

6 March 2017

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133-155 Waterloo Road
London SE1 8UG

T: 020 3747 0000
E: nhsi.enquiries@nhs.net
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By email

By post

Dear [REDACTED]

Request under the Freedom of Information Act 2000 (the “FOI Act”)

I refer to your email of **6 February 2017** in which you requested information under the FOI Act from NHS Improvement. Since 1 April 2016, Monitor and the NHS Trust Development Authority (“the TDA”) are operating as an integrated organisation known as NHS Improvement. For the purposes of this decision, NHS Improvement refers to Monitor and the TDA.

Your request

You made the following request:

- “1. Please provide a copy of your investigation into the implementation of the hearing aid policy described above*
- 2. How many other interventions did you benchmark the scorecard for hearing aid services against in order to come to the conclusion that the policy was robust and applied in a consistent manner across various interventions?*
- 3. In making the decision cited above, did your analysis assess why and how scoring changed during repeat attempts by the CCG to score the hearing aid service?*
- 4. In terms of priority setting decisions in health care, what was the evidence basis (e.g. comparator) for describing the tool this CCG used (e.g. which is subject to significant uncertainty) as robust?*
- 5. Given the most favourable scores given by the CCG to cost-effectiveness and opportunity cost for this intervention, and what this means logically, did the individual/team investigating this for your organisation question*
 - A. Why the CCG initially proposed decommissioning services for mild-moderate hearing loss?*
 - B. Why the CCG later proposed rationing the service for mild-moderate hearing loss based on a mix of threshold and scoring restrictions?*

C. The skills/expertise/qualifications of people making priority setting decisions at the CCG?

We request this information because we also reviewed the CCG's process and were surprised to learn that the NAO and/or Monitor had investigated the process and signed it off as "robust and applied in a consistent manner across various interventions".

Your email is set out in full in Annex 2 to this letter.

We have understood your request to relate to information held by NHS Improvement in relation to our consideration of concerns raised with us about North Staffordshire Clinical Commissioning Group's (CCG) 2015 decision to:

- No longer commission hearing aids for people identified as having mild hearing loss, and
- Apply eligibility criteria to people identified as having moderate hearing loss to determine whether or not they receive a hearing aid.

A formal investigation was not opened in relation to this matter.

As well as the specific information identified in the request, we have understood the requested information to include:

- information provided to NHS Improvement by North Staffordshire CCG, and vice versa;
- correspondence between NHS Improvement and North Staffordshire CCG;
- correspondence between NHS Improvement and third parties; and
- NHS Improvement internal working papers, correspondence and records.

Decision

NHS Improvement holds some of the information requested. We are disclosing a letter from NHS Improvement to the CCG (albeit with minor redactions) as explained in the following paragraphs. We have however decided to withhold most of the information we hold, for the reasons set out below.

Please note that the information falling within the scope of this request was created or obtained by NHS Improvement in the exercise of the functions of Monitor, rather than the TDA. No relevant information is held in relation to the functions of the TDA.

Information Disclosed

Following an enquiry made to us, NHS Improvement wrote to North Staffordshire CCG on 15 December 2015 regarding the commissioning of hearing aids ("the letter"). We have decided to disclose a copy of this letter, with minor redactions to withhold the identity of the group who made the enquiry to us. In relation to the specific information identified in your request, we have provided this information to the extent to which it exists and is included in the released letter.

Ordinarily NHS Improvement would take the view that a letter of this kind would engage the exemption in section 31 of the FOI Act. Information may be withheld under the exemption in section 31 when disclosure would, or would be likely to, cause prejudice to the exercise of NHS Improvement's regulatory functions (this exemption is discussed in further detail below). The letter was written to the CCG in circumstances where an enquiry had been submitted to us on an informal basis, and NHS Improvement would usually consider correspondence of this nature to engage the exemption in section 31. In this case, North Staffordshire CCG tabled a paper at the Healthy Staffordshire Select Committee dated 7 November 2016 about its review of hearing aid policy. That paper identified the involvement of Monitor and indicated that Monitor had undertaken some form of review exercise of the CCG's prioritisation process. The fact that Monitor looked into the CCG's process is therefore publicly available information, put into the public domain by the CCG. Additionally, the CCG has indicated to NHS Improvement that it does not object to the disclosure of the letter. In these circumstances NHS Improvement is of the view that disclosure of this letter will not prejudice the exercise of NHS Improvement's regulatory functions. We have therefore decided to disclose the information contained in the letter, other than the minor redactions.

