Freedom of Information Act 2000 (FOIA)

Decision notice

Date: **5 March 2015**

Public Authority: **NHS England**
Address: **8E02**
Quarry House
Quarry Hill
Leeds
LS2 7UE

Decision (including any steps ordered)

1. The complainant has requested information regarding metal on metal (MoM) hip replacements and whether they were still being used within the NHS following press reports that their use had been stopped. NHS England originally said that it did hold information relevant to his request and attempted to explain the position in respect of MoM hip replacements. It also directed the complainant to another body which it believed held information relevant to his request. At the internal review stage NHS England changed its position and now said that it did not hold the requested information.

2. The Commissioner's decision is that NHS England does not hold any specific record of whether the use of such implants had been banned.

3. The Commissioner does not require the public authority to take any further action in this matter.

Request and response

4. On 4 July 2014, the complainant wrote to NHS England and requested information in the following terms:

"Question 1. It has been reported by that NHS has recently stopped implanting All types of metal on metal hips from February 2014. Is this true and if so what date did the stoppage occur?

Question 2. Has the stoppage of implanting all types of metal on metal prosthesis been implemented on the recommendation of the National Institute for Clinical Excellence (NICE)?

Question 3. What is the official reason given by the NHS for the stoppage of implanting metal on metal hip prosthesis."

5. NHS England responded on 24 July 2014. It stated that it did not hold the requested information and went onto inform the complainant that,

"Not all types of metal on metal (MoM) hip implants have stopped, only some."

6. It then went onto provide details of another public authority, the Medicines Health Regulatory Authority (MHRA), which it said may hold information of interest to the complainant as it was the MHRA which was responsible for ensuring medical devices such as hip implants were safe. It also provided a link to pages from the website of the National Joint Registry (NJR) relating to MoM hip implants. The NJR is contracted by NHS England to monitor the use of joint replacements together with their longer term performance.

7. Following an internal review NHS England wrote to the complainant on 29 August 2014. It stated that its initial response was incorrect and that it did not hold the requested information. It went onto explain the role of the MHRA in ensuring the safety of such implants and issuing safety alerts regarding such devices. It also provided links to guidance produced by the National Institute of Health and Care Excellence (NICE) and provided more information on the role of NJR.

Background

8. Over recent years evidence has come to light that some patients have experienced problems with MoM hip replacements. The problem is caused by soft tissue reactions to the wear debris from the artificial joint. In 2012 MHRA issued a Medical Device Alert which required hospitals to check MoM hip implants on an annual basis. In February 2014 NICE issued new guidance that only prosthetic hips which have a revision rate (ie require replacing or further surgery) of 5% or less after 10 years, should be used. This was stricter than previous guidance. Although the Commissioner has not identified any particular press coverage from February 2014 relating to the publication of the new

guidance, he is aware of earlier press reports and campaigns which anticipated the guidance and said its implementation would effectively ban the use of MoM hip implants.

9. In notes to the press release which accompanied NICE's new guidance, NICE make it clear that the guidance does not ban the use of implants which fail to meet the new standards. The new guidance simply means that the NHS must make sure it has hip implants which meet the new standard, available as a treatment option.

Scope of the case

10. The complainant contacted the Commissioner on 1 September 2014 to complain about the way his request for information had been handled. By this time he had also made a request relating to the same issue to the MHRA and been advised by that body that it did not hold the requested information either, and that MHRA had not banned the use of MoM hip implants.

11. The complainant said that he had received two contradictory responses from NHS England and also been unable to obtain a clear cut answer from MHRA as to whether MoM hip implants were still being used. He believed that at least one of these organisations should be able to answer his queries.

12. The complainant's request is based on the premise that there has in fact been a stoppage or ban on the use of MoM hip implants. Although Question 1) in isolation could be interpreted as being a request for any information or statistics on whether MoM hip implants were still being used, when read in context with Questions 2) and 3) it becomes clear that the questions envisage a conscious and collective decision by the NHS to discontinue the use of MoM hip replacements. The reference to the stoppage being 'implemented' in Question 2) is a reference to the decision to discontinue the use of MoM hip implants being imposed by someone. In other words, that the use of MoM hip implants had been banned.

