National Institute for Health and Care Excellence

Data and Analytics Methods and Standards Programme and Implementation Update

This paper presents the delivery plan for the data and analytics Methods and Standards Programme which aims to provide a clear framework for the use of data and analytics in the development of NICE guidance.

The Methods and Standards Programme is a central enabler of our ambitions to increase and extend the use of data in the development and evaluation of our guidance but will not function in isolation from other transformation. We therefore also provide an update on the wider data and analytics implementation plan. This includes work on building analytical capability across our workforce and detail on other initiatives, both internally and across the health and social care sector.

The Board is asked to discuss and approve the proposed Methods and Standards Programme delivery plan and its prioritisation within the wider data and analytics implementation plan.

Felix Greaves

Director of Science, Evidence and Analytics

January 2021

Introduction

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, which is presented as guidance recommendations, advice or information.

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. At the same time, they offer opportunities to improve timeliness, relevance and efficiency.

Demonstrating leadership in data and analytics has been recognised as a key strategic priority by the NICE Board. A key enabler of this is the data and analytics Methods and Standards Programme. In this paper we describe the delivery plan for this programme. In addition, the paper presents an update on the wider data and analytics implementation plan, as progress is still required across the whole 'health data ecosystem' to support our objectives.

Background

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 developing a framework for the appropriate use of data analytics across NICE’s programmes.

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 November 2019, the Board reviewed revisions to the statement of intent following consultation and approved its publication. Immediate publication was delayed by the period of pre-election sensitivity; the finalised statement was published in January 2020. In March 2020, the Board further approved the development of a Methods and Standards Programme to deliver on the statement of intent.

The programme will focus on the use of data and analytics and adopt, and build upon where necessary, data standards and information governance processes developed by healthcare partners including NHSX and NHS Digital.

While recruiting a senior adviser to lead this programme, we recognised that NICE needed to ensure that the COVID-19 evidence, based on analysis of emerging data sources, was fit-for purpose to inform our recommendations. The well publicised retraction of a hydroxychloroquine study based on unverifiable data demonstrated the importance of developing a robust approach to assessing the provenance and quality of the data and analyses.

In July 2020 we published a (interim) framework to assess the quality of wider sources of data and evidence used to inform our COVID-19 work. This approach involves assessing risk of bias, reporting standards for data sources and analyses, and certainty of outcomes. Since publication, this framework has received approximately 600 views by users from across 50 different countries.

The data and analytics team also established and lead the NICE COVID-19 data and analytics taskforce. The taskforce works with external partners to identify suitable sources of data to address areas of uncertainty within the clinical guidelines. It also assumed several other ad-hoc activities to support NICE's response to COVID-19, including developing an automated method to download COVID-19 preprints and developing an automated script for trial tracking.

In September 2020, the data and analytics team formally became part of the new Science, Evidence and Analytics directorate. This was created to ensure that we are using the best methods and approaches in the development of our products across the Centre for Guidelines and the Centre for Health Technology Evaluation.

The Data and Analytics Methods and Standards Programme

Overview

The primary objective of the Methods and Standards Programme is to ensure that NICE makes the best use of available data to inform guidance and to do so in a timely, robust, and transparent manner. It will achieve this by providing a clear framework for the use of data and analytics in the development and evaluation of evidence. The framework will support those submitting evidence to NICE including the life sciences industry, assessment groups, and NICE staff, and those reviewing and assessing evidence including NICE staff, evidence review groups, and committees. We expect this programme to be a key enabler of NICE's strategic aim of showing leadership in data, science, and evidence.

Randomised controlled trials and the meta-analyses of such trials remain the preferred source of evidence on treatment effects informing NICE guidance. However, we can imagine a future where real-world data has the potential to change the way we work, and inform many of the decisions we make. Where evidence from real-world data can add value, the programme will ensure that the evidence is developed using robust and transparent methods and that the strengths and weaknesses of the evidence are appropriately communicated to committees.

The framework for the use of data and analytics in the development of NICE guidance will be developed in an iterative manner following an agile and modular approach to programme development. In year 1, a draft interim framework will be developed focusing on the principles of robust and transparent evidence development. The framework will then be continually developed over time following a modular approach. This is necessary due to the fast pace of change in technological, methodological, and regulatory environments.

 The Programme will be informed by several activities internally and externally to NICE. This includes literature reviews and gap analysis, reviews of NICE methods guides and guidance, workshops with external stakeholders, methods and tool development, research commissioning, development of internal processes and policies, engagement with national and international initiatives, and several demonstration projects. Demonstration projects allow for a learning by doing approach to framework development and are intended both to inform the development of the framework and allow for it to be tested. We will work with teams across NICE and with external partners to identify, prioritise, and undertake demonstration projects across relevant use cases. We will systematically track and share learnings from these projects.

 The programme builds on the high-quality work undertaken within NICE, including the work undertaken as part of the Centre for Health Technology Evaluation (CHTE) 2020 methods update. The Programme will be developed in close collaboration with centres across NICE.