Withheld information

NHS Improvement has decided to withhold the remaining information that it holds, including the information redacted from the letter referred to above, on the basis of the applicability of the exemption in section 31 (prejudice to the exercise of our regulatory functions) as explained in detail below.

Annex 1, attached, sets out the details of the relevant information that we hold and whether that information is to be disclosed (in part) or withheld from disclosure. Where information is being withheld, we have identified in Annex 1 the exemption which we consider to be relevant, being section 31 of the FOI Act.

Please note that Clinical Commissioning Groups (CCGs) are subject to the FOI Act and as such it is open to you to seek information directly from them. They will need to consider whether information can properly be provided by them in response to any such requests within the terms of the FOI Act.

Section 31 – Prejudice to law enforcement

The withheld information is exempt from disclosure under section 31(1)(g) of the FOI Act which provides a qualified exemption from disclosure where such disclosure would be likely to prejudice the exercise by any public authority of its functions for any of the purposes specified in section 31(2). One of these purposes, contained in section 31(2)(c), is ascertaining whether the circumstances which would justify regulatory action in pursuance of any enactment exist or may arise.

This includes circumstances where NHS Improvement has engaged in discussions with a CCG regarding a potential issue under the Procurement, Patient Choice and Competition

Regulations (the Regulations),¹ but no complaint has been received and/or NHS Improvement has not opened a formal investigation under the Regulations, as in this case. The disclosure of information in these circumstances would be likely to prejudice NHS Improvement's ability to ascertain whether circumstances exist which could justify regulatory action under the Regulations. The taking of regulation action under the Regulations is a function of Monitor.

The effectiveness of our regulatory action depends on the maintenance of confidentiality and ensuring free, full and frank exchanges with individuals and organisations in relation to any of our enforcement functions, including when we are looking into potential issues under the Regulations on an informal basis. In particular, NHS Improvement relies on having an open and cooperative working relationship with commissioners, and a safe space in which they are freely able to share sensitive and confidential information in the knowledge that the information, or any analysis derived directly from it, will not be disclosed more widely. There is a real and significant risk that disclosing the requested information would be likely to have an adverse effect on the willingness of commissioners, or other bodies raising potential issues under the Regulations, to provide us with information on a full, transparent and open basis in the future (and on our relationships with these bodies). Disclosure would also be likely to adversely impact the quality and content of the information provided to us, which would impact on our ability to carry out our regulatory functions effectively.

Public interest test

Section 31 is a qualified exemption and therefore requires that a public interest test be carried out to determine whether the exemption should be maintained. We have balanced the arguments in favour of withholding the information, with the arguments in favour of disclosing the information. We recognised that there is a general public interest in public bodies being accountable and transparent, and a specific public interest in commissioners being accountable and responsible for decisions which affect the use of NHS funds. There is also a public interest in NHS Improvement being accountable for its effectiveness in carrying out its statutory functions under the Regulations.

In relation to the public interest in maintaining the exemption, we have considered the strong public interest in NHS Improvement being able to exercise its regulatory functions effectively and on the basis of full and frank disclosure of information by the bodies concerned. We note that, in the interests of transparency, once a formal investigation into the Regulations has been opened, information about the investigation, including expected timetable, will, where appropriate, be published on the NHS Improvement website. We do not publish details of every complaint we receive or informal advice we provide, and in particular we have not published detailed information on the complaint which is the subject of your request, for the following public interest reasons:

- to maintain a safe space for potential complainants to share their concerns with us;
- to maintain the trust and confidence of commissioners, on whose willingness to voluntarily share information we rely to exercise our functions effectively; and

¹ The National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013.

- because there is a real danger that publishing potentially unsubstantiated complaints or concerns about commissioners without further investigation would have a detrimental impact on commissioners and the carrying out of their functions.

We believe the above approach strikes a correct balance between keeping the public informed of our actions, and ensuring we have access to all the necessary information we need to exercise our regulatory functions effectively and maintain open and cooperative relationships with commissioners.

We also consider that disclosure of the letter to North Staffordshire CCG, subject to minor redactions, in part meets the public interest in transparency in the present case. In respect of the remaining requested information, having weighed up the competing factors set out above, we have decided that there is a strong public interest in maintaining the exemption and withholding disclosure of the requested information.

