



NICE and Appealing?

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Foreword

This research was commissioned by the Acute Leukemia Advocates Network (ALAN), an independent global network of patient organisations dedicated to changing outcomes of patients with acute leukemia by strengthening patient advocacy in that area. We aim to maximise the capacity of members within the network to allow us, together, to deliver tailored services to acute leukemia patients and carers on the national level. All whilst joining forces between organisations on the policy and research level across countries. You can find out more about ALAN from our website: <https://acuteleuk.org/>.

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It is a follow-up to a much wider piece of research that explored patient involvement in HTA of medicines for the purpose of reimbursement across seven countries, including England. ALAN wanted to find out more about the opportunity and impact of appeals because NICE is the only agency where appeals were identified as being part of the formal process compared to the other HTA agencies looked at. Patient groups are one of the stakeholder groups that can appeal NICE recommendations. Allowing for appeals offers an opportunity for patient groups to hold NICE to account.

This research helps us to understand how important appeals are; we can point to how patient groups have appealed and been successful. The difference this makes to NICE recommendations is hard to pin down, but having the option for patient groups and other stakeholders to appeal at all may well have shaped the way in which NICE works for the better. We are keen to see policymakers who oversee other agencies whose work shapes the access of patients to new treatments explore the potential merits of introducing an appeal mechanism as part of how their HTA agencies work.

*Samantha Nier, ALAN Network Director
Jan Geissler, ALAN Chair and Steering Committee Member*

Acknowledgements

With thanks to NICE for reviewing the draft version of this report to check the factual content.



Executive Summary

The National Institute for Health and Care Excellence (NICE) makes recommendations on the use of new treatments for patients on the NHS in England and Wales.

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Recommendations made by NICE can be appealed, including by patient groups. With appeal rarely a formal part of HTA, ALAN wanted to find out how many times patient groups have appealed NICE guidance and the success or otherwise of those appeals.

Patient groups and others designated as consultees have the option to appeal final recommendations made by NICE (typically the Final Appraisal Determination or FAD). Appeals can currently be made on two grounds:

- Ground 1: In making the assessment that preceded the recommendation, NICE has:
 - a) failed to act fairly or
 - b) exceeded its powers
- Ground 2: The recommendation is unreasonable in light of the evidence submitted to NICE.

NICE provides guidance on the appeals process and has set out that appeals need sufficient detail and evidence to be taken forward and will not proceed just because a consultee disagrees with NICE. Appeals can be written or oral, and appeals are heard by an appeal panel that includes representatives from NICE, the health service, the life sciences industry and a patient representative.

NICE committees typically revisit their recommendations when appeals are upheld unless changes from the appeal don't require their consideration. When appeals are dismissed, final guidance is issued by NICE. There is no further scope for appeal at this point, although appellants can choose to take further legal action.

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This research built a database of appeals drawing upon NICE's website as well as a Freedom of Information request to NICE where details of appeals were no longer available on the NICE website. NICE removes guidance that has been superseded. Details were obtained for 96 appeals in total, with no details available for 13 appeals.

A rapid evidence review was also conducted with literature identified via searches of PubMed and Google.

NICE has received 117 applications for appeal since it started work in 1999, relating to 95 unique pieces of guidance. The appeal rate has been just under one in ten pieces of guidance since 1999, but the appeal rate has been falling over time. In 2023/2024, three applications for appeals were made relative to 92 pieces of published guidance (3%).

The majority of applications for appeal have been successful, with eight applications rejected (7% rejection rate). Thirty-nine appeals related to guidance on cancer treatments (36% of appeals), and three were for treatments for leukemia (3% of all appeals, 8% of cancer appeals).

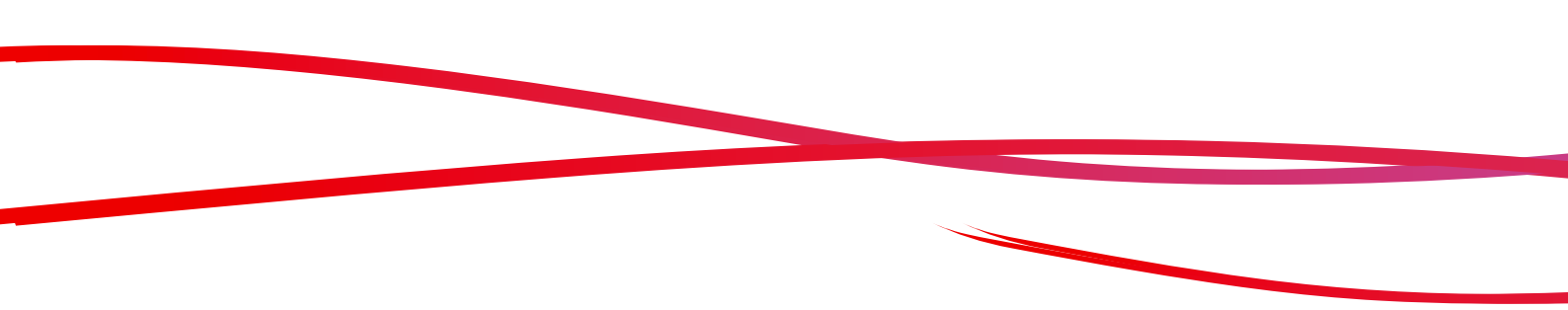
Companies have been involved in 81 of the 96 appeals where information was available. Patient groups were involved in 48, clinicians in 40, commissioners in 7 and providers in three. In five appeals, a patient group was the only stakeholder group to appeal.

Close to half of appeals where information was available were upheld (45 of 96, 47%), and the remainder were dismissed. Patient groups were involved in 30 appeals, which were upheld (66% of the 48 appeals patient groups were involved in). Patient group appeal points were upheld in 21 of these (42% of the 48 appeals patient groups were involved in). Of the five appeals where it was only patient groups who appealed, in only one was their appeal points upheld.

