

National Institute for Health and Care Excellence

**Widening the evidence base: the use of
broader data and applied analytics in NICE's
work**

This report proposes next steps to implement the aims of the statement of intent regarding the appropriate use of data analytics across NICE, focusing on the development of a data and analytics standards framework as the first output from the planned methods and standards programme.

The Board is asked to discuss and agree the proposed next steps for the data and analytics transformation programme.

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Introduction

1. NICE helps the health and social care system to deliver the best outcomes within the resources available. We do this through a range of guidance programmes that share the same core processes, including identification, assessment and interpretation of evidence, presented as guidance recommendations, advice or information.
2. Increases in the amount and breadth of data available, the development of new and efficient mechanisms for analysis, and advances in the way information is labelled, linked and shared, have the potential to significantly enhance our traditional approaches to synthesising research evidence. They also offer opportunities to improve timeliness, relevance and efficiency.
3. In January 2020 NICE published a statement of intent signalling our ambition for the future use of broader sources of data and analytics, including sources commonly referred to as real-world evidence, within NICE's guidance programmes and wider products. This paper describes our progress towards putting these ambitions into practice.

Background

4. Following Board discussions in March and May 2018, recurrent funding was ring-fenced to establish a new data and analytics team. In January 2019 the Board considered a paper on the use of data analytics at NICE, which highlighted progress to date on how NICE is enhancing its capability to identify and use data and analytics in its work. This included the strategic focus to develop a framework for the appropriate use of data analytics across NICE's programmes.
5. Developing the framework, positioned as a statement of intent for the use of data and analytics, was prioritised as a crucial part of both internal transformation and external communication. The statement built on internal advice to guideline developers produced to support the updated guidelines manual published in October 2018. In May 2019 the Board approved making the draft statement of intent publicly available on our website and open to consultation comments from stakeholders.
6. In November 2019, the Board reviewed revisions to the statement of intent following consultation and approved its publication. Immediate publication was delayed by purdah; the [finalised statement](#) was published in January 2020, with a [news article](#) following in February. Since publication, the statement of intent news story has been viewed around 1,150 times and the document itself has been downloaded around 350 times.

7. In November 2019, the Board additionally reviewed and approved priorities for the data and analytics team, with the aim of delivering the vision and ambitions set out in the statement of intent. The Board has also approved the appointment of a new director for Science, Evidence and Analytics to lead this work in future. This post has been advertised, with interviews being held in April. This paper provides an update on progress towards implementing the statement of intent and proposes next steps to realise its ambitions.

Data and analytics methods and standards programme

8. To deliver the ambitions in the statement of intent, the November 2019 NICE Board paper prioritised defining a programme of work to develop:
 - a standards framework for best practice in conducting high quality analyses of data, to inform our own work and that of third parties, especially digital technology companies, who wish to submit evidence based on such (rather than traditional research)
 - a detailed methodological framework for best practice for consideration and use of data analytics across NICE's programmes.
9. The detail of this paper focuses on the first of the bullet points above. The standards framework outlined in Paragraph 16 is intended to be an external-facing output. It describes the standards to be met to ensure that data are suitable for use in analyses, and that the analytical methods applied are appropriate and transparent.
10. By setting out best practice in conducting analyses such that they meet the standards for consideration by a NICE decision-making committee, the framework will therefore be used to inform third parties and encourage consistent standards of practice. The framework will additionally underpin the development of methods for NICE's own broader use of data within its work programmes.
11. The second bullet point in paragraph 8, the delivery of more detailed methods outputs, is intended to be internal-facing and for use by NICE staff, to help ensure consistent standards for the development, use and reporting of analyses across NICE's work programmes and how these should be used to inform committee decision making. This will further develop the elements set out in the standards framework and will represent a second phase of work to commence later in the year.

