Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 12 March 2015

Public Authority: Countess of Chester Hospital NHS Foundation Trust

Address: The Countess of Chester Health Park
Liverpool Road
Chester
CH2 1UL

Decision (including any steps ordered)

1. The complainant made a series of 16 requests to the Countess of Chester Hospital (the Hospital) between the 2 July 2014 and 8 August 2014 in respect of the use of a particular laxative, Movicol, in the treatment of children under five years old. The Hospital provided some information, relied on section 40(2) – personal information, to withheld information on the number of children under five treated with the drug over a given period and denied holding other information. The complainant has complained to the Commissioner about the responses to three of these requests. These include the refusal to provide her with statistics on the use of the drug on under-fives and two requests for information about the risks assessment and approval of the drug which the Hospital denies holding.

2. The Commissioner's decision is that the Hospital has dealt with these requests in accordance with the provisions of FOIA.

3. The Commissioner does not require the public authority to take any further action in respect of these requests.

Request and response

4. The full list of the requests is contained in annex A which accompanies this notice. The three concerns which the complainant has raised relate to request 8), made on the 17 July 2014, request 9), made on 18 July 2014 and request 14) made on 5 August 2014.

5. Request number 8) was made in the following terms;

> "How many children under the age of 5 that (a named doctor) has treated for faecal impaction between 1st January 2009 and 1st January 2014 within the Hospital and the Trust and out of those children how many were prescribed Movicol Paediatric Plan?"

6. Request number 9) was for;

> "All documents relating to the use of Movicol Paediatric Plain for faecal impaction in under 5 year olds in regards to off label use held by the Drugs and Therapeutic Team particularly the risk category marked against the drug.

7. Request number 14) was for;

> "A copy of the new product request form that was submitted for Movicol Paediatric Plain and its use in Children for faecal impaction in under 5's as listed as 3rd line of treatment within the hospital formulary."

8. On the 29 July 2014 the Hospital wrote to the complainant. The letter provided the outcome of the internal review it had carried out in respect of two requests made on the 2 July 2014 as well as providing an initial response to other requests including request 8) and 9). In respect of request 8) the Hospital withheld the number of children treated by the named doctor under section 40(2) – personal information. In respect of request 9) the Hospital advised the complainant that it did not hold any specific documents or risk assessments for Movicol Paediatric Plain.

9. On the 8 August 2014 the Hospital responded to request 14. It said that it had no record of a submission relating to the first time Movicol was used. It went onto explain that Movicol had been in use for a long time and even if a paper application had been made many years ago, it was no longer held.

10. The Hospital advised the Commissioner on 2 September 2014 that it was prepared to forego the opportunity to carry out an internal review of its handling of these requests.

Scope of the case

11. The complainant originally contacted the Commissioner on 9 July 2014 to complain about how the Hospital had handed her initial requests.

12. Through an exchange of correspondence and telephone calls from 29 August 2014 to 1 September 2014 the complainant identified the outstanding issues in respect of the requests she had made up to that point. As well as the information sought by request 8) and 14), she identified particular information captured by request 9) which she believed would be held by the Hospital. The complainant asked the Commissioner to investigate whether the Hospital held this particular information, as well as any general guidance on the use of Movicol for the treatment of under-fives.

13. In respect of the information sought in request 9) the complainant had already been provided with a copy of the Hospital's formulary which sets of the medicines available for use, together with the relevant prescribing information. That formulary showed the use of Movicol as the third line of treatment. The complainant interpreted this as meaning the drug should only be used when other treatments had not been successful. She argued that the Hospital must have carried out some form of risk assessment of the drug for it to be included in the formulary and for it to be reserved as the third line of treatment.

14. The Commissioner considers the issues to be decided are whether the Hospital is entitled to rely on section 40(2) to withhold the statistics on the number of children under five treated by Movicol by the named doctor, whether the Hospital holds the information sought by request 9) including a risk assessment for Movicol relating to its inclusion in the formulary as captured by request 9) and whether the Hospital holds the information sought by request 14).

Reasons for decision

Request 8) The number of children under the age of 5 that (a named doctor) has treated for faecal impaction between 1st January 2009 and 1st January 2014 within the Hospital and the Trust and out of those children how many were prescribed Movicol Paediatric Plan - information withheld under section 40(2)

15. Section 40(2) of FOIA states that a public authority is entitled to withhold information if its disclosure to a member of the public would

breach the data protection principles set out in the Data Protection Act 1998 (DPA).

Is the information personal data

16. The data protection principles only apply to information which constitutes personal data as defined by the DPA, ie information which relates to, and identifies a living individual. The Hospital is concerned that disclosing the information would allow people to identify the children who were treated with Movicol. The first issue which needs to be decided is whether the information could identify these children.