In cancer, 22 (61% of cancer appeals) were upheld, and 14 (39%) were dismissed. Cancer patient groups were involved in 13 of the successful appeals (59%), and at least one or more of their points of appeal were upheld in 11 (50%). A patient group was the only stakeholder group who appealed in one of the upheld appeals.

Appeals have been rarer about NICE exceeding its powers, with appeals more likely to relate to NICE acting fairly or that recommendations have been perverse or unreasonable.

76% of recommendations stayed the same in 41 appeals where the pre- and post-appeal recommendation was available. The recommendation also changed even when appeals were dismissed, with the inference being that other factors changed the re-



commendations in the final guidance. Previous research has found a greater impact of appeals on final recommendations reached.

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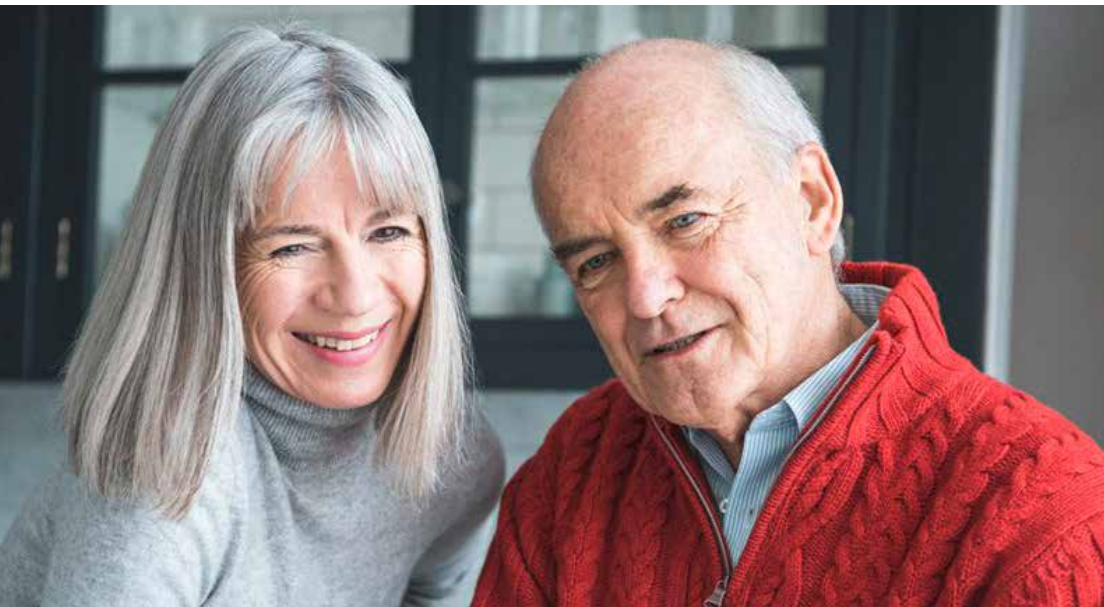
The impact of appeals on NICE is likely to be more than the specific appeals themselves because the prospect of appeals may positively influence how NICE works, alongside the potential for further legal challenge.

Appeals come at a cost which has not been quantified, so it is not possible to say if improvements made because of upheld appeals have been worth the cost incurred. There is also likely to be a trade-off with timeliness with appeals adding to the overall timetable for NICE to produce final guidance.

Policymakers who oversee other HTA agencies should consider whether to introduce an appeals process, including allowing patient groups to be appellants.

Further research could also explore lessons by hearing from patient groups who have appealed, which could help patient groups focus their efforts only when an appeal is likely to be successful. Lessons could also come from legal action that has been taken against NICE.

The missing 13 appeals, as well as the small number where pre and post-appeal recommendations were available, have limited this research. There is also the possibility of unconscious bias and human error, given this research was conducted by a single researcher.



Introduction

The National Institute for Health and Care Excellence (NICE) provides recommendations on the use of new treatments for the NHS in England and Wales. Their recommendations are backed up by a legal requirement to fund treatments that they recommend through their technology appraisal programme.¹

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Among the eight health technology assessment (HTA) agencies operating across seven countries that were examined by ALAN for their approaches to involving patients and patient groups², NICE stood out for appeals. It was the only agency that offered a formal option to appeal to patient groups, as well as other stakeholders.

ALAN commissioned this research to identify:

- How many times have patient groups appealed NICE guidance;
- The success of patient group appeals.

¹ - NICE. (Undated) Technology appraisal guidance. Available at: <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance>

² - ALAN. (2024) Opportunities and impact of patient involvement in health technology assessment of medicines for the purpose of reimbursement: An exploratory comparative report. Available at: https://acuteleuk.org/wp-content/uploads/2023/02/HTA-report_final.pdf



Appeals at NICE

Consultees can appeal

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Consultees to a technology appraisal or a highly specialised technologies evaluation at NICE have the opportunity to lodge an appeal.³ Consultees are those organisations or individuals who are invited to comment during the development of guidance by NICE. They include national groups that represent patients and carers, bodies that represent health care professionals as well as companies.⁴ The Department of Health and Social Care (DHSC), the Welsh government, NHS England and integrated care boards (and their predecessor organisations) are also consultees.⁵

Organisations that are not given the consultee designation cannot appeal.⁶

³- NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

⁴- NICE. (Undated) Glossary. Available at: <https://www.nice.org.uk/Glossary?letter=C#Consultee>

⁵- NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

⁶- NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

Grounds for appeal

The grounds for appeal have changed over time at NICE. Before 1 June 2023, grounds of appeal were:⁷

1. The Institute has failed to act fairly and in accordance with its procedures.
2. The Institute has prepared guidance which is perverse in light of the evidence submitted.
3. The Institute has exceeded its legal powers.

From 1 June 2023 onwards, these were changed to:⁸

- Ground 1: In making the assessment that preceded the recommendation, NICE has:
 - a) failed to act fairly or
 - b) exceeded its powers
- Ground 2: The recommendation is unreasonable in light of the evidence submitted to NICE.

