NHS Improvement

**Summary criteria for the management and creation of National Patient Safety Alerts CONFIRMED May 2019**

| 1. | **Governance arrangements are in place** | |
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| | **Criteria to confirm at NaPSAC** | ***Rationale*** |
| 1.1. | The issuing team/body has documented its governance arrangements for the issuing of National Patient Safety Alerts which includes a statement of the role and/or scope of the team/body to issue National Patient Safety Alerts | *National Patient Safety Alerts should be in line with the statutory requirements on the issuing teams/bodies and 'remit' needs to be clearly understood externally as well as internally, to avoid overlap between bodies* |
| 1.2. | Roles, responsibilities and lines of accountability for the management of the National Patient Safety Alert development process are included in governance arrangements. | *It should be clear to all in the alert-issuing team/body who is responsible and accountable for the National Patient Safety Alert development process.* |
| 1.3. | Systems are in place to manage any identified and/or potential conflicts of interest. | *It is important that each body considers how it will manage conflicts of interest before they arise, so that such conflicts can be managed without delay to the National Patient Safety Alert process. Conflicts may include issues such as a staff member of the alert-issuing body having a financial interest in a pharmaceutical or medical device company which is a competitor to the company whose product is the subject of the National Patient Safety Alert.* |
| 1.4. | There is a process in place to respond to questions, concerns or requests for clarification after National Patient Safety Alerts are issued. | *Despite due process and stakeholder input, some unintended consequences of actions required by a National Patient Safety Alert could remain unforeseen and only be recognised after it has been issued, or some aspect of the Alert could be found to be unclear. Any such issues will need consideration, including whether revision or reissue is required.* |
| 1.5. | Record keeping requirements related to the development of National Patient Safety Alerts are in place. | *Records need to be kept documenting that the correct procedures were followed in developing the National Patient Safety Alert, including the timeliness of response to the issue. The records would be essential evidence if, for example, a manufacturer legally challenged the issuing of a National Patient Safety Alert, or there was public concern on the timeliness of the response.* |
| 1.6. | All staff whose work involves developing, issuing or monitoring National Patient Safety Alerts receive training in the management and implementation of the alert development process. | *Consistent training of staff in running the National Patient Safety Alert development and issuing processes is important to ensure the correct operation of the systems in response to staff changes and organisational churn.* |

| 2. | Processes for identifying and escalating issues with potential to result in a National Patient Safety Alert are in place | |
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| | **Criteria to confirm at NaPSAC** | **Rationale** |
| 2.1. | There is a system for identifying potential issues that may require the issuing of a National Patient Safety Alert | *Each issuing body needs to demonstrate clarity about how decisions are made to issue a National Patient Safety Alert within its scope of authority.* |
| 2.2. | The system includes agreed sources of information to be monitored, these are listed, reviewed and updated on a planned basis; also, how ad hoc information is responded to. | *The criterion is designed to ensure that alert-issuing teams/bodies have considered which are the most relevant sources of information within their field and these are kept up to date as new sources emerge and/or existing sources become less relevant* |
| 2.3. | The system includes the decision-making process for escalating issues that may potentially meet the criteria for a National Patient Safety Alert to the next stage of work-up and how the decision is recorded. | *This criterion aims to ensure that there is clarity within the alert-issuing team/body on the decision-making authority of specific post-holders and/or groups within the team/body to direct the use of resources in response to the identified issues.* |
| 2.4. | The system includes checks that the proposed National Patient Safety Alert meets the NaPSAC agreed threshold of 'more likely than not one or more potentially avoidable deaths or disability[*] in healthcare[†] in England in a year'[‡] | *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, therefore it was agreed that a threshold should be set.* |
| 2.5 | There is a process in place to agree the lead team/body when an issue that may potentially need a National Patient Safety Alert relates to a topic where there may be overlap/partnership with other issuing teams/bodies | *NaPSAC has identified some areas where partnership and co-badged alerts may be appropriate (e.g. between MHRA and PHE if a faulty batch of vaccine requires removal from stock and requires a catch-up vaccination schedule). In these circumstances a lead issuing team/body needs to be mutually agreed to ensure a smooth process and governance arrangements.* |

