Scottish Information Commissioner
www.foi.scot

# Decision Notice 051/2025

## Recommendation of a specific test in the clinical management of breast cancer

Authority: Healthcare Improvement Scotland
Case Ref: 202400472

### Summary

The Applicant asked the Authority for information relating to the clinical and governance rationale for the recommendation of a specific test in the clinical management of breast cancer. The Authority stated that it did not hold the information requested. The Commissioner investigated and was satisfied that the Authority did not hold the information requested.

### Relevant statutory provisions

Freedom of Information (Scotland) Act 2002 (FOISA) sections 1(1), (2), (4) and (6) (General entitlement); 17(1) (Notice that Information is not held); 47(1) and (2) (Application for decision by Commissioner)

### Background

1. On 14 February 2024, the Applicant made a request for information to the Authority relating to the recommendation of a specific test in the clinical management of breast cancer. He asked the Authority to provide:

   - the clinical rationale to explain why, in contradiction to all published guidance, only one of the NHS-funded tests (Oncotype DX) is recommended by the Authority
   - the governance rationale to explain how the nine listed clinical authors ignored all published guidance, including the Authority's own guidance, to recommend the prescribing of only one of the funded tests (Oncotype DX).

2. The Authority responded on 6 March 2024. It issued the Applicant with a notice, in terms of section 17(1) of FOISA, that it did not hold the information requested.

3. On 7 March 2024 the Applicant wrote to the Authority requesting a review of its decision. He stated that he was dissatisfied with the decision because he believed it held the information requested.

4. The Authority notified the Applicant of the outcome of its review on 26 March 2024, which fully upheld its initial response.

5. On 2 April 2024, the Applicant wrote to the Commissioner, applying for a decision in terms of section 47(1) of FOISA. He stated that he was dissatisfied with the outcome of the Authority's review because he believed it held the information requested.

## Investigation

6. The Commissioner determined that the application complied with section 47(2) of FOISA and that he had the power to carry out an investigation.

7. On 30 April 2024, the Authority was notified in writing that the Applicant had made a valid application. The case was subsequently allocated to an investigating officer.

8. Section 49(3)(a) of FOISA requires the Commissioner to give public authorities an opportunity to provide comments on an application. The Authority was invited to comment on this application and to answer specific questions relating to its interpretation of the request and how it established it held no information relevant to the request.

9. The Applicant raised matters in his application to the Commissioner that do not fall within the Commissioner's remit. The Commissioner will therefore not consider these matters in his decision notice. His remit is limited to considering whether the Authority complied with Part 1 of FOISA in responding to the Applicant's request.

## Commissioner's analysis and findings

10. The Commissioner has considered all of the submissions made to him by the Applicant and the Authority.

***Does the Authority hold any relevant Information?***

11. Section 1(1) of FOISA provides that a person who requests information from a Scottish public authority which holds it is entitled to be given that information by the authority, subject to qualifications which are not applicable to this case.

12. The information that is to be given is that held by the authority at the time the request is received as defined in section 1(4). This is not necessarily to be equated with the information an applicant believes an authority should hold. If no relevant information is held by the authority, section 17(1) of FOISA requires the authority to give the applicant notice to that effect.

13. The standard of proof to determine whether a Scottish public authority holds information is the civil standard of the balance of probabilities. In determining where the balance of

probabilities lies, the Commissioner considers the scope, quality, thoroughness and results of the searches carried out by the public authority.

14. The Commissioner also considers, where appropriate, any reason offered by the public authority to explain why it does not hold the information. While it may be relevant as part of this exercise to explore expectations about what information the authority should hold, ultimately the Commissioner's role is to determine what relevant recorded information is (or was, at the time the request was received) actually held by the public authority.

*The Applicant's submissions*

15. The Applicant believed that the Authority held the information requested. He stated that the Authority had failed to adhere to national guidance and produced "misleading bias" for only one product (Oncotype DX), which was affirmed by section 5.4 of the Authority's "Clinical Management of Breast Cancer in NHS Tayside" report[1] (the NHS Tayside report).

16. The Applicant submitted that, regardless of whether the Authority wanted to "deny [it] created a recommendation for Oncotype DX", the question remained: what was the Authority's rationale for section 5.4 and its recommendations?

17. The Applicant argued that the nine authors of the NHS Tayside report must have referenced and employed "clinical or governance evidence, rationale, protocol or guidance" to produce and justify section 5.4 for their remit and their recommendations.

18. As stated above, the Applicant made several comments in his application relating to matters that do not fall within the Commissioner's remit. He will therefore not consider these matters in his decision notice.

*The Authority's submissions*

19. The Authority stated that the fundamental issue in this case was that the Applicant had incorrectly asserted that the Authority made a clinical recommendation for the use of a specific molecular pathology test (Oncotype DX). However, the Authority explained that it had in fact been commissioned in July 2018 by the Chief Medical Officer and the Chief Pharmaceutical Officer for Scotland to undertake a fact-finding exercise around the lack of consensus on the clinical management of breast cancer in what was then called the North of Scotland Cancer Network (NoSCAN).