The appeals process has been changed over time. For example, no longer does the Chair of NICE sit on the appeals committee following a review by the Health Select Committee in 2001/2002.⁹

NICE most recently changed its guidance for appeals in 2023 as part of a wider update.¹⁰

Appeals only apply to final recommendations

Appeals can only be made against final recommendations. Appeals must be lodged in writing within 15 working days of the final draft guidance¹¹ being issued to consultees and commentators. NICE includes this date in their letters sent to consultees.¹²

⁷ - NICE. (18 February 2014, last updated 1 April 2017) Guide to the technology appraisal and highly specialised technologies appeal process (pre June 2023). Available at: <https://www.nice.org.uk/process/pmg18/chapter/foreword>

⁸ - NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/introduction>

⁹ - House of Commons Health Committee. (17 December 2007) National Institute for Health and Clinical Excellence: First Report of Session 2007-08 Volume 1. Available at: <https://publications.parliament.uk/pa/cm200708/cmselect/cmhealth/27/27.pdf>

¹⁰ - Sidley. (19 May 2023) New guidance on appeals against UK health tech appraisals applies from June. Available at: <https://goodlifesci.sidley.com/2023/05/19/new-guidance-on-appeals-against-uk-health-tech-appraisals-applies-from-june/>

¹¹ - This is typically a Final Appraisal Determination (FAD).

¹² - NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

High bar for appeals

Guidance from NICE makes it clear that appeals against Ground 1(a) must be underpinned by detail and evidence, as well as the appellant being able to explain what steps they took to resolve unfairness.¹³ Similarly, under Ground 2 NICE won't accept an appeal due to disagreement with the views or conclusions. According to NICE, an appeal is not an opportunity to ask NICE to consider new evidence or information that was not presented to the advisory committee or to reopen arguments and issues that the advisory committee has decided on. NICE guidance that appeals won't be accepted due to disagreement with the recommendation(s) NICE has reached presumably seeks to avoid misuse of the appeals process.

A NICE non-executive director acts as a gatekeeper to the appeals process. They have the responsibility to determine the arguability and validity of each of the appeal points lodged and decide if an appeal, be that written or oral, will be held. They can take legal advice in doing so.¹⁴

The lead non-executive director for appeals will have regard to past decisions of the appeal panel in determining whether an appeal is held. However, NICE guidance highlights that they are not strictly bound by precedence.¹⁵

Appeal letter

Consultees have to send a letter if they wish to appeal. NICE guidance stresses the need for the appeal letter to be submitted correctly, include the necessary information and be presented clearly.¹⁶

A one-page executive summary is required if the appeal letter is more than five A4 pages. The points of the appeal must be set out in the letter and in the order of the grounds to which they relate. Appellants have to set out specifics; for example, if an appeal is under ground 1, they have to identify the specific paragraph number in the NICE process document that applies that has been contravened.¹⁷

It is also up to the appellant to ensure any commercial-in-confidence or academic-in-confidence information in their appeal letter is identified, supplying two versions of the letter, one with confidential information and another with such information redacted.¹⁸

¹³- NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

¹⁴- NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

¹⁵- NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

¹⁶- NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

¹⁷- NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

¹⁸- NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

The letter must also include a concluding statement.¹⁹ NICE publishes appeal letters on its website.²⁰

NICE will not consider new evidence as part of the appeal process.²¹

Initial scrutiny

The NICE non-executive director for appeals will typically provide their initial views – set out an initial scrutiny letter - on whether the appeal will be taken forward within five days.²²

Typically, the initial scrutiny letter will say whether the lead non-executive director for appeals considers whether the appeal should be held orally or in writing. Exceptionally, a decision may be deferred until points made for an appeal are confirmed at final scrutiny.²³

A written appeal process is adopted only with consultation with appellants.²⁴

If the appeal letter does not present an arguable case under one or more grounds of appeal, the reasons will be set out, and the lead non-executive director for appeals may request further information or clarification via the initial scrutiny letter.²⁵

Appellants have ten working days to respond to the initial scrutiny letter, which can include clarifications, arguments or comments about the non-executive director for appeals' concern that an appeal point raised has no reasonable prospect of success, is unsupported by evidence or is outside the scope for an appeal.²⁶

The appellant will receive a final scrutiny letter, which sets out the final decision on points for appeal, and their decision is final.²⁷

If an appeal is taken forward, NICE confirms this with appellants and will also inform consultees and commentators that an appeal has been received along with details of when the appeal will take place, be that written or orally, the name of the appellant organisation

¹⁹- NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

²⁰- NICE lists past appeals and decisions on their website here: <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/technology-appraisal-and-highly-specialised-technologies-appeals/past-appeals-and-decisions> This page includes live links to the specific appraisals. Under the history tab for each appraisal documents relating to an appeal(s) are included.

²¹- NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

²²- NICE lists past appeals and decisions on their website here: <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/technology-appraisal-and-highly-specialised-technologies-appeals/past-appeals-and-decisions> This page includes live links to the specific appraisals. Under the history tab for each appraisal documents relating to an appeal(s) are included.