17. The Hospital has explained that children will have been treated with Movicol both as inpatients and outpatients. The Hospital uses codes to record how patients have been treated. The level of coding is very detailed for those treated as inpatients. However it is less so for outpatients and is insufficient to identify those treated by the named doctor, over the given period, for faecal impaction and which of those received Movicol. The information could be extracted by searching through all the individual outpatient files. However the Hospital anticipates that the cost of doing so would exceed the appropriate limit; this is the cost limit established by section 12 of FOIA. The cost limit for public authorities such as the Hospital is £450[1]. Where the cost relates to staff time the Fees Regulation allow a public authority to calculate the cost of searching at £25 an hour, this equates to 18 hours search time. If the cost of retrieving the requested information exceeds this cost the public authority is not obliged to comply with the request. In light of this the Hospital has only considered the information available on the treatment of inpatients. The complainant is aware that the Hospital has focussed on the number of children treated as inpatients and has not objected to the approach.

18. The Hospital has said that the figures for the number of inpatients treated for faecal impaction, and the number of those with that condition treated with Movicol for which the named doctor was the lead clinician, are very low, ie five or below. The Hospital has explained that although the number of inpatients treated with Movicol is low this should not be interpreted as meaning Movicol is rarely used. It has advised the Commissioner that a great many outpatients are treated using the drug.

19. The Hospital has argued that if the statistics were disclosed the children involved could be identified. For this information to be deemed personal data under the DPA it is not necessary that the children can be identified solely from the statistical information itself. The DPA provides that

[1] The appropriate limit is set out in Statutory Instrument 2004 No. 3244 – The Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004.

information is personal data if it is possible to identify someone from that information when combined with any other information which is available. As a disclosure under FOIA is considered to be a disclosure to the public at large, the relevant test is whether the children about whom the statistics relate are identifiable by a member of the public using those statistics and any other information which is available.

20. It is not possible to be absolutely certain what other information is in the public domain and therefore in practice the Commissioner has to assess the risk of the children being identified. If the risk that the statistics can be combined with other information to allow identification is greater than remote, or is reasonably likely, those statistics will be regarded as personal data.

21. The Hospital has directed the Commissioner to the 'Netmums' website and in particular discussion groups where mothers share their experiences of their under-fives' treatment with Movicol. The postings on that website include references to the treatment of children at the Hospital. Although the mothers do not provide their full names when posting their contributions the Commissioner considers that the information available from that website and the potential for information to be available from other websites, or sources increases the risk of the children in question being identified. The Commissioner is satisfied that this risk is greater than remote and that therefore the information constitutes personal data.

22. **Would disclosure breach any of the data protection principles**

23. Having established that the information is personal data the next issue is whether disclosing that information would breach any of the data protection principles as set out in the DPA. The data protection principles regulate how personal data is processed. The term processed includes the disclosure of information.

24. The first data protection principle states personal data shall be processed fairly and lawfully and in particular shall not be processed unless at least one of the conditions contained in Schedule 2 can be satisfied. As the statistics relate to the children's physical health it also constitutes sensitive personal data and there is the additional requirement for the processing of sensitive personal data to meet at least one of the conditions in the Schedule 3.

25. When considering the first data protection principle the Commissioner's approach is to start by looking at whether disclosing the personal data would be fair. The fact that the statistics constitute sensitive personal data has a bearing on whether the requested disclosure would be fair. This is because by its very nature sensitive personal data is the sort of

information that people would regard as the most private. The individuals concerned, or as the children are only very young, their parents, would expect not expect such information to be disclosed to the public. In light of this the Commissioner is satisfied that disclosing the information would be unfair and would therefore breach the first data protection principle. It follows that the exemption provided by section 40(2) is engaged. The Hospital is entitled to withhold the information. The Commissioner does not require the Hospital to take any further action in respect of this information.

Request 9) All documents relating to the use of Movicol Paediatric Plain for faecal impaction in under 5 year olds in regards to off label use held by the Drugs and Therapeutic Team particularly the risk category marked against the drug, and in particular information relating to Movicol's inclusion in the formulary – information not held.

26. Section 1 of FOIA requires a public authority to confirm whether it holds the requested information and, if it does, to communicate that information to the requestor, subject to the application of any exemptions.

27. In situations where there is some dispute between the amount of information located by a public authority and the amount of information that a complainant believes may be held, the ICO, following the lead of a number of Information Tribunal decisions, applies the civil standard of the balance of probabilities. In other words, in order to determine such complaints the ICO must decide whether on the balance of probabilities the Hospital held any information falling within the scope of the request at the time it was made.