[*] *Note this encompasses healthcare intervention to reduce or prevent harm from public health issues*

[†] *Note the 'more likely than not' that the death or disability was avoidable is defined in line with points four to six of the scale used in Hogan et al. preventable deaths studies and replicated in the Royal College of Physicians' Structured Judgement Review*

[‡] *Note that that the reference to 'a year' is the time used for expected frequency. It is not a reference to the immediacy of the outcome of death and disability (e.g. exposure to Creutzfeld-Jacob disease could result in disability and deaths many years later).*

| 3. | Processes for developing and issuing the National Patient Safety Alert are in place | |
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| | **Criteria to confirm at NaPSAC** | **Rationale** |
| 3.1. | The system includes the sources of evidence/information that need to be considered to understand the issue and the potential for constructive action to reduce the risk by healthcare providers. | *Setting out key sources of evidence/information in advance ensures these are incorporated in understanding the potential for an issue to be addressed through a National Patient Safety Alert* |
| 3.2. | The system includes how internal and external advisors provide input to the development of a National Patient Safety Alert. | *It is important to include advisors in the development process to gain the benefit of different perspectives and to aid the credibility of the National Patient Safety Alert with the recipients in the service.* |
| 3.3. | The system includes the processes for review and sign-off that a National Patient Safety Alert is to be developed in response to the issue identified. | *This criterion aims to ensure that there is clarity within the team/body on the decision-making authority of specific post-holders and/or groups within the team/body to determine that a National Patient Safety Alert is to be created.* |
| 3.4. | The intended recipients are determined, both the types of provider organisation to which the National Patient Safety Alert is directed and the required level of coordination within a provider organisation (complex or straightforward).<br><br>NaPSAC defines 'straightforward' as when actions can be taken forward by a single leader per provider organisation through their own team members. All other National Patient Safety Alerts would be considered complex. | *Healthcare provision is complex, but providers find it frustrating if irrelevant alerts are directed at them (e.g. directed at mental health trusts when related to surgical procedures they do not undertake)*<br><br>*National Patient Safety Alerts will only be issued for safety-critical issues, but these may be complex (involving multiple departments and professional groups) or straightforward (e.g. Chief Pharmacist ensuring a batch of drugs are recalled and withdrawal creates no shortages and has no other clinical implications, Medical Devices Manager ensuring a medical device is withdrawn or repaired when this creates no shortages and has no other clinical implications)* |
| 3.5. | There is a procedure for the development of actions required in the National Patient Safety Alert that includes:<br><br>1. An assessment of the actions for potential unintended consequences is carried out<br>2. An assessment of the likely effectiveness of the actions in reducing future harm is carried out<br>3. The feasibility of the actions is confirmed<br>4. Except where actions are clearly of minimal cost, a cost analysis of the implementation of the actions and its | *1. In a complex system any action can potentially have unintended harmful consequences (e.g. separate storage of a drug to reduce selection error could delay access to it in emergencies, standardisation to a single device type could create fragility in supply) that need mitigation. Assessment methods, testing or piloting may be appropriate depending on the actions required.*<br>*2. National Patient Safety Alerts cannot always identify 'strong' barriers that eliminate the problem, but alert issuers should understand the efficacy of the actions if fully implemented, including whether they provide strong, medium or weak barriers.* |