Programme scope

The Methods and Standards Programme is concerned with the use of both quantitative and qualitative data from real-world data sources including electronic health records, patient registries, digital health technologies, and social media. It also includes data from randomised controlled trials where observational methods are used for analysis. We will consider the use of such data across all study designs (including randomised controlled trials) to inform all types of evidence including programme benefits or treatment effects (from here, effectiveness) across all stages of evaluation. We will constantly review the equality implications of the programme throughout its development.

Programme structure

The programme consists of two interconnected work streams, as depicted in Figure 1. Work stream 1 (WS1) is concerned with developing guidance relating to the building blocks of high-quality evidence, namely data quality, the use of appropriate methodologies, and good research governance. In WS2 learnings from WS1 and engagement with wider transformational activities in NICE and the wider healthcare system will be used to develop a framework for the use and evaluation of real-world data in the development of NICE guidance. Each work stream is described in greater detail below.

Figure 1. Simplified schematic representation of the methods and standards programme



Work stream 1 (WS1) consists of 3 related sub-streams.

* 1. In WS1a we will develop a generalised approach to assessing and conveying data quality. This will provide an understanding of data integrity and its fitness-for-purpose encompassing evidence quality and relevance to the decision context. This will include consideration of the use and applicability of synthetic data and data from outside the UK. Other topics include feasibility assessments for data collection in managed access, the selection and validation of real-world endpoints, including patient experience data, the validation of unstructured clinical or high-density data, and data standards and information governance.
	2. WS1b will provide advice on appropriate methodologies for analysing real-world data for different study designs and evidence types (including effectiveness), and for characterising, quantifying, and conveying uncertainty and bias. Priority topics will be identified through formal prioritisation exercises.
	3. WS1c will define principles of good research governance throughout the evidence generation process and identify tools and reporting templates to help convey this information.

Data quality and relevance, methods, and research governance jointly determine the quality of evidence and its acceptability for decision-making. Work stream 2 (WS2) consists of 2 related sub-streams.

* 1. In WS2a - Real world evidence framework - we will take the outputs and learnings from WS1 to provide a clear framework for the use of real-world data in guidance development, including definition of appropriate use cases and expectations of evidence quality across use cases.
	2. In WS2b - Processes and implementation - we will engage with transformational changes across NICE and the wider healthcare system to further develop processes and policies relating to the use of data and analytics in guidance development.

Further detail on the scope of each work stream is provided in Annex A.

Partnerships and collaborations

Where appropriate the activities described in the preceding section will be undertaken in a collaborative fashion with key UK healthcare partners including the Medicines and Healthcare products Regulatory Agency (MHRA), NHS England, NHSX, Health Data Research UK (HDRUK), NHS Digital and other external partners in the life sciences sector. We will work with the NICE Decision Support Unit and External Assessment Centres to commission work where required. We will also communicate the programme across the 'What Works Centres' network and continue to engage, where possible, with ongoing national and international initiatives in this area. Key initiatives include the European Medicines Agency's (EMA) Big Data Steering Group, the United States Food and Drug Administration's (FDA) Real World Evidence Program, and activities of the Canadian Agency for Drugs and Technologies in Health (CADTH).

NICE and the MHRA 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 the Methods and Standards Programme is aligned with the activities of the MHRA and new regulatory pathways.

Timelines

The resulting framework will need regular review and development over the long-term to reflect ongoing learnings from the greater use of data and analytics in guidance development and keep pace with continuing developments in technologies and methods, as well as wider changes to the health and social care system and regulatory environment. This is facilitated by the agile and modular approach to programme development. The programme can be separated into two phases. In phase 1, a framework is developed incorporating a research governance and data quality assessment framework, and selected methods guidance. Phase 2 will focus on the sustainability of the framework. This paper describes the delivery plan for phase 1.

The duration of phase 1 depends on the initial ambitions of the programme (or its scope) and the resources available. We recommend a minimum duration for phase 1 of 2 years because of the time required to develop and test a data quality assessment framework, initiate and complete several demonstration projects, engage extensively internally within NICE and with external partners, and the time required for consultation. However, as stated above, a preliminary framework focusing on principles of robust and transparent evidence will be developed in the first year of the programme. In Figure 2 we present a 2-year timeline for delivery. For comparison, the FDA Real World Evidence Programme is due to last three years and the EMA Big Data Steering Group Workplan 2 years. In both cases further activities will take place beyond this initial period.

Figure 2. Gantt chart describing the timeline of key activities for the Methods and Standards Programme



Programme Finance

The agile, modular structure of the programme allows for flexibility in timelines and outputs contingent on the resources available. Here we describe the resources required to deliver Phase 1 of the programme in 2 years. With fewer resources, we recommend that the duration of phase 1 is increased or the scope further refined. Costs for a 2-year phase 1 are summarised in Table 1.