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, I am happy to discuss it to try to resolve any concerns informally. 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 and the attached information 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,



Dipen Gadhia
Inquiries Lead
NHS Improvement

Annex 1

Details of relevant information we hold	Exemption being applied to withhold information	Application for exemption
Internal correspondence between May and Dec 2015	Section 31(2)(c)	Prejudice to the exercise of our regulatory functions
Two presentations to senior managers in the Cooperation and Competition Team to determine next steps	Section 31(2)(c)	Prejudice to the exercise of our regulatory functions
Information provided to NHS Improvement by North Staffordshire CCG, and vice versa	Section 31(2)(c)	Prejudice to the exercise of our regulatory functions
Letter from NHS Improvement to CCG on 15 December 2015	Disclosed, but redactions on basis of section 31(2)(c)	Prejudice to the exercise of our regulatory functions
Correspondence between NHS Improvement and North Staffordshire CCG	Section 31(2)(c)	Prejudice to the exercise of our regulatory functions
Information submitted to NHS Improvement by third parties	Section 31(2)(c)	Prejudice to the exercise of our regulatory functions
Correspondence between NHS Improvement and third parties	Section 31(2)(c)	Prejudice to the exercise of our regulatory functions
Other internal working papers, correspondence and records	Section 31(2)(c)	Prejudice to the exercise of our regulatory functions

Annex 2

NAO and Monitor (now NHS Improvement)

Background:

NHS Commissioners in North Staffordshire currently ration access to hearing aid services. The Clinical Commissioning Group (CCG) has cited both the NAO and Monitor in a review of its policy, as follows:

- *"7. Following the implementation of the hearing aid policy, the CCGs prioritisation process was investigated by external bodies, including Monitor and the National Audit Office. These investigations have found the policy to be robust and applied in a consistent manner across various interventions" (ref. Hearing Aid Policy Review, **as attached**)*

Fol Request:

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2. How many other interventions did you benchmark the scorecard for hearing aid services against in order to come to the conclusion that the policy was robust and applied in a consistent manner across various interventions?
3. In making the decision cited above, did your analysis assess why and how scoring changed during repeat attempts by the CCG to score the hearing aid service?
4. In terms of priority setting decisions in health care, what was the evidence basis (e.g. comparator) for describing the tool this CCG used (e.g. which is subject to significant uncertainty) as robust?
5. Given the most favourable scores given by the CCG to cost-effectiveness and opportunity cost for this intervention, and what this means logically, did the individual/team investigating this for your organisation question
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 - C. The skills/expertise/qualifications of people making priority setting decisions at the CCG?

We request this information because we also reviewed the CCG's process and were surprised to learn that the NAO and/or Monitor had investigated the process and signed it off as "robust and applied in a consistent manner across various interventions".

Kind Regards

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

Tel: [Redacted]

[Redacted]

15 December 2015

Mr Marcus Warnes
Chief Operating Officer
North Staffordshire Clinical Commissioning Group
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By email: Marcus.Warnes@northstaffs.nhs.uk

Dear Mr Warnes

Commissioning of hearing aids by North Staffordshire CCG

Earlier this year, we were contacted by [REDACTED] in relation to North Staffordshire CCG's decision to:

- no longer commission hearing aids for people identified as having mild hearing loss;
- apply eligibility criteria to people identified as having moderate hearing loss to determine whether or not they receive a hearing aid.

[REDACTED] has not made a formal complaint. However, we have been looking into this matter informally and we wanted to update you on our progress.

We last spoke and corresponded about this matter in October. At that time, we told you that our consideration of [REDACTED] concerns about the commissioning decision had been narrowed to the following issues:

- whether North Staffordshire CCG failed to take into account relevant evidence on the benefits of hearing aids when scoring the intervention against the 'strength and quality of evidence' criterion under its published prioritisation policy;¹
- whether North Staffordshire CCG's scoring of hearing aids was inconsistent with its prioritisation policy and its scoring of other services.

We discussed the scores that were awarded by North Staffordshire CCG's Clinical Priorities Advisory Group (CPAG) in its assessment of hearing aids for non-complex audiology (referred to in this letter as the intervention) against the CCG's prioritisation policy and the reasons for those scores. You also helpfully sent through some further information we requested.

¹ We have referred to version 2.1 of the Policy on the Prioritisation of Healthcare Resources found [here](#).

We have reviewed all of the information that has been provided to us and considered the best way to proceed with this matter having regard to the potential direct and indirect benefits to patients and the resource implications of our actions. We are writing to you to request that North Staffordshire CCG take some steps to improve the transparency of its process for deciding which services to commission in accordance with its prioritisation policy. This letter sets out our specific concerns about the transparency of the process and our suggested next steps. We would be very happy to talk through this with you.