28. The information captured by request 9) includes any general guidance on the off label use of Movicol Paediatric Plain for faecal impaction in under-fives. A drug is used 'off label' when used for a purpose other than that described in its licence. The Hospital has explained that Movicol is licenced for use with children, however this does not extend to its use for the treatment of children under five. It is understood that it is common for medicines to be unlicensed for this particular age group and the statutory regime governing the use of medicines does not prohibit the off label use of medicines in this way.

29. Although the request is broad in its scope it is limited to the information held by the Hospital's Drugs and Therapeutic Team. The Hospital has stated that this refers to its pharmacy team. It therefore focussed its

searches on the information held by that team and any related committees.

30. The Hospital has been unable to find any guidelines in current use relating specifically to the use of Movicol Paediatric Plain and which are held by the pharmacy team. Its searches included information held on shared networks drives. This has included a search of its 'S' drive which contains information held on the shared drives used throughout the entire hospital. The Hospital also searched the personal network drives of key members of staff including the Director of Pharmacy, Principal Pharmacist Medicines Management and the Medicines Information Pharmacist. The email accounts of these key staff were also searched. These searches were conducted using the brand name 'Movicol and the name of the active ingredient 'macrogol'.

31. The Hospital is aware that the complainant is particularly interested in the guidelines that were in use during 2011 and, when making her request, she had told the Hospital that she expected the guidelines would have been held from 2008 and would have been subject to periodic review. In light of this the Hospital searched through the pharmacy team's archives.

32. The Director of Pharmacy and Medicines Management has confirmed the extent of those searches. Archived records, held by what was originally the Drugs and Therapeutic Committee were searched. These included a search of manual records. The electronic records were searched using terms 'Movicol' and 'macrogol'. These searches did not return any information.

33. The Drugs and Therapeutic Committee was superseded by what was originally known as the Locality Medicines Management Committee sometime between 2002 and 2006, this later became the Area Prescribing Committee. The electronic archives of the Locality Medicines Management Committee and the NICE New Drugs and Formulary Committee were searched, again, using the search terms 'Movicol' and 'macrogol'. Again, no information was found.

34. The Hospital has explained that over the period covered by its searches there have been significant changes in personnel, office moves and a revision of how its paperwork was stored. Computers are replaced on a rolling programme and any hardware older than 3 to 4 years would have been replaced. Therefore the Hospital is unable to say with absolute certainty that it has never held guidance on the use of Movicol for the treatment of under-fives or any associated risk assessment. However it is confident that the searches it has conducted would have unearthed any information if it was still held. Furthermore the Hospital has said that as it considers Movicol to be a low risk, commonly used product, it

does not have any business need to keep guidance or risk assessments on its use. The National Patient Safety Agency publishes alerts if risks are discovered in the use of any medicine. There have been no risk alerts in respect of the use of Movicol. The Hospital has also confirmed that there is no statutory requirement to maintain records in respect of the use of Movicol.

35. The complainant has said she was advised by the Department of Health that it would expect hospitals to hold guidance on the off label use of medicines such as Movicol. The Hospital has countered that the Department of Health does not require it to have policies relating specifically to Movicol. The Hospital does have a policy titled 'Unlicensed Medicines, Prescribing, Procurement and Supply Policy'. This has already been disclosed to the complainant. However the policy explicitly excludes guidance on the off label use of medicines and instead directs clinicians to national guidance. The Royal College of Paediatrics and Child Health produces guidance on the off label use of medicines[2]. The complainant has been provided with a copy of this document, which in turn directs clinicians to the prescribing guidance available in the British National Formulary for Children. The Hospital has said that it relies on this formulary when prescribing for children. The complainant has been provided with access to the children's formulary.

36. As the Hospital is able to rely on the guidance in the British National Formulary for Children when using Movicol, its use would not be considered contentious. In light if this, the Hospital has advised the Commissioner that it is entirely plausible that Movicol Paediatric was introduced without any formal governance process being followed.

37. Nevertheless the complainant has identified particular information on the use of Movicol which she expects the Hospital would hold. She has obtained a copy of the Hospital's formulary, which is available on the Hospital's website. The link to the relevant section of that formulary is https://s3.amazonaws.com/COCH/PDF/Joint+Medicines+Formulary/1.+Gastrointestinal+System.pdf . Under point 1.6 there is a flow diagram entitled 'Management of Constipation'. In respect of chronic constipation Movicol sachets are listed as the third line of treatment. The complainant argues, very reasonably, that for the Hospital to have produced this formulary it must have taken the decision that Movicol should only be used as the third line of treatment. Therefore the Hospital must have carried out some form of assessment of Movicol. It is

[2] The Royal College of Paediatrics and Child Health's statement on the off label use of medicines can be found here - http://www.rcpch.ac.uk/system/files/protected/page/The%20use%20of%20unlicensed%20medicines%20or%20licensed%20medicines.pdf

that assessment that she seeks. The Commissioner has put that argument to the Hospital.