Table . Estimated costs for delivery of phase 1 of the Programme over 2 years

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Cost Category | Description | WTE | 2021/22 £000 | 2022/23 £000 | Total £000 |
| Programme delivery team pay costs | Existing posts | 1.50 | £105 | £109 | £214 |
| Programme delivery team pay costs | Additional new posts required  | 5.00 | £302 | £314 | £615 |
| Programme board and working group pay costs | Existing posts | 0.47 | £48 | £50 | £98 |
| Information service review pay costs | Existing posts | 0.05 | £19 | £8 | £27 |
| Information service review non-pay costs | Additional non-pay costs required | 0.00 | £4 | £2 | £5 |
| Editorial services pay costs | Existing posts | 0.13 | £7 | £7 | £14 |
| Total cost | NA | 7.16 | £483 | £490 | £973 |
| Total additional funding required | NA | 5.00 | £305 | £315 | £620 |

The total cost of Phase 1 of the programme is estimated at £970,000. The main component of this is direct staff costs totalling £830,000. This was estimated based on a core programme team including the programme lead, 5 advisers/analysts, and part-time project management support. Other costs include the opportunity costs of staff time where they support the programme in an advisory capacity through its governance arrangements, literature reviews, and editorial support. Additional costs beyond posts already funded (programme lead and project management support) is £620,000.

The total cost of resource estimated covers the full project cost, however, some of this is already in baseline budgets. The additional funding required is for 5 new posts (at average band 8a) which have been bid for in the spending review and are included in the SEA business plan 2021/22. If this is not available, then aspects of the programme may require reprioritisation. All other costs are in NICE baseline budgets and covered by existing posts, these are opportunity costs as we assume the post holders will need to reprioritise their work to undertake this project but no backfill will be required.

Some activities of the programme will be undertaken in collaboration with external partners. Partners will be expected to contribute resource to these activities.

Benefits statement

The need for clarity on the appropriate use of data and analytics in NICE guidance development is well recognised by all stakeholders. We anticipate substantial benefits of this programme to NICE and its stakeholders. We will identify approaches to measuring benefits and compare baseline measures to those at the conclusion of the programme. This will include stakeholder feedback.

The methods and standards programme will ensure that NICE uses the best available evidence in development of its products and develops its guidance in a timely manner, while maintaining its rigorous standards of evaluation. It will also help maintain NICE's position as a world leader in evidence evaluation and support the development of new and valuable collaborations with external partners. Demonstrating leadership in data, research, and science, and ensuring world-leading analytic capabilities are key strategic goals of NICE.

The programme also aligns with the strategic aims of other healthcare and healthcare data bodies including the MHRA, NHSX, NHS Digital, and Health Data Research UK (HDRUK). NICE has committed to developing a common approach to the use of real-world data and AI in guidance development and decision-making. Forming a joint understanding of data quality is a key component of this. NHSX is developing a national health and social care data strategy and promoting common standards in data collection. Finally, HDRUK has developed a 'data utility evaluation matrix' to convey data quality and relevance to all data users, and the Innovation Gateway to support the identification of UK health data. This programme will further support these activities and ensure alignment with NICE's priorities.

We anticipate several benefits to the wider UK health and social care system. A clear and integrated national strategy for the use of routine data is an essential part of a learning healthcare system which is recognised as a future priority. It helps guide the collection of data with an understanding of how that data will be used to inform practice, and ensures the data is converted into actionable evidence. Finally, it will ensure that the UK remains a key market for life sciences and innovation.

The public are expected to benefit from the greater use of real-world data in guidance development and alignment between the MHRA and NICE, both to improve decision-making where uncertainties are great, and to support faster access to safe and effective treatments. Finally, it is important that the data people provide during their care is used to benefit them and other people in the future.

For the life science and medical technology industries, the programme will provide clarity as to the appropriate uses of observational and non-randomised data and an understanding of the expectations regarding evidence quality. The appropriate use of such data will also support faster market access to new and effective treatments. Healthcare data and analytic companies will also benefit from clear guidelines about the use of data and analytics in guidance development.

Risks and dependencies

The pace of technological and methodological development in this area is substantial. It is important to ensure that the programme's outputs do not become obsolete because of these developments. To mitigate this the framework must be flexible and adaptable. In addition, there will be a need for regular development of the framework beyond the timeframe of the programme.

There remain uncertainties as to the future regulatory landscape for the UK in light of the UK exit from the European Union. Strong collaboration between NICE and the MHRA in aligning data standards is essential.

It is essential for the success of the programme that external stakeholders and committees accept the standards developed. The acceptability of the standards could be compromised if they are perceived to differ excessively from other influential frameworks currently under development (e.g., the outputs of the EMA's Big Data Steering Group and the FDA's Real World Evidence framework) or because satisfying the standards is considered too onerous. We will work with stakeholders throughout the programme to ensure it is acceptable and feasible while upholding NICE's standards of evaluation.

The programme could be disrupted by external crises such as that caused by COVID-19. In such an eventuality, NICE and its partner organisations may have reduced capacity to contribute to this programme, and engagement may also be reduced.