20. The Authority stated that it had established that the Oncotype DX test was not in use within NHS Tayside through comparison of NHS Tayside guidelines with published national policy and evidence-based clinical guidance and through discussion with the clinical team. The Authority noted that NHS Tayside subsequently directed the test to be used in practice within NHS Tayside.

21. The Authority explained that the recommendation referred to in the request related to the following recommendation (recommendation C) from the Authority's NHS Tayside Report (the report that resulted from the fact-finding exercise):

    "NHS Tayside to use the strengthened governance processes (recommendation A and B), to confirm appropriate use of Oncotype DX by June 2019. NOSCAN, if required, should consult

[1] https://archive.healthcareimprovementscotland.scot/www.healthcareimprovementscotland.org/NHS-Tayside-Cancer-Medicines-Report-Apr19a0f5.pdf?docid=ea0f63a6-2d70-4cc6-af79-e00b4feefe24&version=-1

with MPEP if there are still concerns about the evidence base guiding national advice on its use."

22. The Authority explained that it had interpreted the request as seeking explicit clinical and governance criteria that supported a clinical recommendation. However, the Authority confirmed that the remit of the commission was not to recommend, based on clinical or governance rationale, the use of any clinical test.

23. The Authority explained that part of the commission was to establish whether the Oncotype DX test was available for use in NHS Tayside as NoSCAN had identified that it potentially was not. This was at variance with published national and UK-wide evidence-based guidance, which recommended that the Oncotype DX test should be an option for clinicians.

24. The Authority stated that its role was to establish if practice in NHS Tayside took into consideration the most up-to-date evidence-based guidance. As such, the Authority explained that it did not require an explicit decision-making criterion to compare local guidance with national guidance in search of factual differences. It was simply seeking feedback from the clinical team within NHS Tayside on whether a test was part of local protocol.

25. The Authority confirmed that the meaning of recommendation C was that NHS Tayside should apply the processes detailed in recommendation A and B to confirm the use of the Oncotype DX test in line with Scottish and UK-wide evidence-based guidelines. The Authority stated that it was not a recommendation that NHS Tayside implement a single choice of clinical test.

26. The Authority submitted that it believed the Applicant's starting position was therefore based on an incorrect interpretation and a misunderstanding of the task that the Authority was commissioned to conduct. The Authority confirmed, as stated above, that the scope of the commission was not to recommend specific clinical tests. As no clinical recommendation regarding diagnostic testing was made in the report, the Authority held no clinical or governance rationale to underpin such a recommendation.

27. The Authority confirmed that it had not initially undertaken searches in response to the request as it had established that the request was predicated on a false assertation and therefore the information requested did not exist. However, the Authority explained that for completeness it carried out searches in response to the Applicant's requirement for review. The Authority detailed these searches and confirmed that they identified no information relevant to the request, which it expected as no information relevant to the request was ever created or held.

28. The Authority further explained, in response to the Applicant's points (at paragraphs 16 and 17), that:

    - the evidence-based guidance referred to in section 5.4 and referenced on page 20 of the NHS Tayside report provided the standard to which NHS Scotland clinical practice should have referred in 2019
    - section 5.4 of the NHS Tayside report and the report references detailed the "clinical or governance evidence, rationale, protocol or guidance" used in this fact-finding exercise
    - it did not hold copies of the guidance extant at the time of publication and referenced within the NHS Tayside report.

*The Commissioner's view*

29. The Commissioner has taken account of the submissions provided by the Applicant, in which he explained why he believed that the Authority held information falling within the scope of his request. He has also closely considered the terms of the request and the submissions provided by the Authority relating to its interpretation of the request.

30. The Applicant's request specifically asked for information relating to the Authority recommending that only the Oncotype DX test is used in the clinical management of breast cancer. Having fully considered the Authority's submissions and the content (and fact-finding purpose) of the NHS Tayside report, the Commissioner accepts that the Authority made no such recommendation.

31. In all the circumstances, the Commissioner is satisfied that the Authority took adequate, proportionate steps in the circumstances to establish whether it held any information that fell within the scope of the request.

32. The Commissioner accepts that the Authority's interpretation of the request was reasonable, and he is satisfied, on the balance of probabilities, that the Authority does not (and did not, on receipt of the request) hold any information falling within the scope of the Applicant's request.

33. While the Applicant believed and expected the information requested to be held by the Authority, the Commissioner is satisfied that this was not the case. Consequently, he finds that the Authority was correct to give notice, in terms of section 17(1) of FOISA, that it did not hold the information requested.

## Decision

The Commissioner finds that the Authority complied with Part 1 of the Freedom of Information (Scotland) Act 2002 in responding to the information request made by the Applicant.

## Appeal

Should either the Applicant or the Authority wish to appeal against this decision, they have the right to appeal to the Court of Session on a point of law only. Any such appeal must be made within 42 days after the date of intimation of this decision.

**Cal Richardson**
**Deputy Head of Enforcement**

**25 February 2025**