Development of the data and analytics methods and standards work programme scope

12. The data and analytics methods and standards work programme will draw on the robust and comprehensive methods already in place in our guidance programmes and, where necessary, build on them to expand the use of different sources of evidence, both qualitative and quantitative. In some cases, it may be appropriate to reframe existing methods outputs to ensure they can be used and understood by different audiences, or be applied more widely across all of NICE's programmes.
13. NICE's Science Policy and Research Programme has an established programme of scientific policy and research activities to develop improved methods for health technology assessment and guideline development. The data and analytics methods and standards programme will draw on methodological research supported, commissioned and influenced by this programme. This includes the outputs of the Innovative Medicines Initiative (IMI) GetReal Initiative, in which NICE is a partner. This aims to develop tangible solutions to key challenges associated with using real-world data in drug development and subsequent regulatory and health technology assessment.
14. The Centre for Health Technology Evaluation (CHTE) 2020 programme is carrying out a review of its methods to produce an updated and consolidated methods manual. The data and analytics team have contributed to relevant areas of this programme. The data and analytics methods and standards programme will build on many areas considered in the CHTE programme, including those developed by the sources and synthesis of evidence, managing uncertainty and equalities task and finish groups.
15. An outline scope of the data and analytics methods and standards programme was developed by drawing on expertise from within the data and analytics team and a review of comments received during consultation on the statement of intent. This draft scope was reviewed and revised by the cross-NICE data and analytics steering group and additional NICE colleagues with an interest in this area. Topics to be featured in an external-facing standards framework were identified from the overall programme scope.

Work to develop a data and analytics standards framework

16. To develop a standards framework for best practice in conducting high quality analyses of data, to inform our own work and that of third parties, there are a number of elements of work. Table 1 summarises the topics that need to be featured in the framework. In carrying out this work we will ensure that we

identify and explore commonalities across NICE's programmes, while recognising that we may need to be flexible to meet the needs of different programmes and use cases.

17. The proposed topics featured in the framework were reviewed by the data and analytics external reference group, representing organisations with expertise in analysis of data and significant data owners. This group agreed that a standards framework would be a welcome output, while highlighting the importance of flexibility and responsiveness to a fluid landscape. The group were keen to see NICE 'learning by doing' and developing standards by applying them to a variety of use cases.
18. The external reference group additionally commented on the language used, suggesting that it may need to be adapted for different potential users such as digital health technology-oriented audiences. To ensure that the outputs of this programme are fit for purpose, the emerging standards will be shared with targeted external stakeholders for further comment. Wider consultation is then envisaged as confidence in the content, value and utility of the standards grows.

Table 1: Summary of main topics featured in the data and analytics standards framework

Topic	Content of framework	Issues to consider
Research governance	These standards will set out how an analysis should answer a clear research question, providing confidence that it has been carried out in a transparent manner, meeting appropriate ethical standards.	This topic will consider standards for defining the research question, pre-registering the research protocol, ensuring the project team has sufficient domain, analytical and data expertise and demonstrating that sample size has been considered. It will also consider standards to ensure that ethical approval, information governance and informed consent have been managed appropriately, and that a timeline is available if the project has not yet been carried out.
Data	These standards will set out how the quality of data on which any analysis is based can be assessed.	This topic will consider standards to ensure that data provenance and characteristics of the dataset are fully described, and that the output of any data quality assessment is reported. It will also consider standards to ensure that information is provided about variables and features included

Topic	Content of framework	Issues to consider
		in the analysis, any data linkages, and decisions made during data processing and cleaning, and code is supplied if possible.
Analysis	These standards will set out how an analysis should be conducted so it is repeatable, objective and grounded in reality, clearly demonstrates how uncertainty has been understood and managed and that the results robustly address the initial research question.	This topic will consider standards to ensure that the suitability of the analytical method is justified, and that evidence is provided to show that validity, reproducibility and generalisability have been considered in the selection of method. It will also consider standards for fully describing the method and supplying the analytical code if possible.
Results	These standards will set out the appropriate reporting of results and findings, so that NICE can ensure any output directly relates to and accurately addresses any pre-specified protocols, and that all deviations from pre-specified protocols are explained.	<p>This topic will consider standards to ensure that the characteristics of people included and not included in the analysis are described and that full details of the main analysis and any sub-group analyses are provided, including any intermediate steps, details of model selection and rationale for sub-group analysis if not pre-specified.</p> <p>It will additionally consider standards to ensure that any deviation from the research protocol is documented and that evidence of internal and external validation are provided where appropriate.</p>
Dissemination	These standards will set out an approach to making findings publicly available and accessible, as far as possible.	<p>This topic will consider appropriate reporting standards, ensuring that relevant information has been captured.</p> <p>It will additionally consider whether standards should be set out regarding intent to publish in a peer-reviewed journal.</p>

Additional topics in scope of the data and analytics methods and standards programme