We intend to work closely with external stakeholders across all aspects of the programme and throughout its duration. This includes commissioned research, tool development, and case studies. Careful management will be required to ensure the programme meets its timelines.

The focus of the methods and standards programme is on the analysis of data. However, many guidance programmes (e.g., NICE's Medical Technologies Evaluation Programme [MTEP]) rely extensively on already completed studies which may not be of the expected quality or it may not be possible to ascertain this. It is important that we do not have differential standards by type of evidence.

The scope and success of the project will partly depend on the ability to attract income to support its development. We have outlined a minimum viable product which will deliver substantial benefits to NICE and the wider healthcare system even in the absence of additional external funding.

Update on the wider Data and Analytics Implementation Plan

International leadership

There is great potential for NICE to leverage its reputation to work with international partners 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.

In November 2020 we met with the Department of Health and Social Care International teams to discuss the 2021 G7 summit. They expressed an interest in our ambitions and plans with data. The collective opportunity would be the formal launch of the Methods and Standards programme, with ministerial backing, in May and thus the visibility and global awareness this would create.

The data and analytics methods and standards programme will then act as a framework to help to support common data models that enable better use of data in future pandemics. This will likely include a federated network that has standardised data reporting and quality management, with full data sharing across countries. The team will continue to develop this dimension with NICE International and external partners.

Digital Health and Artificial Intelligence (AI) Methods development

In its organisational strategy NICE is committing to both leadership in data and being at the forefront of evaluating new and emerging technologies, including digital technologies. NICE will therefore need to promote its role in the area of digital health, particularly in the evaluation of digital health technologies.

There are no clearly defined boundaries between analytics and AI which is becoming more prominent and complex within digital health technologies. Methodology for both real-world evidence and AI evaluation has a core focus on data quality. The Board previously approved that combining the two topics will ensure optimum use of resource and the team has continued to explore synergies in more detail. This includes leading on AI deployment within NICE as part of an agreed 'learning by doing' approach.

NICE also needs to have clearly allotted capacity to engage with other key system partners, such as NHSX, to increase its ability to influence policy in the field of digital health. The data and analytics team will support a new Office for Digital Health which will internally coordinate and shape activities in digital health across the institute. Externally the office and data and analytics team will work together to promote NICE's role in data, innovation and digital health and to influence policy in this area. This includes continuing to support the Accelerated Access Collaborative with their Phase 4 AI award and ensure NICE is a key player in the Digital Health Technology space. NICE is also currently working with MHRA and NHSX on a joint project to develop a common framework to understand the efficacy and safety of AI-driven technologies.

Data Analytics and Digital Technology enablers

Health and Social Care Sector data strategy

The COVID-19 response has shown the power of data on a large and urgent scale, both on the frontline and for wider planning and policy decisions. Control of Patient Information (COPI) Notices, IG guidance and statements by the National Data Guardian (NDG) and the Information Commissioner's Office (ICO) gave the system confidence to share data to respond to the public health crisis. NHSX wants to ensure the benefits and lessons learned from the COVID-19 response are realised, whilst continuing to ensure data security and patient confidentiality, and maintain and increase public trust in the system.

NICE’s ambitions for broader use of data as set out in our ‘Statement of Intent’ are hugely dependent on the evolution across the data ecosystem that NHSX promises to drive and are captured in Annex B. NHSX have also reformed the Data Coordination Board with a Data Alliance Partnership Board (DAPB) which includes NICE as a core member.

NHSX's role in the co-ordination of the development and management of terminology and structured content as part of a wider ‘content strategy’ is also essential for consumers of knowledge across the system, thus a dependency for our Connect transformation programme. It is also vital to underpin the establishment of a truly Learning-Health-System.

Analytical capability across our workforce

The data and analytics team is collaborating with HEE on the Building a Digital Ready Workforce programme across the NHS following the Topol review. The team is also working with other central bodies as Ministers have shown support for increased professionalisation of data science and analytics across the NHS. This includes introducing learning paths, training passports, PhD internships, fellowships in advanced analytics, tying learning to business need and an analytics market exchange.

NHS England will also be growing their analytical footprint within the North West and so we will want to ensure there is a community and fluid movement to develop a collective analytical resource.

Within NICE, the team have continued to support data and analytics capability building. An internal mailing list receive frequent updates and staff have been supported through formalised learning and the Government Digital Service's Data Science Accelerator Programme.

There are, however, further steps that can be taken to identify what training might be of value, and how best to develop desirable skills in data science. We will therefore be working closely with NICE HR to undertake a comprehensive Data Science Maturity assessment against six key pillars in line with the Government Data Science Partnership recommendations. These are:

DATA - How the organisation manages, organises, secures, and makes its data available

APPLICATION - How data science is being applied to problems in the organisation

PEOPLE - Skills, teams, recruitment, career progression, learning and development

TECHNOLOGY - The hardware and software available in the organisation; making sure data users have access to the tools they need

ETHICS AND GOVERNANCE - Awareness of data ethics and processes around data governance

ORGANISATIONAL CULTURE - Awareness of data science in the leadership team and the wider organisation

An Analytical capability working group will then develop a framework where NICE staff exhibiting early promise or high potential can be given tailored development plans to ensure they are retained within NICE and given ample opportunities to develop and progress their talents and careers in data science at NICE.