²³- NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

²⁴- NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

²⁵- NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

²⁶- NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

²⁷- NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

and the date for the appeal. NICE also puts details on their website two working days after they have informed consultees and commentators. On the morning of an appeal, NICE will also put appeal documentation on their website with any confidential information removed.²⁸

Appeal panel

NICE has an appeal panel that hears appeals. Each panel member is approved by the Secretary of State for Health. The panel has five members: a non-executive director of NICE, a health service representative, a representative of the life sciences industry, and a patient representative.²⁹

An external member acts as a chair. The chair can be someone who represents the health service or a patient representative (either a patient or carer or a representative of patients and carers).³⁰

Appeal panel members will not have had any involvement in the technology appraisal or highly specialised technology evaluation that is being appealed. Conflict of interest declarations are required from each panel member in line with NICE's conflict of interest policy. Appellants can raise it with the Chair of the appeal panel within ten days of receiving the list of members of the appeal panel if they feel that any member of the appeal panel has an interest that could favour or disfavour appellants. The panel could be changed if NICE considers it necessary.³¹

Oral appeals

Oral appeals are held in public, and NICE opens up registration to attend at least 20 working days before the oral hearing is held. Up to 25 places are available, which can be taken up by consultees, commentators, members of the public and the press. NICE can limit the number of representatives per organisation.³²

Appellants are allowed up to five representatives at the hearing, including any legal representatives. If there are more than three appellants, this can be reduced to three representatives per appellant.³³

Public observers are not permitted to participate in discussions, record or take photographs.³⁴

²⁸ - NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

²⁹ - NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

³⁰ - NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

³¹ - NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

³² - NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

³³ - NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

³⁴ - NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

Appellants can provide introductory statements at an oral appeal and are expected to ensure that their statement is relevant to the appeal, avoid repetition and be as clear and concise as possible. The Chair can intervene if statements are irrelevant or duplicative. The Chair determines the order in which appellants make their statements. Visual aids are not accepted. NICE describes the hearings as inquisitorial, not adversarial, with questions made through the Chair, and there is no direct questioning between appellants and representatives of the NICE advisory committee and NICE staff. Comments are made with an opportunity for response, and brief concluding statements are invited before the hearing is closed.³⁵

Confidential information can be heard in private. This is allowed when the appeal panel is satisfied that it is necessary for an effective oral appeal.³⁶

Written appeals

The written process uses an exchange of letters. The appeal panel will still meet, but there will be no appellants, advisory committee members, NICE staff, press or the public in attendance.³⁷

Post appeal

The appeal panel aims to communicate their decision in writing to NICE within 15 working days of the appeal, although there can be times when more time is needed.³⁸ The Guidance Executive at NICE – that includes the NICE Executive Team and Chaired by the NICE Chief Executive - will consider the appeal decision.³⁹

When an appeal is upheld, the final draft guidance is then returned to the NICE advisory committee. They decide how to act on the decision of the appeal panel. When the appeal panel requests changes to the final draft guidance, they may not require further consideration by the committee. If the appeal has been dismissed and the appeal panel has not requested any changes to the final draft guidance, the final guidance is then published.⁴⁰

There is no further opportunity for appeal once an appeal panel has come to its final decision. Appellants do have the option to apply to the High Court for a judicial review. This is a type of court proceeding where a judge reviews the lawfulness of a decision by a public body. As the Courts and Tribunals Judiciary explains, judicial reviews are “a challenge to the way in which a decision has been made, rather than the rights and wrongs of the conclusion reached.”⁴¹

³⁵- NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

³⁶- NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

³⁷- NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

³⁸- NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

³⁹- NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

⁴⁰- NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

⁴¹- Courts and Tribunals Judiciary. (Undated). Judicial Review. Available at: <https://www.judiciary.uk/how-the-law-works/judicial-review/>

Application for a judicial review must be done within three months of NICE publishing final guidance.⁴²

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Rejected appeals

Where scrutiny has rejected all grounds of appeal, NICE will then inform appellants, consultees and commentators that the appeal is rejected. They will also inform them of the new date anticipated for publication of final guidance. Details are also placed on the NICE website.⁴³

Cancelled appeals

Appellants can withdraw their appeal, or NICE may withdraw final draft guidance. In these instances, any appeal is marked as cancelled, and details are also placed on NICE's website.⁴⁴

⁴² - NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

⁴³ - NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>

⁴⁴ - NICE. (26 April 2023) Guide to the technology appraisal and highly specialised technologies appeal process. Available at: <https://www.nice.org.uk/process/pmg41/chapter/who-can-lodge-an-appeal-and-on-what-grounds>



Approach

Identifying Appeals

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An appeals database was put together, drawing upon publicly available sources.

NICE has a webpage that lists past appeals, rejected appeals and cancelled appeals.^{45, 46}

For technology appraisals and highly specialised technology evaluations that were current in August 2024, the final appeal decision(s) was identified by going to the webpage for each technology appraisal/highly specialised evaluation and the history page, which includes documents relating to appeals.

A Freedom of Information request was used to source the final appeal documents for superseded guidance, although NICE was not able to provide these for all appeals.

⁴⁵ - NICE. (Undated) Past appeals and decisions. Available at: <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/technology-appraisal-and-highly-specialised-technologies-appeals/past-appeals-and-decisions>

⁴⁶ - This listed six cancelled appeals, 8 rejected appeals, and 108 appeals (a total of 122) in August 2024. TA504, TA501 were each listed once on the NICE list but had two appeals. TA078 was listed as having an appeal but the history page does not include any reference to an appeal. This results in a total of 123 (i.e. 122 + 2 - 1).

Details were obtained for 96 appeals in total (56 from the NICE website and 40 from the Freedom of Information response). Based on 109 appeals heard⁴⁷, this means details for 13 appeals were not available for this analysis.

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Initial recommendations⁴⁸ and final recommendations⁴⁹ were obtained from the NICE website, where these were available⁵⁰ or from NICE's downloaded spreadsheet that provides details on technology appraisals.⁵¹

Rapid evidence review

The wider literature on NICE appeals was identified using a search on PubMed for NICE appeals as well as searches in Google.

⁴⁷- This is based upon 123 – 14 with the 14 (the sum of six cancelled appeals and 8 rejected appeals).

⁴⁸- Set out in FADs with the FADs issued before the appeal used in this analysis, as these are appealable.

⁴⁹- i.e. the final recommendation that NICE reached in guidance.

⁵⁰- These are not available for superseded appraisals.