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| | justification in the context of reduction in the associated risks is undertaken<br>5. An assessment of the actions for equality impact is made<br>6. How the defined actions are SMART<br><br>The procedure includes requirements for piloting or testing when appropriate, and how the results of the pilots, tests or assessments and analysis are documented and agreed | *3. Actions need to be feasible (e.g. not rely on purchase of equipment that is unavailable at the scale needed) and where appropriate to have confirmed feasibility through testing/piloting*<br>*4. Assessing costs and benefits of mandated actions (likely to be simple and standard for most drug and equipment recalls) ensures funding is not diverted from other safety initiatives where it could have greater impact.*<br>*5. Actions should not create inequalities or disadvantage groups, for example, actions to ration devices during supply shortages that disadvantage patients without their own transport or who have disabilities.*<br>*6. SMART actions are: Specific, Measurable, Achievable, Realistic and Timely.* |
| 3.6. | Where an alert will involve a patient review or notification exercise* or generate concern with the public who think they may have been personally affected, the alert issuer has systems in place to work with relevant organisations to ensure local and/or national contact points are in place to provide advice to concerned or affected individuals.[§] | *Setting up arrangements in advance is important to ensure any people personally affected can receive the advice and/or investigation and treatment they need as soon as possible, and to ensure people who are unnecessarily concerned receive early reassurance.* |
| 3.7. | The timescale for the agreed actions to be completed is set at the level that is challenging but realistic for all healthcare provider organisations to which it is directed. | *As failure to complete actions by required date will be subject to regulatory scrutiny, it is important to set a realistic date.* |
| 3.8. | The system sets out what types of supporting materials should be provided by the alert issuing team/body for complex National Patient Safety Alerts. | *There is a balance to be struck between issuing a National Patient Safety Alert as soon as possible and centrally providing a full suite of support materials/network opportunities to help providers with implementation, but the issuing teams/bodies need to set out in advance the type of support materials/network opportunities that would be provided when the alert is issued or during the implementation period.* |
| 3.9. | There is a system that the National Patient Safety Alert is reviewed, fact-checked, and checked for clarity prior to sign-off and issue. | *It is important that every effort is made to ensure that National Patient Safety Alerts contain accurate information. Content also needs to be checked to ensure clarity for the non-expert reader on the nature and level of the risk and the actions required in response.* |

[§] *[a link to PHE guidance on managing such patient recalls (currently in draft) will be added when this is published]*

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| 3.10. | Systems for approval to publish National Patient Safety Alerts and supporting materials are built into overall organisational publication approval procedures, including systems for rapid and out-of-hours approval if required. | *Alert issuing teams/bodies may exist within wider organisations that have organisational processes for approving publications, and/or controls on how website material is developed. It is important that the alert issuing team/body has arrangements in place that allow them to publish National Patient Safety Alerts and publish and update any supporting material without undue delay. The short form of National Patient Safety Alerts makes it essential for alert issuers to have access to a website where supporting material can be provided when necessary (and updated with further resources or information, etc.)* |
| 3.11. | The system includes wider stakeholder involvement in the consultation process on draft National Patient Safety Alerts.<br><br>The circumstances that would preclude or limit stakeholder consultation are set out in advance, and in these cases, the decision to curtail or bypass stakeholder consultation is recorded. | *Consultation with a range of stakeholders will provide the benefit of different perspectives to aid in ensuring clarity of wording on the risks and appropriateness of the required actions. Any ambiguities or differences of interpretation that emerge can be resolved before the alert is issued to the service. It is recognised that the consultation process may be curtailed or by-passed, in cases of urgent need to issue a National Patient Safety Alert, but it is important those circumstances are set out in advance. In practice some limited key stakeholder consultation (even if only over hours) appears to have been incorporated in even the most urgent past circumstances.* |

| **4.** | **Quality assurance of the National Patient Safety Alerts is in place** | |
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| | **Criteria to confirm at NaPSAC** | **Rationale** |
| 4.1. | The process for National Patient Safety Alert generation is audited by the alert-issuing team/body on a planned basis. | *Audit allows for the systematic review of the process and associated documentation. It is a check on compliance with the system's policies, procedures and processes. It should be carried out in a planned way with the aim of reporting findings to feed into improvement.* |
| 4.2. | Feedback and evaluation of the issuing team/body's National Patient Safety Alert-issuing process and outputs is sought, considered, and acted upon. | *Whilst the overall new system of National Patient Safety Alerts should have a broader feedback loop and/or formal evaluation, there will be aspects of specific to each alert-issuing team/body and to the main users of their National Patient Safety Alerts where they can seek proactive feedback and build that into improvement loops.* |
| 4.3. | All documentation related to the creation and issuing of National Patient Safety Alerts is subject to document control. | *Document controls ensure that all documentation is current when signed off and when distributed.* |