19. In addition to the topics featured in the standards framework, NICE's data and analytics methods and standards programme is likely to consider:
- how we develop, assess and prioritise research questions or projects which may be suitable for a data analytics approach
 - how and when we will consider commissioning analyses or data collection
 - how and when we might support utilising patient records to have more clinical trials at pace, scale and lower cost, to reduce evidence gaps while maintaining the benefits of randomisation
 - how and when we will consider non-UK data sources, or analyses based on these, as suitable sources of evidence
 - how we assess the suitability of specific analytical methods
 - when it may be appropriate to perform a synthesis of primary and secondary evidence, and how we handle discrepancies between different types of evidence
 - how we ensure that our committees are able to make use of findings from different types of data, and how they address uncertainty.
20. The well-established 'hierarchy of evidence' does not fully capture the potential benefits and challenges of using data derived from the health and care system at scale. For example, a clinical audit may present data as a consecutive case series, which would be considered a lower quality form of evidence, but if the audit captures data on every single clinical case across the country, then this data source may have less selection bias than a small study conducted with a more highly rated study design.
21. As part of methods development, the team will look at alternative conceptualisations of the hierarchy of evidence which more accurately represent how insights from routinely collected data may differ from other study types, and the impact this has on evidence quality assessment.
22. Additional crosscutting issues which are relevant to all uses of data within NICE may be more appropriately managed as standalone workstreams, with outputs to be determined. These will include:
- transparency and public trust, including the handling of any individual level health and care data held or accessed by NICE,
 - how we ensure we continue to advance equality when using broader sources of data, including the impact of the 'digital divide'.

Programme delivery

23. To deliver a programme developing standards and methods for the wider use of data across NICE's programmes, the data and analytics team have begun the process of recruiting a methods lead. Work within the current team to define the programme of work and engage with internal and external stakeholders will continue, but it is expected that the delivery of outputs will be driven by the new post-holder, with leadership provided by the Director of Science, Evidence and Analytics.
24. The data and analytics external reference group identified a significant appetite for collaboration across the health and care sector. This may be delivered by NICE taking a lead or forming a consortium with system partners to consolidate and agree elements such as standards for data quality which have the potential to apply across the sector.
25. The Medicines and Healthcare products Regulatory Agency (MHRA) are a key system partner. MHRA and NICE have established a core strategic group to develop an ambitious, integrated approach to regulation and health technology assessment that gives patients safer and earlier access to innovative medicines and medical technologies. A core element of the collaboration is to develop a common approach to the use of real-world evidence and artificial intelligence in advising company product development plans and to support manufacturers' submissions to both MHRA and NICE. We will ensure that methods and standards development is aligned with MHRA throughout the delivery of the programme.
26. Early engagement has identified that components of the methods and standards programme will be best delivered via an open call for academic or industry partners, and this will be further explored as the scope continues to be developed.
27. We have begun and will continue to explore which elements of the programme have an international component. This will involve exploring how and when we will consider the use of non-UK data, and when we might work with international partners to develop elements of the methods and standards framework to enable this. The potential for NICE to leverage its reputation to work with international partners is in line with The Office for Life Sciences Industrial Strategy, which aims to position the UK as a global leader in linking and unlocking the potential of existing data sources.

Artificial intelligence (AI) methods development

28. Following the Government's establishment of an AI Lab and the inclusion in the overall business case of £24m of capital funding for the Radical Regulation

Incubator (RRI), NICE submitted an outline business case for RRI funding to develop methods to inform the evaluation of AI technologies. If this outline bid is successful, NICE will be invited to submit a fully costed business case in April 2020.

29. The bid sets out a programme to deliver methods to validate and evaluate the use of AI in digital technology. This is likely to include: what the future methods for decision making and addressing uncertainty are in this field; how real-world data can complement more traditional studies; how to set standards in this area along the lines of the evidence standards framework for digital health technologies; and how to select topics pragmatically that can be implemented in the NHS.
30. There is significant overlap between delivering this proposal and the work to develop a methods and standards programme for the wider use of data and analytics in NICE. If NICE's bid is successful, these overlaps will be explored in more detail and the synergies considered as the programme scopes are further developed.

Data and analytics enablers

31. To support the implementation of the statement of intent, and in addition to developing the outline of a methods and standards programme, the data and analytics team are leading initiatives across NICE to identify and put in place the infrastructure and processes to allow NICE to access and make use of wider sources of data and analyses based on these across its programmes.