⁵¹- This Excel spreadsheet includes the final recommendation for superseded appraisals as well as current appraisals. Available for download from: NICE. (Undated) Technology appraisal data. Available at: <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/data>



Findings

One in ten pieces of guidance appealed

NICE has received a total of 117 applications for appeal since it began its work in 1999. These relate to 95 unique pieces of guidance because more than one appeal has been made against the same guidance.⁵² That translates to just under one in ten pieces of guidance (9%⁵³) that stakeholders have wanted to appeal (NICE has published 978 technology appraisals (resulting in 1338 recommendations)⁵⁴ and 31 highly specialised technologies guidance).⁵⁵

The appeal rate varies by year (*Figure 1*). This suggests that over time, the appeal rate has fallen, perhaps as NICE and stakeholders have gained more experience over time. This is broadly consistent with the findings of previous research, where a review of appeals from 2010 to 2011 found that a quarter of appraisals resulted in an appeal.⁵⁶

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⁵² - GID-TAG387, TA006, TA32, TA33, TA064, TA104, TA135, TA160, TA161, TA219, TA482, TA504 and HST27 have been appealed twice, so this means that it is 109 appeals – 14 to provide the sum of 95 unique pieces of guidance appealed.

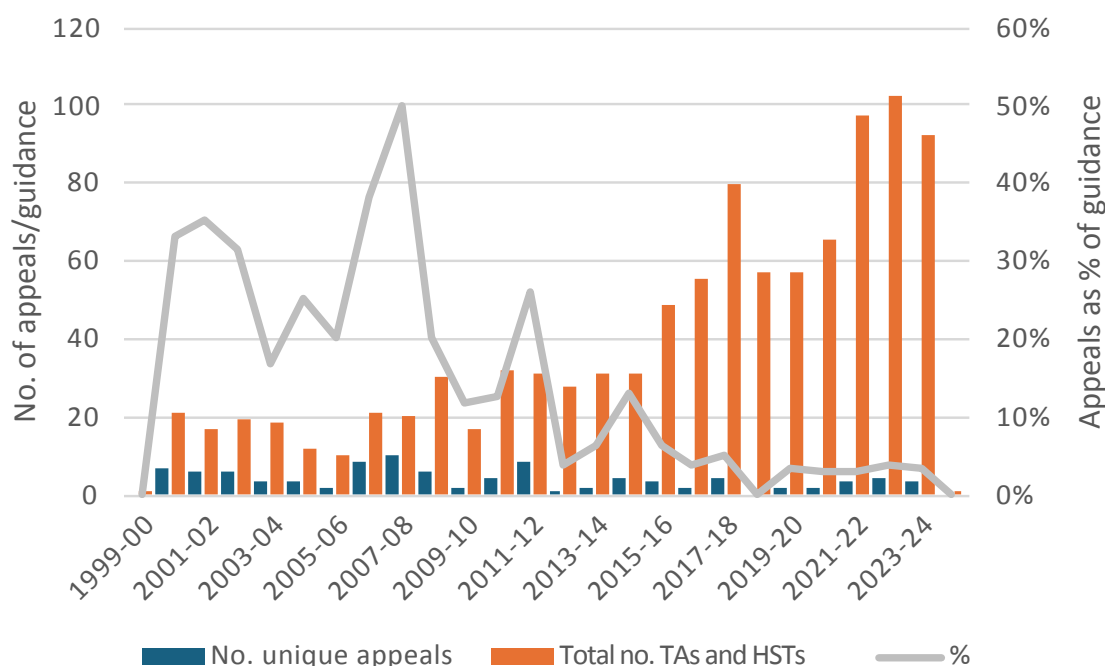
⁵³ - This is based upon 95 divided by 1009 (which is the sum of 978+31). NICE states 978 for the total number of published appraisals with the webpage updated 8 August 2024, but their graph for appraisals published each year sums to 963. Their excel sheet to download for the graph is also mislabelled for the years.

⁵⁴ - <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/data/appraisal-recommendations> last updated 8 August 2024

⁵⁵ - <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/data/appraisal-recommendations>

⁵⁶ - Xcenda. (15 May 2017) When the Outcome of an Appraisal is Not NICE: An Overview of the Appeal Process. Available at: <https://www.xcenda.com/insights/hta-spring-2017-outcome-of-appraisal-is-not-nice>

Figure 1: Number of appeals and guidance published by year



Note: NICE data for technology appraisals published by year sums to 963, not 978. This suggests that the data for the graph that NICE hosts differs from the headline figure of 978 given on their NICE statistics webpage as of 18 August 2024. There have been 31 HSTs, which are also included in the graph based on a list of HSTs from the NICE website on 18 August 2024. The first year of the appraisal for each guidance is used when appeals have been held in different years to avoid double counting of appeals.

Appeals may relate to the prevailing working approach of NICE, as the agency has seen changes to the guidance covering their appraisal work,⁵⁷ but this has not been explored in this research.

Majority of Applications for Appeal Result in an Appeal

The vast majority of applications for appeal are successful, with eight rejections in response to 117 applications, a 7% rejection rate.⁵⁸

Thirty-nine appeals were for cancer treatments (36% of all appeals), and of those, three were treatments for leukemia (3% of all appeals, 8% of cancer appeals).

Companies Appeal the Most

Companies have been involved in 81 of the 96 appeals heard where the details on the final appeal decision are available (84%), followed by patient groups in 48 (50%), organisations representing clinicians in 40 (42%), commissioners in 7 (7%) and providers in three (3%).

Twenty-four appeals were made by a company(ies) alone with no other stakeholder group involved (25%). Eighteen appeals were made with no company(ies) involved (18%).

⁵⁷ - Xcenda. (15 May 2017) When the Outcome of an Appraisal is Not NICE: An Overview of the Appeal Process. Available at: <https://www.xcenda.com/insights/hta-q-spring-2017-outcome-of-appraisal-is-not-nice>

⁵⁸ - This based upon 8 rejections divided by 117 (which is 123-6 cancellations).

In five appeals, a patient group was the only stakeholder group to appeal (5%).