The Working Group will also bring the existing data science community within NICE (Python/Data Science Club) under the central umbrella of the data and analytics team, with the hope of broadening its remit and appeal across all NICE staff.

It will also develop a programme that improves data literacy for wider stakeholders across both NICE and its committees. This will include an education programme on technical terms in line with the taxonomy established within the data and analytics methods and standards programme.

Data Management

Civica completed a short Data Management healthcheck in March 2019. They identified that NICE had particular problems in managing contact and planning data. They therefore recommended that developing a single view of contacts and a single view of plan data was a crucial first step in improving data management at NICE.

 Civica also identified several other fundamental problems and made associated recommendations that would need to be delivered ahead of tackling the issues of data management. These included establishing a joint Digital and IT directorate/strategy and that investment in digital workplace platforms to support collaboration should be implemented. These were both progressed in 2020.

From a data architecture perspective, NICE is now focusing on the contact data to map and model the business entities used and to reach agreement on the terminology used to describe and manage contacts. In addition to this we are seeking further external support to help in establishing the appropriate data quality and governance mechanisms required. Once the appropriate architectural models and management principles are defined for contacts data, we will look to expand this approach to other forms of data in NICE.

Infrastructure

The data and analytics team has greater requirements for hardware and software than the typical NICE team. We need access to statistical programming language environments, servers with sufficient data processing power, secure data storage locations, specialist software and other tools. We also need IT and network permissions that are less restrictive than the general case, aligning more with the environments of teams in Digital Services than for other teams in NICE. For example, work scraping patient experience forums required the use of the Digital Services network as the general NICE network blocks access to external APIs. These requirements need to be recognised as a required input for the data and analytics team to be able to work to their full potential.

Projects and Research

The data and analytics team has established matrix working across the organisation with staff embedded in the Centre for Guidelines and the Centre for Health Technology Evaluation business units to ensure a 'learning-by-doing' and customer-centric approach.

The team are supporting the NICE response to the Independent Medicines and Medical Devices Safety (IMMDS) review, working with system partners to co-create databases and registries which could be used to inform our guideline development. We hope that the dataset created for procedures used to treat pelvic organ prolapse will be 'live' and interoperable with other sources by April 2021 to allow for exploratory analysis.

We continue to support the COVID-19 team and initiatives to address areas of uncertainty in the suite of rapid COVID-19 guidelines. We are utilising data across several other clinical guidelines currently in development including Management of gout; Skin Tumours; Stroke rehabilitation and Integrated health and social care for people experiencing homelessness.

The team are also collaborating with the HDR UK British Heart Foundation Cardiovascular Disease COVID Consortium which has been established to investigate the relationship between COVID-19 and cardiovascular diseases using multiple linked UK population healthcare datasets. Projects include considering the risk of venous thromboembolism and arterial thrombotic events in SARS-CoV-2 infection and direct and indirect effects of the COVID-19 pandemic in individuals with cardiovascular disease. The novel data infrastructure to support this work is promising and a suitable exemplar for other disease areas. A project considering data management and analysis methods is also being undertaken to share appropriate learning.

The data and analytics team are working to support the development of the Innovative Medicines Fund (IMF), an expansion of the Cancer Drugs Fund to encompass non-cancer technologies. We are working with partners to develop the necessary data infrastructure to support the IMF. This stream of work includes developing partnership agreements between NICE, NHSE/I and appropriate data repositories, establishing funding approaches to supporting data collection and creating quality assurance processes for data collected through managed access agreements.

We are establishing an effective working relationship with the National Institute for Cardiovascular Outcomes Research (NICOR) who collect data and produce analyses concerning the care and outcomes of patients with cardiovascular disease. The aim is to enable access and use of their data in our work, for example they are currently collecting additional data to support research for the interventional procedures guidance on intravascular lithotripsy for calcified coronary arteries (IPG673).

Science Policy and Research (SP&R) is also involved in a range of methodological research and partnerships aimed at helping us to improve how NICE works. Current research is aligned with NICE’s 9 research priorities, one of which is data science and analytics.

Externally funded work has delivered material that will be informative for the data and analytics methods and standards programme. Examples include the RWE Navigator which matches potential evidence gaps with real-world study designs (from IMI GetReal) and recommendations on design, analysis, and interpretation of non-randomised studies (from Horizon 2020 IMPACT-HTA).

The European Health Data and Evidence Network (IMI EHDEN) will, over the delivery period, further develop and implement federated data networks and a common data model. The concept allows large-scale use of real-world clinical data for primary and secondary research. Deliverables include analytical tools, case studies to enable outcome-based models, and assessment of the suitability of the common data model approach for delivering meaningful evidence in health technology assessments.

