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12 April 2017

[redacted]
By email
[redacted]

Dear [redacted]

Request under the Freedom of Information Act 2000 (the "FOI Act")

I refer to your email of 16 March 2017 in which you requested information under the FOI Act from NHS Improvement. Since 1 April 2016, the Patient Safety functions under section 13R of the NHS Act 2006 have been exercised by the NHS Trust Development Authority, as part of the integrated organisation known as NHS Improvement.

Your request

You made the following request in relation to the NHS Improvement Patient Safety Alert NHS/PSA/2016/008 '*Restricted use of open systems for injectable medication'*:

Under the Freedom of Information Act, I would request that:

1) You detail your level of involvement with the cardiac professional societies including BCIS and BHRS, in determining your awareness of procedures that this may affect.

2) Details of involvement with other non-cardiac professional societies, organisations or representatives during the formulation of the directive.

3) The term "indefensible" is clarified in the context of performing standard safety equipment preparation.

4) Formal documentation of a potential impact assessment during the formulation of this directive.

5) The numbers of cases of harm, identified as being caused by non-use of the "open injectable system". (A single case of amputation was referred to in the directive.)

6) Was it considered by the directive formulation group that modern practice now uses single use chlorhexidine cleaning sticks, rather than bowls of antiseptic, and that in the majority of

operating environments this has practically eliminated the risk of the "adverse event" occurring. Was this formally considered as an alternative to the current directive?

Provision of clarity relating to the 'open system' patient safety alert

In your request you raised concerns about the impact of the "Restricted use of open systems for injectable medicines" patient safety alert, issued in September 2016, on surgeons' ability to undertake specific cardiac procedures, including 'the insertion of equipment into the heart' and the requirement to prepare this equipment underwater. We responded to your email on 17 March 2017 (set out at annex 1) to clarify that the original alert does not relate to these procedures. We have also contacted a national expert in the field to see if this misinterpretation is more widespread. They agreed that, given the Alert title and text clearly refers to 'injectable medicines', it is unlikely that the alert would be misinterpreted. However, we are keen to hear of specific examples where this may have occurred.

In this letter, we respond to your specific requests for information relating to the Alert, in accordance with our obligations under the FOI Act; however, we would encourage you to make contact with the national patient safety team at NHS Improvement via patientsafety.enquries@nhs.net outside the Freedom of Information process if you have any remaining concerns about the Alert.

Decision

NHS Improvement holds some of the information that you have requested as outlined below. NHS Improvement has decided to release all of the information that it holds.

1) You detail your level of involvement with the cardiac professional societies including BCIS and BHRS, in determining your awareness of procedures that this may affect.

2) Details of involvement with other non-cardiac professional societies, organisations or representatives during the formulation of the directive.

We are answering questions (1) and (2) together as we use Royal Colleges and non-specialist societies as our contact route to specialist groups such as cardiac societies. We do this because during the development of a patient safety alert it is impossible to consult with all professional societies.

All patient safety alerts go through a rigorous process of review and consultation to ensure that the information contained within is relevant, appropriate to address the issue at hand, and does not, where possible, have unintended consequences that could have a negative effect on patient safety.

In this instance, we were advised on alert content and the alert was endorsed by;

- NHS England Surgical Patient Safety Expert Group (PSEG) – this included;
    - Royal College of Surgeons
    - Royal College of Anaesthetists
    - College of Operating Department Practitioners
    - Association for Perioperative Practice
    - Association of Anaesthetists of GB & Ireland

    - Royal College of Nursing
    - Royal College of Ophthalmologists
    - Royal College of Obstetricians & Gynaecologists
- NHS England Patient Safety Steering Group – this included;
    - NHS England
    - Chair of NHS England Medical Specialties PSEG (on behalf of PSEG)
    - Chair of NHS England Women's Health PSEG (on behalf of PSEG)
    - Chair of NHS England Children and Young People PSEG (on behalf of PSEG)
    - Chair of NHS England Mental Health and Learning Disability PSEGs (on behalf of PSEGs)
    - Chair of NHS England Primary Care PSEG (on behalf of PSEG)
    - Care Quality Commission
    - Health Education England
    - Sign up to Safety
- Safe Anaesthesia Liaison Group (SALG) – core membership includes RCoA and AAGBI with the wider membership also including the Faculty of Intensive Care Medicine
- Royal College of Physicians
- Medication Safety Officers Network
- Royal College of Radiologists
- British Society of Interventional Radiology

As this was a Directive Alert we had encouraged all the stakeholders above to work with their sub-committees and specialist groups to ensure there were no other procedures where drawing up injections from open containers was clinically required. The British Cardiovascular Intervention Society and the British Heart Rhythm Society were not directly consulted by NHS England or NHS Improvement, however the Royal College of Physicians were a key contributor to the development of the alert and may have asked for their views.