Appeals Upheld and Dismissed

Of the 96 appeals for which the final appeal decision is available for analysis, 45 (47%) were upheld,⁵⁹ and 51 were dismissed (53%). This split is not dissimilar to the findings of previous research, which found that of appeals from 2000 to 2011, 41 % were upheld, and 59% were dismissed.⁶⁰

Patient Groups Involved in Successful Appeals

Patient groups were involved in 30 appeals which were upheld (66%). In 21 of these, the patient group's appeal point(s) were upheld (43% of the 48 appeals patient groups were appellants).⁶¹ In the five appeals where it was only a patient group appellant, four were dismissed (8% of the 48 appeals patient groups were appellants), and one was upheld (2% of the 48 appeals patient groups were appellants).

In cancer, 22 (61% of cancer appeals) were upheld, and 14 (39%) were dismissed.⁶² Cancer patient groups were involved in 13 of the successful appeals (59%), and at least one or more of their points of appeal were upheld in 11 (50%). A patient group was the only stakeholder group who appealed in one of the upheld appeals.⁶³

In leukemia, in two of the three appeals, the overall appeal was upheld, and at least one or more points of appeal were upheld in those same two appeals.⁶⁴ In one of these appeals (TA193), the patient group appealed alongside clinicians in a joint appeal, in one, they were an appellant along with the company (TA251) and in another (TA541), along with the company and clinicians.

Grounds of Appeal

Twenty-nine appeals were heard against the current grounds of appeal and 66 on historic grounds of appeal.⁶⁵

Appeals relating to legal powers are made less often than those relating to following processes, and unreasonable/perverse guidance and appeals made against these have been more likely to have been upheld ([Table 1](#)).

⁵⁹- This does not mean that all points of appeal were upheld. It means that at least one or more points of appeal were upheld.

⁶⁰- Xcenda. (15 May 2017) When the Outcome of an Appraisal is Not NICE: An Overview of the Appeal Process. Available at: <https://www.xcenda.com/insights/hta-spring-2017-outcome-of-appraisal-is-not-nice>

⁶¹- An appeal is counted as upheld where any appeal point made by any appellant was successful. In 21 cases at least one appeal point from a patient group was upheld.

⁶²- In 36 appeals the appeal outcome is available, in 3 it could not be determined.

⁶³- In the appeal of GID-TAG507. The guidance was subsequently discontinued.

⁶⁴- The patient groups were UK Chronic Lymphocytic Leukaemia (CLL) Forum, The CML Support Group and Leukaemia CARE.

⁶⁵- In this case, the total is 95 not 96 appeals. This is because the appeal for TA696 was available when the desk research started and details for the outcome of the appeal were abstracted but a second pass to add in further details later in the research found that this TA has now been superseded. The grounds for appeal are therefore missing for this appeal.

Table 1: Frequency and proportion of appeals made against current and historic grounds of appeal

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Current (29 appeals)	Ground 1: In making the assessment that preceded the recommendation, NICE has: a) failed to act fairly	Ground 1: In making the assessment that preceded the recommendation, NICE has: b) exceeded its powers	Ground 2: The recommendation is unreasonable in the light of the evidence submitted to NICE
	20 (69%)	9 (31%)	28 (97%)
Upheld	14 (70%)	2 (22%)	16 (57%)

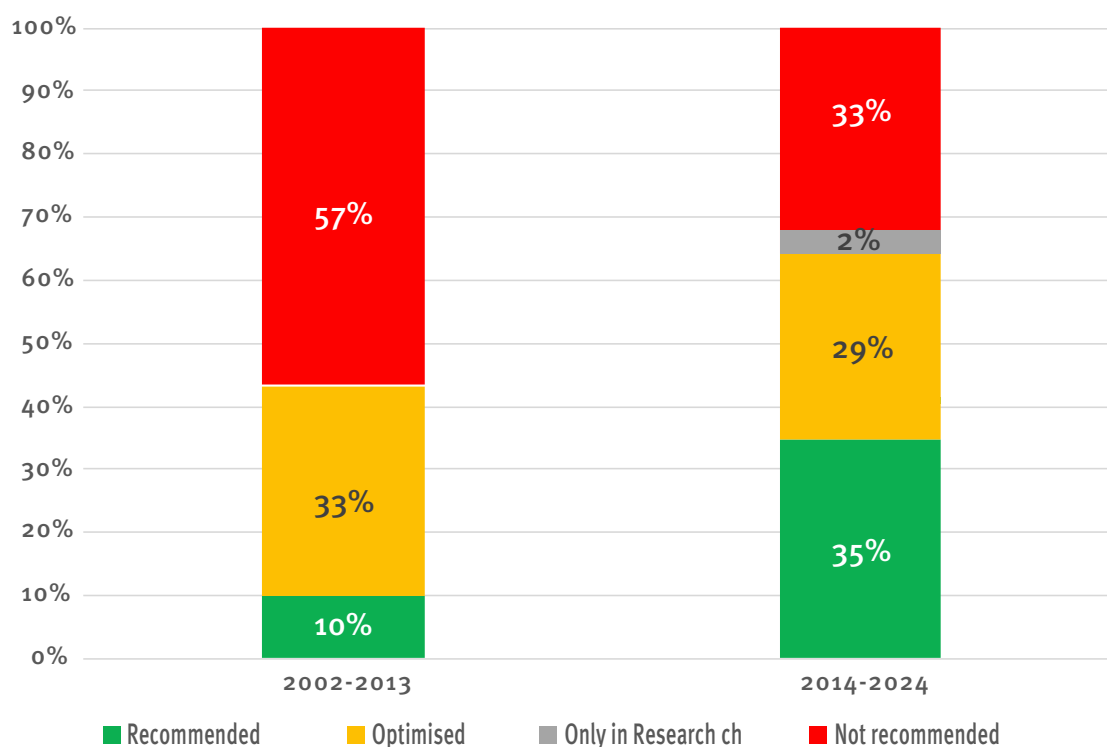
Historic (66 appeals)	1) the Institute failed to act fairly and in accordance with its procedures	2) the Institute prepared guidance which is perverse in light of the evidence submitted	3) the Institute exceeded its legal powers
	59 (89%)	60 (91%)	24 (36%)
Upheld	18 (31%)	16 (27%)	0 (0%)

Note: These relate to 95 appeals in total. In two appeals, the appeal panel could reach no findings.