SP&R also supports external work in the area of data science. We worked with the MRC to produce a highlight notice focused on methods for synthesising real-world data. A number of NICE staff provide advisory capacity to a large research project funded from this highlight notice. The project aims to deliver methods for inferring relative treatment effects from observational data combined with randomised trial data.

NICE research recommendations

In our current process for developing research recommendations, committee members are asked to specify a suitable study type to answer the research question. Preliminary analysis suggests that most NICE research recommendations specify RCTs as the preferred study type. While this may be appropriate for some areas, it is inconsistent with our ambition to make appropriate use of a broad range of evidence.

Focusing on the evidence gap, rather than study type, is a way to ensure that the research question is fully understood and appropriate evidence is developed for that particular question. Removing the requirement to specify a study type may encourage the generation of broader evidence types which can adequately address our most important evidence gaps. However, it will be important to understand the impact of taking a less prescriptive approach. For example, the eligibility criteria for the evidence review may need to be adjusted to ensure broader sources of evidence are being used.

External engagement

The Partnerships and collaborations set out within the data and analytics methods and standards programme is not exhaustive. The team will continue to contribute to other pertinent initiatives, and both build on existing partnerships and establish further collaborative opportunities that support NICE’s ambitions.

The team is currently feeding into the cross-NICE strategic engagement plan and developing a renewed partnership agreement with NHS Digital. It will prioritise this and a new partnership agreement with the Office for National Statistics in the next 3 months.

NICE now has an established partnership with HDRUK and has contributed to several initiatives on data utility and standards; and its Better Care programme. NICE developed a prototype data catalogue, detailing over 300 sources of health and care data, which was shared with HDRUK as part of the partnership to help with their Innovation Gateway project. We also tested and gave feedback to HDRUK on the gateway in its beta phase.

In July 2020 NICE also became a member of the International COVID-19 Data Research Alliance, led by HDRUK and funded by the Gates foundation. This aims to accelerate progress in the understanding of COVID-19 by encouraging widespread access to structured and unstructured clinical, administrative, imaging, genomic and other data. NICE engagement with this network will be valuable both to support our COVID-19 work and future international data and analytic collaborations.

Information Governance (IG)

The NICE Audit and Risk Committee annual review of information governance 2019/20 acknowledges any increase in the amount of sensitive data at NICE, will likely see a corresponding increase in the amount IG support required to help gain access to, and manage this data.

The infrastructure put in place by the NICE Information Governance team (DSPT, information asset register, IT security etc.) creates a platform to build upon. In some areas across NICE there is potentially an issue in identifying individual level data and how this should be treated. Steps are being taken to create education around this.

Data is generally accessed under a data sharing agreement (DSA) contract, so we will look to establish a structured process for approaching and signing these going forward.

DSAs may place stringent requirements on how the data are used and stored that could be difficult to meet. For example, only allowing access in a ‘secure space’ where the user cannot be overlooked or being stored in a ‘restricted access environment’ where outputs are monitored. How these requirements could be met should be considered.

Related to DSAs is the concept of arranging access to data for third parties, i.e., NICE accesses a dataset and commissions an external partner to create analysis that will inform a guideline using that data. This will also need further exploration with the IG team.

Public Trust, Ethics and Transparency

Data is an extremely valuable resource and should only ever be used in a responsible, ethical and secure way that is in the interest of society. NICE is committed to working with The Wellcome Trust, The Open Data Institute and other partners to ensure it continues to utilise and promote robust, trustworthy, transparent and ethical approaches in all aspects of its work.

Conclusion

The data and analytics team will continue to ensure that NICE makes the best use of available data to inform guidance and to do so in a timely, robust, and transparent manner. It will achieve this by prioritising the Methods and Standards Programme to provide a clear framework for the use of data and analytics in the development and evaluation of evidence. The framework will support those submitting evidence to NICE including the life sciences industry, assessment groups, and NICE staff, and those reviewing and assessing evidence including NICE staff, evidence review groups, and committees. We expect this programme to be a key enabler of NICE's strategic aim of showing leadership in data, science, and evidence.

Issues for decision

The Board is asked to:

* Approve the data and analytics methods and standards programme delivery plan as the main priority within the data and analytics portfolio.
* Note the complexity of the data and analytics transformation portfolio and relationship to other wider initiatives, such as the national health data strategy.
* Note the plans to continue to improve analytical and data science capability across the NICE workforce.