38. The Hospital acknowledges that it produced the formulary referred to. However it clarified that the formulary does not relate specifically to the prescribing of medicines for children, rather the formulary covers the general, adult use of medicines. The adult formulary was produced following discussions with clinical teams in the hospital. Only where a particular drug choice was contentious would the Hospital deem it necessary to review the use of that drug and carry out some form of risk assessment. In respect of a laxative like Movicol, which was in common use throughout the health service, the Hospital considers the drug to be low risk and therefore the Hospital would not necessarily expect a risk assessment to have been carried out when including the drug in its formulary. Furthermore, the Hospital has explained that the formulary was only produced in 2005 by which time the Commissioner gathers Movicol was already widely used in the Hospital. Considering the scope and complexity of producing a formulary the Hospital has explained that it is likely that it would have been informed by the formularies of other hospitals when compiling its own in respect of the inclusion of what were deemed low risk treatments. In respect to the use of Movicol in paediatric care the Hospital again stated that it relies on the British National Formulary for Children.

39. The Hospital has explained what information it relies on when prescribing Movicol for under-fives. It has stated that there is no business need to hold specific guidance on the use of Movicol or any associated risks, and that it may never have produced such information when compiling its formulary. It has also explained what searches it carried out when trying to locate any guidance held by its pharmacy team on the off label use of Movicol for the treatment of under-fives. Based on these explanations the Commissioner is satisfied that, on the balance of probabilities, the Hospital does not hold the information sought in question 9). The Commissioner is satisfied that the Hospital has fulfilled its obligations under section 1 of FOIA by confirming that it does not hold the requested information. The Commissioner does not require the public authority to take any further action in respect of this element of the complainant's request.

40. However when searching its 'S' drive, which houses the information held on all the shared drives used by the organisation, the Hospital did discover two documents which had not previously been disclosed to the complainant. As these documents are held by the Paediatric Team they do not fall within the scope of request 9) which is limited to information held by the pharmacy team. The documents in question are as follows;

- 'Inpatient Management of severe constipation in children' - which was approved for use in June 2013,

- 'Diagnosis Investigation and management of childhood constipation' - which is described as a guideline document produced and approved in January 2011.

41. Although these documents do not fall within the scope of the request their discovery does demonstrate the thoroughness of the searches that were conducted. The Hospital has advised the Commissioner that it is happy to disclose this information to the complainant and that it will do so in the near future.

Request 14) A copy of the new product request form that was submitted for Movicol Paediatric Plain and its use in Children for faecal impaction in under 5's as listed as 3rd line of treatment within the hospital formulary – information not held.

42. The Hospital has said that it does not hold the requested information. As with the previous request the Commissioner will decide whether on the balance of probabilities, the Hospital does hold the information. If the Commissioner concludes that the information is not held, it follows that he will be satisfied that the Hospital has met its obligations under section 1 of FOIA.

43. The complainant has explained she believes a form would have been completed seeking approval for the off label use of Movicol on the occasion it was first used for the treatment of faecal impaction in under-fives. This belief is founded on forms she has obtained relating to the first off-label use of Movicol by Alder Hey Children's Hospital. The first of these forms is headed 'Request for a new drug or change of drug use' and appears to relate to the general use of Movicol for children as young as two years old. The second appears to relate to Movicol's use for the treatment of a particular child. The forms, which date back to 2003, were completed by clinicians and submitted to the Clinical Pharmacy Manager for consideration by Alder Hey's Drug and Therapeutics Committee. The complainant has argued that if such procedures were in place at Alder Hey, then it is reasonable to expect similar procedures to have been followed and documented at the Hospital. Copies of the forms obtained from Alder Hey were provided to the Hospital to clarify the information which was being sought.

44. The Hospital has provided the Commissioner with a copy of the forms which are currently in use for requesting the use of a new medicine or a significant change in the way a medicine is used. It appears from the date on the form that this procedure has been in place from September

2009 at the latest. As with the Alder Hey process, the form has to be submitted to senior staff in the pharmacy team.