Change in Recommendations

Initial recommendations were available for 42 appeals. Final recommendations were available for 72 ([Figure 2](#)). These are descriptive statistics and do not imply appeals as a cause of change.

Figure 2: Recommendations before and after appeals



Note: n = 42 appeals pre-appeal, n = 72 after appeal.

In 41 appeals, the recommendations pre and post-appeal were available. Of these, 10 saw a change in the recommendation (24%). These included:

- Not recommended to recommended 4 (10%)
- Not recommended to optimised 4 (10%)
- Not recommended to only in research 1 (2%)
- Optimised to recommended 1 (2%)

Patient groups were appellants with at least one appeal point upheld in five appeals where the recommendation changed (12%). These included:

- Not recommended to recommended 3 (7%)
- Not recommended to optimised 2 (5%)

For upheld appeals the recommendation changed in six cases. In all these cases, patient groups had at least one of their appeal points upheld. This also means that in four cases, the recommendation changed even when the appeal was dismissed, suggesting other factors shaped the final NICE recommendations made.

That there is little change in recommendations is contrary to previous findings from research which looked at 36 appeals since 2010. In that research, 54% of re-appraisals resulted in what the authors describe as more favourable reimbursement decisions. It's not possible to compare the details underpinning the findings between this research and theirs.⁶⁶

A more recent review covering appeals up to 2020 also found that changes to recommendation were more frequent, with 46% of upheld appeals leading to a substantive recommendation improvement. Substantive recommendation improvement was defined as “not recommended” and changed to “recommended”/“optimised”. Similarly, it is not possible to compare the details that underpin the findings between this research and theirs.⁶⁷

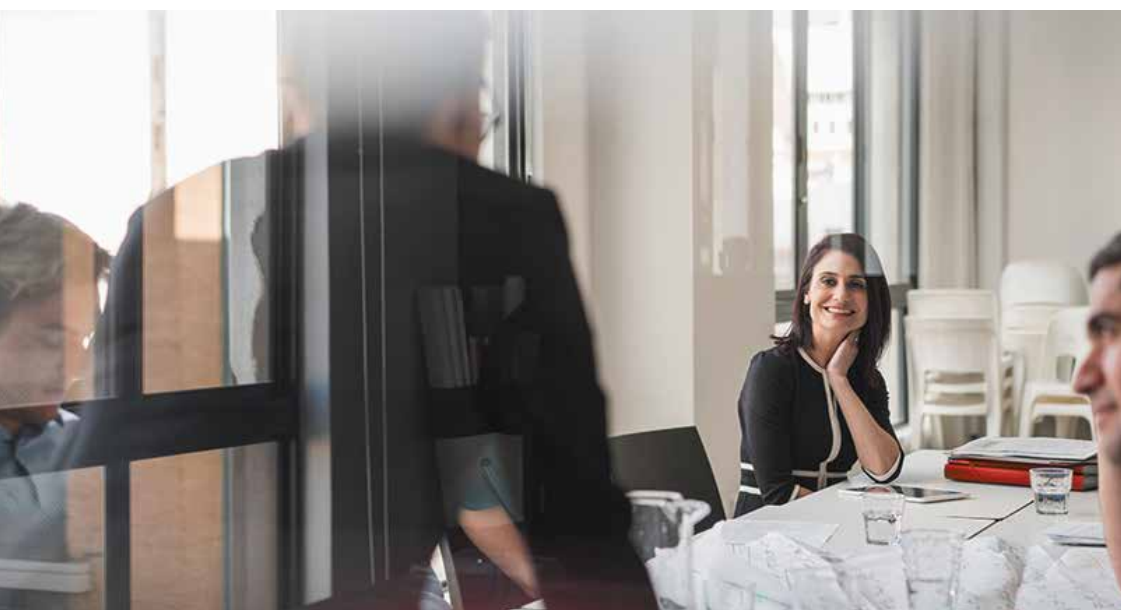
This research did not find as many changes as previous research suggests that the degree of missing details of initial recommendations is material and affected the findings. It may also reflect the specifics of the 13 appeals that were not available for analysis.

Whilst no longer contemporary, experience from the first seven years of NICE appeals highlighted how even when appeals were upheld, the changes to the wording were often only small.⁶⁸

⁶⁶- Their research is reported in an abstract so the details of appeals are not available. See Illingworth, N., Ruane, P.J., Tallentire, C.W. (2020) PDG66 A Review of the Outcomes of NICE Health Technology Appraisal Appeals. Value in Health. 23 (S2) S530. Available from: [https://www.valueinhealthjournal.com/article/S1098-3015\(20\)33005-9/fulltext](https://www.valueinhealthjournal.com/article/S1098-3015(20)33005-9/fulltext)

⁶⁷- Their research is reported in an abstract so the details of appeals are not available. See Carr, D. and Macaulay, R. (2021) PNS61 The Second Coming of the NICE Appeal Process? Value in Health 24 (S1) S184 Available at: [https://www.valueinhealthjournal.com/article/S1098-3015\(21\)01133-5/fulltext](https://www.valueinhealthjournal.com/article/S1098-3015(21)01133-5/fulltext)

⁶⁸- House of Commons Health Committee. (17 December 2007) National Institute for Health and Clinical Excellence: First Report of Session 2007-08 Volume 1. Available at: <https://publications.parliament.uk/pa/cm200708/cmselect/cmhealth/27/27.pdf>



Discussion and Recommendations

NICE guidance has regularly been appealed over time, albeit the rate of appeals has fallen as the organisation has matured. It is now close to one in ten pieces of guidance appealed, far lower than historical rates.