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January 2021

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| Annex A - detailed specification of Data and Analytics Methods and Standards Programme contentWork stream 1a - DataWP1.1 - Data quality assessment framework |
| Aims | Develop a generalised framework for the assessment of data quality and relevance. |
| Rationale | Concerns about the quality and relevance of real-world data sources are commonly cited as key barriers to the use of real-world data in decision-making. The development of a framework for the assessment of data and a simple tool to convey this information would help inform the appropriate use of data in guidance development and support committees.  |
| Scope | 1. Develop a generalised framework for assessing the quality of data. 1.1. Assessment of overall data source quality (or integrity) without reference to its use, focusing on data governance and quality management 1.2. Assessment of data in relation to specific research questions, focusing on its quality (e.g., completeness, accuracy, etc.) and relevance. Where possible, the framework should be agnostic to the source of data and will build on existing tools where appropriate. 2. Consider approaches to conveying outputs to committees and data custodians.3. Consider timing of assessments and process. |
| Activities | 1. Intelligence gathering - identification and review of existing approaches to data quality assessment 2. Multi-stakeholder workshop and gap analysis3. Define principles of data quality assessment (interim framework)4. Develop a framework including tools to support assessment of data quality and its communication 5. Consultation on framework6. Develop and test framework using demonstration projects |
| Deliverables (timing in months) | 1. Report on current approaches to data quality assessment and gap analysis (M6)2. Interim data quality assessment framework (M12-18)3. Results of demonstration projects (M12-24)4. Data quality assessment tool (M18-24) |

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| WP1.2 - Data collection, processing, and validation |
| Aims | To provide guidance on best practices for data collection, data processing, and validation, adopting where appropriate data standards established by healthcare partners like NHSX and NHS Digital.  |
| Rationale | It is important to provide clear expectations around data quality to inform the collection and handling of data. This is intended to support higher quality data in the future, both in managed access and elsewhere. |
| Scope | 1. Guidelines for assessing the feasibility of high-quality data collection.2. Data standards and information governance. 3. Selection and validation of endpoints from real-world data and digital health technologies including patient experience data4. Methods for processing and validating data including from unstructured clinical notes and high-density data from digital health and other technologies.  |
| Activities | 1. Intelligence gathering across WP scope2. Develop framework for assessing feasibility of collecting high-quality data3. Develop guidance on primary data collection, processing, and validation4. Consultation  |
| Deliverables (timing) | 1. Guidance for data collection feasibility assessment (M18)2. Guidance on data standards and information governance (M24)3. Guidance on endpoint selection and validation (M24) |

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| WS1b - Methods (WP1.3) |
| Aims | To provide clear guidance on best practice methodologies for the use of real-world data and advanced analytics. |
| Rationale | Estimation of non-randomised or observational data may be compromised by risks of bias due to selection, confounding, poor quality data, or poor study design. Clear methodological guidelines are required to ensure that evidence is generated using appropriate methods and that uncertainty and bias can be fully understood and described.  |
| Scope | The scope for this work package is broad and will be further refined during the programme itself through prioritisation activities including multi-stakeholder workshops. Key topics include: 1. Study planning and designDescribe the role of different study designs (e.g. observational cohort studies, external control arms, randomised controlled trials, qualitative studies) in evidence generation for different types of evidence, and the definition and selection of exposures, outcomes, and important covariates. 2. Statistical methodsDescribe best practice statistical methods for different types of evidence using different study designs. This will include detailed consideration of methods for causal estimation. It will also include methods for dealing with other risks of bias including selection and information bias (e.g. missing data, misclassification, etc.). 3. UncertaintyDescribe approaches to understanding and characterising uncertainty and bias for example using sensitivity analysis, quantitative bias analysis, replication, and triangulation.4. Evidence synthesis and integrationMethods for synthesising evidence from RCTs and non-randomised studies, and non-randomised studies of different designs. This includes extrapolating from trial data to different biomarkers, histologies, or treatment combinations/sequences using real-world data. 5. Digital health technologies using patient dataConsider methods for the generation and validation of clinical decision support tools estimated from patient data including AI/ML approaches 6. Other topicsA range of other topics are of interest including methods for time-varying confounding, extrapolation using external data, rare diseases, opportunistic qualitative evidence, etc. |
| Activities | 1. Multi-stakeholder workshops to identify priority areas for further methodological guidance2. Intelligence gathering across prioritised and some non-prioritised topics3. Guideline development for prioritised topics (with partners where relevant) incl. consultation5. Interim guidance for non-prioritised topics6. Research commissioning |
| Deliverables (timing) | 1. Report on multi-stakeholder workshops and prioritised topics (M6)2. Methods guides (interim for consultation and final) [M12-24]; each guide is expected to take 6-9 months to develop3. Results from commissioned research (M18-24)The number of topics with detailed methods guides will depend on the funding available |