13. As Questions 2) and 3) are dependent on there being a ban in place, the Commissioner will start by considering NHS England's response to the first question. Therefore the first issues to be decided is whether NHS England holds information that would allow it to answer Question 1) and if the answer to question 1) is that MoM hip implants have been banned. If they have, the Commissioner will go onto consider whether information is held in respect of Questions 2) and 3).

Reasons for decision

14. Section 1 of FOIA states that upon the receipt of a request for information a public authority is obliged to confirm whether it holds that information and, if so, to communicate that information to the applicant, subject to any exemptions. It is important to recognise that FOIA only provides a right of access to recorded information.

15. The actual information that is being requested in the first part of question 1) is a record of whether there has been a ban. If there had been a ban, it is likely that NHS England would have a record of it. The Commissioner understands that NHS England is not itself responsible for banning medical products. Therefore any record it held relating to a ban is likely to take the form of a memorandum, some type of alert or report from the body imposing the ban. If such information existed it could be provided to the complainant in response to question 1).

16. However the Commissioner is satisfied that there has not been a ban imposed on the use of MoM hip implants. NHS has confirmed this in response to the Commissioner's enquiries. The Commissioner has also read the relevant guidance published by NICE and the notes to the press release which accompanied the publication of that guidance which explicitly stated the guidance did not ban the use of MoM hip implants. The Commissioner has also made enquiries of the MHRA which is responsible for the safety of medical devices marketed in the UK. MHRA has been clear that it has not banned the use of MoM hip implants

17. In the absence of any ban the Commissioner considers it is difficult to envisage what document NHS England would hold which specifically recorded the fact that there was no ban on the use of MoM hip implants. When originally responding to the request in July 2014 NHS England was able to confirm that there had not been any ban of, or stoppage in the use of these implants. Its response was based more on NHS England's knowledge of the current issues within the health sector. In particular it was aware of the problems detected with MoM hip implants by virtue of the monitoring of hip replacements carried out by the NJR. It was through an accumulation of this health sector knowledge that NHS England felt confident in informing the complainant that there had been no stoppage.

18. Nevertheless it did not hold specific, recorded information to the effect that there was no ban. It was therefore wrong to confirm in its original response that it did hold information for the purposes of section 1 of FOIA. At the internal review stage it corrected that mistake and advised the complainant that it did not hold any recorded information. It has maintained this position during the Commissioner's investigation.

19. The complainant had pointed to the contradiction in the two responses to support his complaint against NHS England. However the purpose of the internal review procedure is to provide a public authority with the opportunity to remedy any mistakes it made when initially responding to a request. This is what NHE England has done. Even though it changed its position on whether it held a specific record of whether MoM hip implants had been banned, NHS was consistent in trying to direct the complainant to other sources of information which it believed would help explain the issues surrounding the use of MoM hip implants, the safe guards that were in place in respect of their use and the roles played by different bodies in monitoring and regulating their use. Unfortunately the structure of the NHS is complex and the Commissioner recognises that the complainant was left feeling he was unable to obtain a straight answer to his questions.

20. In light of the above the Commissioner is satisfied that there has been no stoppage of the use of MoM hip implants. Although NHS was aware this was the case, technically, it did not hold any recorded information to that effect for the purposes of FOIA. Therefore the Commissioner is satisfied that NHS was correct when it informed the complainant at the internal stage that it did not hold any information in response to question 1). It follows that as there is no ban in place, the subsequent questions posed by the applicant do not arise.

21. The Commissioner does not require NHS England to take any further action in this matter.

Right of appeal

22. Either party has the right to appeal against this decision notice to the First-tier Tribunal (Information Rights). Information about the appeals process may be obtained from:

    First-tier Tribunal (Information Rights)
    GRC & GRP Tribunals,
    PO Box 9300,
    LEICESTER,
    LE1 8DJ

    Tel: 0300 1234504
    Fax: 0870 739 5836
    Email: GRC@hmcts.gsi.gov.uk
    Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

23. If you wish to appeal against a decision notice, you can obtain information on how to appeal along with the relevant forms from the Information Tribunal website.

24. Any Notice of Appeal should be served on the Tribunal within 28 (calendar) days of the date on which this decision notice is sent.

Signed .....

Pamela Clements
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