Gina Radford	Dame Sally Davies	Chief Medical Officer*
-	-	DHSC Supply Disruption*
John Wilkinson	Ian Hudson	MHRA (Medical Devices)*
June Raine	Ian Hudson	MHRA (Drugs)*
Manpreet Pujara	Martin Severs	NHS Digital*
David Geddes	-	NHS England (Operations)*
-		NHS England (EPRR)
Michael Bellas	Simon Corben (from c.16:30)	NHS Improvement (Estates and Facilities)*
Frances Healey		NHS Improvement (Patient Safety)*
Meng Khaw	Paul Cosford	Public Health England
* Indicates bodies/teams already issuing their own alerts directly via current CAS process (or set up to do so)		

Observers:

Richard Owen (for link to the National Quality Board)

Paul Stonebrook (for DHSC)

Apologies:

Stephen Groves (NHS England EPRR)

David Wathey (DHSC Supply disruption)

1. Welcome and introductions
AF welcomed all parties and emphasised this endeavour is an opportunity to ensure the production and implementation of safety alerts becomes a more powerful and effective mechanism for improving the safety of patients, with leadership, improvement and regulatory attention directed to best effect.
2. Brief updates on any significant developments since last meeting
AF noted continued high levels of Ministerial interest in the aims of NaPSAC and the recent press statement by Caroline Dinenage welcoming the initiative. FH updated on recruitment of support for NaPSAC; hoping to secure secondment agreements and anticipating some interim support over next few weeks to carry forward next steps agreed later today. TB updated on the progress of CQC's thematic review of Never Events, which is also expected to shed broader light on the existing challenges of response to alerts and their implementation.
3. Draft notes of last meeting and outstanding actions
Draft notes of last meeting agreed as a correct record. All past actions completed or taken forward as agenda items today.
4. Draft Terms of Reference (ToR)
Discussed and agreed with the following changes (Note numbering in this section of notes reflects section numbering in the ToR document) 1.1. Clarity amends to wording (see track changes) 2.1 Clarity amends to wording (see track changes) 4.3 DG confirmed NHS England envisages two separate alert issuing functions 4.4 Two patient and public voice (PPV) representatives agreed, process discussed and agreed as invitation via NaPSAC members' existing standing PPV panels but with short selection process, aiming for experience/understanding of alerting systems but able to help us see with fresh eyes and overall balance. 4.6 One observer from each of the devolved nations agreed, each nation to decide who would best represent various interested parties and communicate within their nation Accountability to NQB agreed – RO to advise on formalities of proposing this to NQB and will become NaPSAC member to provide strategic link GR asked about links to DHSC and AD clarified expectation of updating the Minister on progress at regular meetings and confirmed AD & PS will develop understanding of requirements for SoS updating at those.
5. Feedback on 'look back' proformas completed by Alert issuers and implications for core criteria
FH summarised information received from Alert issuers and their implications for areas of clear consensus/consistency, and areas that needed further discussion. See slide set and consider notes below in context of information and questions posed on those slides. 5.1 <u>Process criteria</u>

Headline process criteria in slide set agreed. Discussion around piloting/testing for feasibility and efficacy; all agreed that an additional criterion of ***'appropriate piloting/testing for feasibility and efficacy'*** should be added. Discussion noted that 'appropriate' needed to be included in the criteria because the need to pilot/test would relate to nature of required action (e.g. not required for replacing faulty drug batch; would be required for new method of swab counting). TB emphasised the importance of this in terms of regulatory scrutiny of implementation of actions required by alerts.

Discussion on nature of actions; AD, JW and JR noted the potential for a national alert to require organisations to take some action at an early point of understanding of a risk (as in an NHSI 'Warning Alert') and follow up with a further alert with more specific actions once the issue and how to best address it was fully understood (as in an NHSI 'Directive Alert'). FH noted that the distinction can be important for alert issuers to consider, but from the perspective of receiving organisations, feedback NHSI had previously received suggested being clear what was being asked of them was the important thing. All agreed that SMART actions can be set out even before a very specific requirement/engineered out solution can be set out (e.g. separate rooms for intrathecal and IV chemotherapy to reduce risk of confusion, even before we had NrFIT to engineer out intrathecal and IV confusion).

FH emphasised these process criteria are not intended as elaborate or paper heavy, but as providing key assurance of the basis for the actions in a national patient safety alert.

Situations requiring rapid issue of an Alert discussed; confirmed mutual understanding is that an expected part of agreeing process would be setting out in advance the circumstances where normal processes would justifiably be suspended or shortened e.g. when no stakeholder consultation would take place.

5.2 Format criteria

The headline format criteria were agreed. The need for design/Comms/behavioural insights support in developing a national format, including use of pictures, key words and symbols was discussed and noted. Design implications of follow-up alerts when actions further developed highlighted by JR (needs design distinction so recipients realise it is second or third alert on same or similar issue). The importance of the agreed criterion on language accessible to non-experts (CEOs, non-execs, clinicians for technical issues and vice versa, inspectors) strongly emphasised.