We have not made a substantive decision about North Staffordshire CCG's compliance with the Procurement, Patient Choice and Competition Regulations, nor should this letter be taken as an endorsement of the CCG's decision.

Consistency of scoring against the prioritisation policy

The scoring of the intervention appears to be inconsistent with North Staffordshire CCG's prioritisation policy for the criterion 'strength and quality of evidence' and 'addresses health inequality or health inequity'.

We discussed with North Staffordshire CCG the score of 10 awarded to the intervention for the 'strength and quality of evidence' criterion by the CCG's CPAG. Having regard to the prioritisation policy, we would have expected the score to be higher on the basis that a systematic review² relied on by the CPAG included a randomised control trial.³ North Staffordshire CCG has advised that its CPAG takes a critical and conservative approach to evaluating this criterion which reflects current practice in critical appraisal of clinical literature. In particular, North Staffordshire CCG said that where confidence in the clinical literature is weak, as in this case, the CPAG take a more flexible approach to that set out in the framework so that the score awarded is reflective of the level of confidence in the literature. Based on the sample we have seen, this approach appears to be applied in a broadly consistent way across other interventions the CCG's CPAG has scored. However, it is a more flexible approach to scoring the criterion than that stated in the prioritisation policy.

Likewise, the scoring of the 'addresses health inequality or health inequity' criterion appears to be inconsistent with the prioritisation policy. North Staffordshire CCG explained that where an intervention does not specifically target a group affected by known health inequalities or health inequities then the score will be zero. North Staffordshire CCG explained that its CPAG does not take account of socio-economic gradients when the intervention is accessible by the population as whole. This approach appears to be applied consistently across other interventions scored by the CCG's CPAG that we have seen, but it is not sufficiently explained in the prioritisation policy.

North Staffordshire CCG can improve its commissioning process by reviewing and re-issuing its prioritisation policy so that it accurately reflects the CPAG's actual practice of scoring interventions. Improved transparency about the criteria and how it is applied will make it

² Chisolm TH, et al., A Systematic Review of Health-Related Quality of Life and Hearing Aids: Final Report of the American Academy of Audiology Task Force on the Health-Related Quality of Life Benefits of Amplification in Adults. *Journal of the American Academy of Audiology*. 2007; 18(2):151-183. This study was referred to in the adult hearing service non-complex audiology evidence log.

³ See page 13 of version 2.1 of the policy.

easier for interested stakeholders and patients to understand the commissioning decisions North Staffordshire CCG makes and may help to avoid this type of complaint in future.

Recording and publication of reasons for decisions

Improvements could be made to the way North Staffordshire CCG's CPAG records the reasons for the scores it awards when assessing interventions against the CCG's prioritisation policy. We discussed with North Staffordshire CCG the reasons for the scores the CPAG awarded when assessing the intervention. However, the records we saw of the scores did not include this explanation. Recording the reasons for each score would improve transparency of North Staffordshire CCG's CPAG's assessment of interventions against the CCG's prioritisation policy and of the CCG's decisions in reliance on those assessments. Decisions would be better understood and able to be scrutinised by patients and other interested stakeholders.

Reviewing the commissioning policy for hearing aids for non-complex audiology

We understand that North Staffordshire CCG undertook to the Healthy Staffordshire Select Committee to review the service within 12 months and to report back to them about the outcomes of the policy and the impact on Health and Wellbeing.⁴ We would expect this review to be conducted consistently with the CCG's updated prioritisation policy. We also note recently published guidance from the Department of Health and NHS England, the Action Plan on Hearing Loss.⁵ This guidance may be relevant to your criterion on national priorities when you undertake your review.

We will be speaking to [REDACTED] to update them on our progress in looking into this matter. We intend to indicate to them that we have made some suggestions to North Staffordshire CCG about the matters set out in this letter.

If you would like to discuss any matters in this letter, then please do not hesitate to contact Dipen Gadhia either by telephone on 020 3747 0115 or by email on Dipen.Gadhia@Monitor.gov.uk.

Yours sincerely



John Pigott

Competition Inquiries Director

⁴ Minutes of the Health Staffordshire Select Committee Meeting held on 8 June 2015, which can be found [here](#).

⁵ The Action Plan on Hearing Loss can be found [here](#).