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A variety of stakeholders have appealed, with companies being the group most likely to appeal (appealing in 81 of 96 appeals where details are available, 84%). Patient groups have also been appellants (in 48, 50%) and have had at least one of their appeal points upheld in close to half the times that they have appealed (in 21 appeals, 46% resulted in upheld points of appeal).

Appeals have been upheld almost half the time (47% of 96 appeals where details were available were upheld). That suggests that there have been opportunities to improve NICE's work and decision-making in these instances.

Overall, more recommendations have stayed the same when an appeal has taken place than have changed (76% of recommendations stayed the same in 41 appeals where the pre and post-appeal recommendation was available). This is lower than reported in previous research, suggesting that the limited data available for this analysis is likely to miss the full impact of changes prompted by appeals.

Even where recommendations have changed, the difference appeals make is difficult to disentangle from changes in evidence and/or prices offered by companies. Recommendations have changed following the appeal, even when the appeal has been dismissed on all points.

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Appeals have likely played a wider role in shaping the work of NICE because lessons are learned as a result of appeals, be they upheld or dismissed. In this way, the “impact” of appeals will likely be far more than the sum of appeals and the appeal panel’s determination. In a sense, just having the option to appeal could also play a role in influencing NICE’s work on its own. The scale of appeals has been part of the political scrutiny of NICE in the past.⁶⁹ Research has found that there is a perception that the existence of appeal rules, as well as legal challenges through judicial review, can reduce the scope for NICE committees to use their own judgement as part of forming recommendations.⁷⁰

Appeals have a cost – this has not been quantified in the case of NICE, but with the time appeals take as well as legal costs, it is likely to be material – but that may help to improve the quality of decision-making. There will also be trade-offs with the speed of guidance, as appeals can add to timelines.⁷¹

It is recommended that policymakers who oversee HTA agencies in their country consider the merits of introducing the option to appeal, including allowing patient groups to be appellants.

⁶⁹- House of Commons Health Committee. (17 December 2007) National Institute for Health and Clinical Excellence: First Report of Session 2007-08 Volume 1. Available at: <https://publications.parliament.uk/pa/cm200708/cmselect/cmhealth/27/27.pdf>

⁷⁰- Charlton, V. (2020) NICE and Fair? Health Technology Assessment Policy Under the UK’s National Institute for Health and Care Excellence, 1999-2018. Health Care Anal. 28(3) pp.193-227. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7387327/>

⁷¹- House of Commons Health Committee. (17 December 2007) National Institute for Health and Clinical Excellence: First Report of Session 2007-08 Volume 1. Available at: <https://publications.parliament.uk/pa/cm200708/cmselect/cmhealth/27/27.pdf>

Further research could explore:

- Lessons from successful appeals by patient groups by not only looking in more detail at the nuanced appeal points that have been upheld in the past but also by hearing directly from those patient representatives involved.⁷² If patient groups could focus only on appealing where the chance of success is highest, this could help them to optimise their limited resources.
- Lessons from legal action.⁷³ Whilst an appeal panel decision is final within that procedure, there is the option to pursue legal action.

This research has some limitations, including the gaps in appeal documents available for analysis. That means a comprehensive analysis was not possible. The analysis was also completed by a single researcher with the risk of unconscious bias as well as misclassification in the database due to human error despite best efforts.

⁷²- This could build on existing research, for example, Livingstone, H. and Pitan, M. (23 December 2022) PD53 Improving patient involvement in the National Institute for Health and Care Excellence's Appeals Process. International Journal of Technology Assessment in Health Care. 38 S1 Abstracts from the HTAi 2022 Meeting in Utrecht, Netherlands Available at: <https://www.cambridge.org/core/journals/international-journal-of-technology-assessment-in-health-care/article/pd53-improving-patient-involvement-in-the-national-institute-for-health-and-care-excellences-appeals-process/290B931E22877C30A1FBB18C4A52BFCD>

⁷³- NICE has been challenged in the courts. For example in the case of using the highly specialised technologies evaluation approach to appraise a treatment for phenylketonuria. See Baldwin, T. (17 December 2020). Social Welfare Update: Court of Appeal held NICE was right to use the Highly Specialised Drug procedure to appraise a new drug for treatment of phenylketonuria (PKU). Available at: <https://www.gardencourtchambers.co.uk/news/social-welfare-updates/social-welfare-update-court-of-appeal-held-nice-was-right-to-use-the-highly-specialised-drug-procedure-to-appraise-a-new-drug-for-treatment-of-phenylketonuria-pku> and Herbert Smith Freehills (24 September 2020) Court of Appeal Upholds Regulatory Judgement in Technical Field. Available at: <https://www.herbertsmithfreehills.com/notes/publiclaw/2020-09/court-of-appeal-upholds-regulatory-judgment-in-technical-field> and <https://www.judiciary.uk/wp-content/uploads/2020/08/Cotter-v-NICE.pdf> and Eisai appealed to the Court of Appeal in 2007. See House of Commons Health Committee. (17 December 2007) National Institute for Health and Clinical Excellence: First Report of Session 2007-08 Volume 1. Available at: <https://publications.parliament.uk/pa/cm200708/cmselect/cmhealth/27/27.pdf> and Banks, F. (August 2007) R (Eisai Ltd) (Alzheimer's Society & Shire Ltd) v. the National Institute for Health and Clinical Excellence ~ The Wider Implications. Monckton Chambers. Available at: <https://www.monckton.com/wp-content/uploads/2008/11/AlzheimersAug07FB.pdf> and Herbert Smith Freehills. (Undated) NICE, but unreasonable: the Court of Appeal quashes a decision of NICE on the grounds that it is inadequately reasoned. Available at: <https://www.lexology.com/library/detail.aspx?g=5a54d4b6-74d5-4d53-9c8a-015966f4f0f3>



NICE and Appealing?

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