3) The term "indefensible" is clarified in the context of performing standard safety equipment preparation.

The word 'indefensible' was agreed by the stakeholder groups above to convey that there was no justification for drawing up injectable medication from open containers, with the single exception of embolization particles stated in the Alert.

4) Formal documentation of a potential impact assessment during the formulation of this directive.

NHS Improvement does not hold this information.

The stakeholder groups listed above advised NHS Improvement on clinical impacts of the restriction and agreed that, with the single exception identified in the Alert, there were no areas where the requirement would have a negative impact. Initial discussions were held at the Surgical Services Patient Safety Expert Group prior to the Alert being drafted. Members of the PSEG were then asked to review and provide further comment by email. Final endorsement of the alert by members of the Patient Safety Steering Group was again undertaken by email, and this endorsement was their confirmation that they believed the

Alert directions could be complied with without a negative clinical impact. We would undertake financial impact assessments when a Directive Alert required the purchase of new or more expensive types of equipment or medication, but this was not required by this Alert.

5) The numbers of cases of harm, identified as being caused by non-use of the "open injectable system". (A single case of amputation was referred to in the directive.)

NHS Improvement does not hold this information.

In relation to this alert, it was not possible to search the National Reporting & Learning System to ascertain the specific number of incidents relating to the use of 'open systems' due to the difficulty in determining appropriate keyword search terms. The criteria for issuing Alerts are based on potential for future death or severe harm (see https://improvement.nhs.uk/resources/patient-safety-alerts/) rather than the number of past harms. In this instance the alert was based on clinical feedback that, despite an initial alert in 2007 highlighting the problem, the use of 'open systems' continued in some organisations and specialities.

6) Was it considered by the directive formulation group that modern practice now uses single use chlorhexidine cleaning sticks, rather than bowls of antiseptic, and that in the majority of operating environments this has practically eliminated the risk of the "adverse event" occurring. Was this formally considered as an alternative to the current directive?

The Patient Safety Clinical Lead developing the alert, and the relevant stakeholders, were aware of the increasing use of chlorhexidine cleaning sticks and swabs when preparing the Alert, but, as the Alert states, the inadvertent administration of skin antiseptic by injection is by no means the only potential harm that can occur from the use of open systems for injectable medication as this practice also risks one medication being confused with another, medication being confused for other substances not intended for injection, and increases the risks of bacterial contamination. Meeting notes did not record this part of the discussion.

Review rights

If you consider that your request for information has not been properly handled or if you are otherwise dissatisfied with the outcome of your request, you can try to resolve this informally with the person who dealt with your request. If you remain dissatisfied, you may seek an internal review within NHS Improvement of the issue or the decision. A senior member of NHS Improvement's staff, who has not previously been involved with your request, will undertake that review.

If you are dissatisfied with the outcome of any internal review, you may complain to the Information Commissioner for a decision on whether your request for information has been dealt with in accordance with the FOI Act.

A request for an internal review should be submitted in writing to FOI Request Reviews, NHS Improvement, Wellington House, 133-155 Waterloo Road, London SE1 8UG or by email to nhsi.foi@nhs.net.

Publication

Please note that this letter will shortly be published on our website. This is because information disclosed in accordance with the FOI Act is disclosed to the public at large. We will, of course, remove your personal information (e.g. your name and contact details) from the version of the letter published on our website to protect your personal information from general disclosure.

Yours sincerely,

NHS Improvement

Annex 1

Email sent from Patient Safety Enquiries

Dear Sir,

Many thanks for your FOI request that we currently dealing with and we will respond to fully within the required 20 working days. However, we wanted to provide clarity on a fundamental issue. The patient safety alert that was issued in September 2016 (available here) relates specifically to the use of 'open systems' for **injectable** medicines.

The procedure that you refer to in your opening paragraph relates to 'the insertion of equipment into the heart, and require it's preparation underwater to remove air… these are safety critical steps.' The patient safety alert that was issued was never intended to cover these types of procedure but to restrict the use of 'open systems' in the preparation of injectable medicines to be directly administered to patients.

We are concerned that the alert has been misinterpreted and that others, like yourself, may have concerns about potentially having to change critical safety steps in cardiac surgery. We wanted to contact you immediately to assure you that this alert does **not** relate to these procedures.

Thank you for bringing this to our attention and we are going to speak to our network of professional societies and experts to understand if other people have also interpreted the advice in this way. If we can find evidence that others have misinterpreted the information then we may need to issue a clarification. Any additional evidence or feedback that you can offer to that effect would be also appreciated.

We will be in touch shortly with a full response to the questions you raise.

With thanks

NHS I Patient Safety Team

Please note that all FOI requests to NHS Improvement are dealt with centrally through our FOI inbox (nhsi.foi@nhs.net), so please direct any future requests for information, or any correspondence relating to your current request, to this address. Further information about making a request for information is contained on our website at the following link: click here.