Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 1 July 2024

Public Authority: NHS England
Address: PO Box 16738
Redditch
B97 9PT

Decision (including any steps ordered)

1. The complainant has requested NHSE to disclose information around the testing, short and long term effects and obtaining informed consent for COVID-19 vaccines. NHSE confirmed that it does not hold the requested information.

2. The Commissioner's decision is that on the balance of probabilities NHSE does not hold the requested information. He has however recorded a breach of section 10 of FOIA, for failing to respond to the request within 20 working days of receipt.

3. The Commissioner does not require further steps to be taken.

Request and response

4. On 10 October 2023, the complainant wrote to NHSE and requested information in the following terms:

> ""Re Covid 19 vaccinations. I write to request your confirmation of some vital requirements for the vaccinations to be lawful. Please answer the following three points:

EXPERIMENTAL OR TESTED.

Please advise whether the vaccinations on offer continue to be experimental or whether it has been subject to the usual human and animal testing period of eight to ten years before being approved and released for public health purposes?

SHORT AND LONG TERM EFFECTS

Please confirm whether both the short and long term effects of the proposed vaccination are known?

INFORMED CONSENT Please confirm that the vaccination will be subject to the legal requirement of informed consent prior to application and if so I ask how this consent can be given without detailed information of the content of the vaccine on offer?

Will it be, for example an MRNA vaccine such as the Moderna, Astra Zeneca, or Pfizer varieties including the spike protein which are known to attack the natural immune systems of recipients? If the proposed NHS vaccination remains experimental please confirm that it will be offered exclusively under the legal requirement of prior informed consent as laid down by the International ruling of the Nuremberg Code, and the legal terms of the UK Montgomery Judgement (Supreme Court ruling 2017)."

5. NHSE responded on 5 December 2023. It stated that it does not hold the requested information. In relation to the third element of the request (informed consent), it explained what guidance clinicians are expected to be familiar with around consent and provided a link and confirmed how all staff are made aware of this guidance through training and, additionally, provided a link to the consent process across the whole of the NHS.

6. The complainant requested an internal review on 7 December 2023.

7. NHSE carried out an internal review and notified the complainant of its findings on 9 January 2024. It confirmed again that it does not hold the requested information and explained how under FOIA it is not obliged to create new information in order to answer a request.

Scope of the case

8. The complainant contacted the Commissioner on 16 January 2024 to complain about the way their request for information had been handled. They stated that NHSE has failed to answer their questions. They confirmed that they believed NHSE's:

   "…reply is disingenuous if only on the grounds that to apply a Covid 19 vaccine which is publicly proclaimed as "safe and effective" is impossible without the basis and necessary medical, and legal information which must be present for a minimum level of informed consent requires under the law.

   My objection is grounded on current law of the internationally recognised Nuremburg Articles, and the UK Supreme Court Montgomery judgement of 2019 when informed consent was made a legal requirement before application of a medical intervention."

9. The Commissioner considers that the scope of his investigation is to determine whether on the balance of probabilities NHSE holds the requested information.

Reasons for decision

Section 1 – general right of access

10. Section 1 of the FOIA states that any person making a request for information is entitled to be informed in writing by the public authority whether it holds information of the description specified in the request and, if that is the case, to have that information communicated to them.

11. In cases where a dispute arises over whether recorded information is held by a public authority at the time of the request, the Commissioner - following the lead of a number of First-tier Tribunal decisions – applies the civil standard of the balance of probabilities. In essence, the Commissioner will determine whether it is likely, or unlikely, that the public authority holds information relevant to the complainant's request.

12. NHSE confirmed that on receipt of the original request subject matter experts were consulted in the COVID-19 vaccine deployment programme, including clinicians, as well as NHSE's legal team to review its response. It said that following the Commissioner's request, it reviewed the original response again.

13. NHSE explained its role in the delivery of COVID-19 vaccines. It stated that it is responsible for the delivery of the COVID-19 vaccines making them accessible to the public, following vaccine approval by the regulator, the Medicines and Healthcare products Regulatory Agency (MHRA) and Ministerial approval of guidance provided by the Joint Committee on Vaccination and Immunisation (JCVI).

14. It confirmed that the UK Health Security Agency (UKSHA) provides scientific and operational leadership, working with local, national and international partners to protect the public's health and build the nation's health security capability.

15. In relation to the first element of the request, it therefore confirmed again that it does not hold this information. NHSE said that this is for MHRA to respond to as the regulator.

16. Concerning the second element of the request, it advised how it is not responsible for reviewing academic literature on the short and long term effects of vaccinations, nor is it NHSE's responsibility to administer the Yellow Card system on side effects of vaccines and medicines.

17. It stated that UKSHA provides information on side effects of the COVID-19 vaccine and MHRA also monitors the safety of vaccines, including the Yellow Card system. It confirmed how very basic information on the common and rare COVID-19 side effects are shared by NHSE in public facing materials, for example 'About COVID-19 vaccination, safety and side effects – NHS (www.nhs.uk)'[1] but this is sourced from UKSHA publications and it does no break it down to 'short and long term effects'.

18. NHSE said how it also provides links to additional information provided by UKSHA and gov.uk pages on vaccines, their types and safety. But the complainant should direct their request to UKSHA and MHRA, as they are the organisations that produce and hold this information and would be best placed to address the complainant's request. It stated again that it does not hold any recorded information that would answer the questions posed.

19. With regards to the third element and consent, it advised that vaccine administration is subject to the same consenting process as any other care or health treatment process. Clinicians are expected to follow the usual Green Book guidance produced by UKHSA – information readily available on line – and will have their own medical professional guidance

[1] About COVID-19 vaccination, safety and side effects - NHS (www.nhs.uk)

from their governing bodies , for example the Nursing and Midwifery Council or General Medical Council and so on, which are in the public domain.

20. The Commissioner has made the necessary enquiries to NHSE and asked it to go through the request again to ensure that it does not hold any recorded information. NHSE is confident that it does not and has explained above why that is the case and why the request would be best directed MHRA and UKSHA. The Commissioner has not received any evidence to suggest otherwise and he has no reason to doubt the quality or extent of NHSE searches and enquiries. For these reasons the Commissioner has concluded that on the balance of probabilities NHSE does not hold the requested information.

Procedural matters

21. NHSE breached section 10 of FOIA by failing to respond to the information request within 20 working days of receipt.

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: 0203 936 8963
    Fax: 0870 739 5836
    Email: grc@justice.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.

Samantha Coward
Senior Case Officer
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