External engagement

32. The team continues to engage with potential partners and stakeholders across the sector, including cross-sector and governmental organisations such as HDR UK, NHSX, NHS Digital and MHRA, charities and foundations such as the Health Foundation and the Wellcome Trust, potential international partners such as the Joanna Briggs Institute and the Cochrane Collaboration, and key industry partners.
33. The team will continue working to establish a clear external stakeholder management plan which seeks to both build on existing partnerships and establish further collaborative opportunities that support NICE's ambition. The team is additionally working to feed into the cross-NICE strategic engagement plan.

Governance and public trust

34. It is important that NICE continues to be compliant with information governance and data protection regulations, not only for the purposes of the data and analytics programme but also from the point of view of protecting NICE and maintaining public trust.
35. The data and analytics and information governance teams are developing handling rules and processes for individual level health and care data so that there is a framework for how they should be dealt with in NICE. These rules will support any requirements specified by the data owners in order to access the data. The rules will be risk-based and defined by the type of data (anonymous, pseudonymous or identifiable) and the proposed processing task. Where appropriate, ethical considerations will be approached through a similar process to that in place for research governance.

Tools

36. Carrying out projects making use of wider sources of data, or effectively quality assuring analyses based on these, will require access to IT hardware and software resources, and IT support. These resources and support are essential to comply with good data governance principles, including the requirements set out in the Data Security and Protection Toolkit, and enable effective collaboration with external partners. The team have begun work on preparing a detailed scope of these requirements and will work closely with NICE's new IT function to identify how best to deliver them.

People

37. The team have committed to supporting data and analytics capability building within NICE. An internal mailing list has been established and regular bulletins listing training and development opportunities, webinars, conferences and other relevant events are circulated to around 70 interested colleagues.
38. As a result, NICE staff have attended events held by organisations such as the Open Data Institute, the Institute for Data Science and AI at the University of Manchester, and the Royal Statistical Society. Three staff were supported to attend a week-long causal inference course and the team supported a colleague's successful application to the Government Digital Service's Data Science Accelerator Programme.
39. The data and analytics team is also collaborating with Health Education England (HEE) on the Building a Digital Ready Workforce programme across the NHS following the Topal review. The team will continue to support NHSX taking the stewardship role in implementing professionalisation of data science and an analytical function across the NHS and arm's length bodies.

Data and analytics portfolio alignment

40. Implementation of the data and analytics statement of intent feeds into the overarching NICE Connect transformation programme. Reflecting findings from broader types of data and new evidence in a timely way is highlighted as an important challenge for NICE Connect.
41. Strategic oversight of the data and analytics portfolio has therefore been moved from a standalone Data and Analytics Steering Group to the existing NICE Connect expert groups. The Process, Methods and Analytics and the Data Management expert groups will each oversee elements of the data and analytics portfolio. This will ensure that programmes are in alignment and synergies are realised across NICE.
42. Further synergies will be realised by working alongside the Science Policy and Research Programme and the information and evidence services teams when the data and analytics team moves to become part of the new Science, Evidence and Analytics Directorate.
43. This directorate will bring together teams responsible for ensuring that NICE uses the best available evidence in its guidance. It will build on existing work to ensure that the approach set out in the statement of intent is taken forward across NICE, and ensure that the use of data and analytics across NICE continues to develop by drawing on the Science Policy and Research Programme's horizon scanning expertise.

Risks and dependencies

44. NICE will seek to mitigate key risks as we further develop our data and analytics work.
45. The development of common standards and knowledge interoperability, currently being led by NHSX, are crucial for NICE's ambitions to expand our use of data. Delays in the development and implementation of system-wide knowledge management will impact on NICE's plans.

Conclusion

46. The data and analytics team proposes to develop an external-facing standards framework as the first output from its methods and standards programme. This output will be driven forward by the recruitment of a methods lead, under the leadership of the new Science, Evidence and Analytics Directorate. While recruitment is underway, the data and analytics team will continue its current work of engaging with the sector and supporting the wider use of data and

analytics across NICE, in order to realise the ambitions set out in the statement of intent.

47. The Board is asked to:

- Agree the proposal to begin the development of a standards framework, setting out best practice in conducting analyses, as the first output from the planned data and analytics methods and standards programme.

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