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| WS1c - Research Governance (WP1.4) |
| Aims | To specify research governance processes to be followed when using real world data in evidence submissions and to ensure clear presentation of evidence to committees. |
| Rationale | Insufficient transparency in the conduct and reporting of research is a major impediment to evidence-based decision-making. This problem is especially true for retrospective studies of observational data and is recognised by all stakeholders as a major barrier to its wider use. Ensuring all aspects of study conduct are reported from study planning through to reporting of analyses and study results should improve the available evidence base, allow for robust critique of evidence, and ultimately increase confidence in its use for decision-making. |
| Scope | We will consider topics of research governance across the following areas:1. Study planning and registrationThis includes approaches to data identification and selection, and the registration of protocols (including statistical analysis plans) prior to study conduct, and choice of register.2. Data extraction, transformation, and analysisThis will consider the extent to which developers are expected to detail the use of data in their study, and how this information should be conveyed. 3. Study conduct and reportingThis will consider approaches to conveying data quality, analytical choices made, the reporting of study results, and the use of risk of bias and other tools.There may be a need for further tool development where important gaps are found. |
| Activities | 1. Intelligence gathering - literature reviews and stakeholder engagement to understand current tools to communicate study conduct across evidence generation2. Selection of tools and identification of areas where further tools are needed3. Develop interim research governance framework4. Demonstration projects 5. Development of governance tools and commissioning where required6. Final research governance framework |
| Deliverables | 1. Report on current approaches to reporting studies (M6)2. Interim research governance framework (M12)3. Results of demonstration projects (M12-24)4. Tool development/commissioning (if needed) [M24]5. Final research governance framework (M24) |

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| WS2a - Evidence Framework  |
| Aims | To take learnings from WS1 to develop a clear framework for the use of data and analytics in the development of NICE guidance and define evidence standards across use cases. |
| Rationale | Clarity is needed on when NICE will consider, or even expect, submissions using real-world data, and the evidence standards across different use cases. |
| Scope | 1. Provide clarity on the appropriate uses of data and analytics in NICE guidance development2. Develop an evidence standards framework to define expectations around evidence quality across different use cases, incorporating guidance on data, methods, and research governance from WS1  |
| Activities | 1. Develop a taxonomy of data and analytic uses in NICE, and consider the use of risk-based categorisations2. Development of an interim evidence standards framework 3. Demonstration projects4. External engagement and consultation 5. Iterative updates to evidence standards framework |
| Deliverables | 1. Report on taxonomy of use cases and risk-based categorisation (M6)2. Interim evidence Framework (M12)3. Results of demonstration projects (M12-36)4. Final evidence Framework (M12-24) |

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| WS2b - Implementation |
| Aims | To ensure that the evidence standards frameworks aligns with transformational changes within NICE and the wider regulatory environment, and that NICE's processes and policies support the timely and robust inclusion of evidence in guidance development.  |
| Rationale | Evidence standards alone will not ensure that robust evidence from real-world data sources is included in guidance development. It is essential that processes support the timely inclusion of such evidence in decision making.There are several transformational projects within NICE and in the wider regulatory system that are likely to inform the role of real-world evidence in decision-making. It is essential that the development of evidence standards and processes aligns with, and supports, these developments. |
| Scope | The scope of this work stream is broad and will adapt to reflect ongoing transformational activities within NICE and the wider regulatory system. Key topics are:1. Ensuring NICE processes support the timely and robust inclusion of real-world data in guidance development where it adds value. This may include:i. Defining the role of scoping and surveillance activities and scientific advice in identifying the need for, and value of, real world data in guidance development and supporting its inclusion in evidence submissionsii. Supporting technical engagement with those developing evidence during guidance developmentiii. Defining processes and policies for supporting further evidence generation and research recommendationsiv. Providing submission templates to support the complete and robust presentation of evidence from real-world datav. Considering the role of data visualisations in decision makingvi. Considering the role of a centralised data function within NICEv. Training of evidence assessment and review groups, NICE staff, and committees2. Ensuring alignment with transformation changes, including:i. Internal NICE transformational activities (e.g. NICE Connect)ii. Wider activities including the Innovative Licensing and Access Pathway, the Innovative Medicines Fund, the Accelerated Access Collaborative, and the multi-agency advice service for digital health technologies3. Engagementi. Stakeholder engagementEnsure that the Programme provides benefits to all stakeholders and is widely accepted and supportedii. External initiatives in data and analyticsIt is important that the Programme is informed by international best practice, and that alignment with international standards is achieved where necessary. |
| Activities | 1. Supporting the development of NICE processes and policies2. Engagement with transformational activities within NICE and UK healthcare system3. Engagement with international initiatives in data and analytics 4. Stakeholder engagement |
| Deliverables | 1. Updated processes (M12-24) |

Annex B – National Data Strategy Outcomes

NHSX intends for the National Data strategy to set out what has been done so far and an action plan for each of the following 8 areas:

* 1. The public trusts the health and care system to handle their data appropriately and to respect their confidentiality
	2. Staff and system leaders are empowered and confident to share and handle data, through simple, unified, information governance guidance and a clear understanding of legal safeguards
	3. The sharing of data to enable joining up care is supported by technology, policies and processes
	4. Information about what data the health and care system holds and how it is used, is routinely made available
	5. Policy development and the planning and commissioning of health and care services is informed by the appropriate and timely access to and use of high quality data
	6. Research to improve health and care outcomes for people is supported by the appropriate and timely access to and use of high quality data
	7. The public receives a fair share of the benefits from data access agreements entered into with third parties where a piece of research can be commercialised, regulated by our robust legal safeguards
	8. Safe, effective and ethical use of data-driven technologies such as Artificial Intelligence delivers fairer health outcomes