45. The Hospital has argued that the searches carried out when looking for the guidelines and risk assessments captured by request 9) would also have identified the application form for the first time use of Movicol if such a document was held. The Hospital has said that requests for new medicines would be held in the meeting records of the relevant committees. If there was an application in respect of the first off label use of Movicol it would be held in the same archives that were searched when responding to request 9). Those searches included the archives of both the Drug and Therapeutic Committee and the Local Medicines Management Committee. The Hospital has informed the Commissioner that no application form was located.

46. As stated earlier, the Hospital does not consider the introduction of Movicol for the treatment of under-fives to be controversial and that therefore it is plausible that its use was introduced without any formal governance process. It has gone onto say that it is possible that it was introduced in response to Alder Hey's adoption of the drug. Patients being treated with Movicol at Alder Hey may have been transferred to the Hospital where their treatment with Movicol continued. Similarly, doctors from Alder Hey may have transferred to the Hospital and continued to prescribe the drug they were familiar with in their new post. The Hospital has stated that it would be quite reasonable for it to have followed a leading children's hospital like Alder Hey and adopted the use of the drug without deeming it necessary to repeat the assessments already carried out by Alder Hey.

47. The Hospital has explained the extent of the searches that were carried out. The searches targeted the relevant business area within the Hospital, ie its pharmacy team, and included a search of its archives going back as far as 2003. These searches failed to locate the requested information. The Hospital has also explained that it does not consider the off label use of Movicol to be in any way contentious and that therefore it would not necessarily expect its introduction to be documented. This is particularly so in light of the drugs use by Alder Hey, a leading children's hospital. The Commissioner is therefore satisfied that, on the balance of probabilities, the Hospital does not hold an application form which seeks approval for the first time Movicol was used for the treatment of under-fives. Therefore the Commissioner is satisfied that the Hospital has complied with its obligations under section 1 and does not require to any further action in respect of this request.

Right of appeal

48. 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

49. 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.

50. 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 .....

Steve Wood
Head of Policy Delivery
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Annex A

On 2 July 2014 the complainant made the following request for information under the FOIA for:

1) "How many children under the age of 5 were treated for faecal dis-impactation and were treated using Movicol Paediatric Plain between the time periods as stated and under which consultant/doctor.

2) The hospital policies and procedures in place covering 1st September 2011 for off label/unlicensed medicine use."

On 11 July 2014 the complainant requested,

3) "Figures between 2009 and 2014 of how many children were treated for chronic constipation at the hospital, and out of those children how many children under 5 years of age were given the drug Movicol Paediatric Plain for dis-impaction regime and by which doctor.

4) A copy of the policy and procedures that the hospital has in relation to prescribing off label unlicensed medication for these time periods."

On 14 July 2014 she requested,

5) "Copy of policy and procedures that the hospital has in relation to prescribing off label unlicensed medication for these periods"

The complainant also referred to accountability officer for the Trust and asked for:

6) "Can you please advise me who this person is and how I can contact them for this information."

On 16 July 2014 she requested,

7) "Copies of all risk assessments and any governance documents relating to off label drug prescribing in the Trust between 1st January 2010 and 1st January 2014"

On 17 July 2014 she requested,

8) "How many children under the age of 5 that (named doctor) has treated for faecal impaction between 1st January 2009 and 1st January 2014 within the Hospital and the Trust and out of those children how many were prescribed Movicol Paediatric Plain?"

On 18 July 2014 the complainant requested,

9) "All documents relating to the use of Movicol Paedatric Plain for faecal impaction in under 5 year olds in regards to off label use held by the Drugs and Therapeutics Team particularly the risk category marked against the drug. You have advised that you suspect this information will be held around 2008 and be subject to reviews on its use periodical.

10) I would also like to see all documents, policies and procedures and copies of risk assessment carried out by the pharmacy department in relation to this drug and its use off label."

The complainant made six further requests on the 5 August 2014 via two separate emails. In her first email of the 5 August 2014 Miss Wilson asked for,

11) A copy of the Hospital Formulary that would have been in use for 2013.

12) A copy of the guidelines used to produce this formulary specifically in relation to constipation and Movicol Paediatric and its use for faecal impaction in children under 5's as on off label use.

13) Information of when this drug was approved by the Drugs and Therapeutics Committee for use in this way and also any reviews that have been carried out between 2008 and 2014."

In her second email of the 5 August 2014 Miss Wilson asked for,

14) "A copy of the new product request form that was submitted for Movicol Paediatric Plain and its use in Children for faecal impaction in under 5's as listed as 3rd line of treatment within the hospital formulary.

15) I have also found a document from East Cheshire NHS Trust. I would like a copy of your document

16) A copy of the assessment that would have been carried out at the time of the new product request form, together with the minutes of the Drugs and Therapeutics Committee of when this drug was approved, together with any relevant restrictions in place.