5.3 Terminology and mutual support

Discussed and all agreed way forward suggested in slide set.

5.4 Alerts in public domain

Discussed and agreed strong expectation that this should be the case unless very direct risk of harm from publication (e.g. alert describing a mechanism of suicide) with detail of this to be worked up.

5.5 Remit of Alert issuing bodies

Importance of being able to clearly describe remit (the areas that each alert issuer would, and would not, consider as within their remit) including any potential for overlap agreed, and all confirmed willingness to work until clear and mutually understood.

5.6 Directing Alerts at provider groups

Agree Alerts must have nationwide focus, but this could relate to all providers of a specialist or super-specialist service (e.g. all providers of paediatric cardiac surgery) rather than only broad provider groups (e.g. all acute trusts, all general practices, all MH trusts, etc.)

5.7 Look-back on potential numbers of National Alerts based on previous draft criteria

FH summarised results of lookback exercise (see slide set); very few past CAS publications were considered by their issuers not to meet the previously proposed threshold for a national Alert, and other partners had suggested issues which were not CAS alerts but in hindsight would have met criteria (e.g. Roche FSN). However, differences between alert issuers in how they had interpreted the thresholds had informed proposals for how we could agree a more consistent interpretation that should lead to improved focus – these were discussed as below.

5.8 'Messages' that may meet future criteria for national alerts if required actions were systemic

Discussion on potential for some 'messages' traditionally directed at individual health practitioners that could instead be addressed more effectively through system actions directed at providers (e.g. requiring a general practice organisation to build in new blood monitoring requirements for a specific medication in their electronic record systems, rather than providing information on the need for blood monitoring to individual general practitioners). MP noted upgrades of systems were often feasible to embed these kind of systemic reminders/prompts, but there would also be an organisational responsibility to adopt/install. DG welcomed these types of approaches where feasible.

5.9 Likelihood of death or disability.

DG asked for detail of disability definition to be worked up, ideally adopting an existing established definition; all agreed general sense is some significant impairment of daily living, whilst acknowledging that for some individuals more minor harm could be disabling (e.g. finger injury for violin player).

FH explained that from the 'look-back' exercise the key aspect of variation between Alert issuers at present is not so much level of potential harm, but where the likelihood of that harm occurring is on a spectrum ranging from a theoretical possibility to very likely to occur. AD emphasised we need to agree a common position on threshold in terms of likelihood as well as level of pharm today, as this is a key issue for consensus before taking forward work on detail.

Discussion followed on whether need to be set differently to proposed text on likelihood as 'more likely than not one or more potentially avoidable deaths or disability in England in the following year'. SC noted that this is the right place from an Estates and Facilities perspective, as in this context any death or disability is very rare, so any single death is very significant. In context of setting lower (e.g. slight possibility in following year, or more likely that not one potentially avoidable death or disability in five years) AD noted NaPSAC has been convened in recognition that issuing a very high number of alerts is detrimental to taking effective action on those issues presenting the greatest risks, rather than safer. MC asked if more imminent period needed (e.g. in next three months) but JR noted some harms may take longer to manifest. Some level of subjectivity acknowledged in determining likelihood, but all in agreed that the proposed common threshold for a national alert as ***'more likely than not one or more potentially avoidable deaths or disability in healthcare in England in the following year'*** represented the level that was most likely to achieve the most effective focus on improving the safety of patients.

5.10 Other criteria/threshold related issues

MC asked that given varying remits of partners at NaPSAC we should be referring to healthcare (not NHS-funded care) in any shared criteria – agreed by all.

MB raised question of issues that would not meet the criteria for a national alert – AD noted NaPSAC will revisit that discussion once criteria for national alerts finalised but NaPSAC needs to take care not to try and solve the much broader issue of all safety and quality related communication. All agreed on the need

for equally effective channels for safety advice solely addressing risk of harm to staff, but this will not be within aegis of NaPSAC.

6. Confirm if all NaPSAC members agree proposed core criteria at principles level

All NaPSAC members confirmed they agreed with core proposed criteria that had been presented in the slides at the principles level, subject to the addition and clarification noted above.

7. Agree next steps

FH noted that when NaPSAC support secured, expectation of:

- Expanding stakeholder work to key recipients and interested parties
- Continue discussions with alert issuers individually and/or together in areas outlined on slide set
- Work up the detail of criteria agreed in principle today for discussion/confirmation at next NaPSAC
- Work up potential national alert format, including design aspects discussed today
- Work on consultation/communication proposals

8. Agree agenda items for next NaPSAC

A briefing prepared by the MHRA Central Alerting System team was shared and this was agreed as a major agenda item at the next NaPSAC.

ACTIONS (in addition to mutual commitments to progress all areas discussed above)

FH to provide form of words for members with existing PPV representatives/panels and ask them to encourage applications to be PPV representatives on NaPSAC

AD to email relevant contacts in each devolved nation and ask them to agree and confirm their observer

RO to advise on proposing NaPSAC as sub-committee of NQB as item for inclusion in next NQB agenda

DATE OF NEXT NaPSAC

To be confirmed