NICE “research recommendations”

Calls for real-world evidence (RWE) studies from a health technology assessment (HTA) agency

NICE National Institute for Health and Care Excellence

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About NICE

- The health technology assessment (HTA) agency for England
- Provides guidance to the healthcare system

- Key principles:
  - evidence-based medicine
  - opportunity cost

Want to learn the basics of HTA?
EHDEN Academy course:
Introduction to health technology assessment

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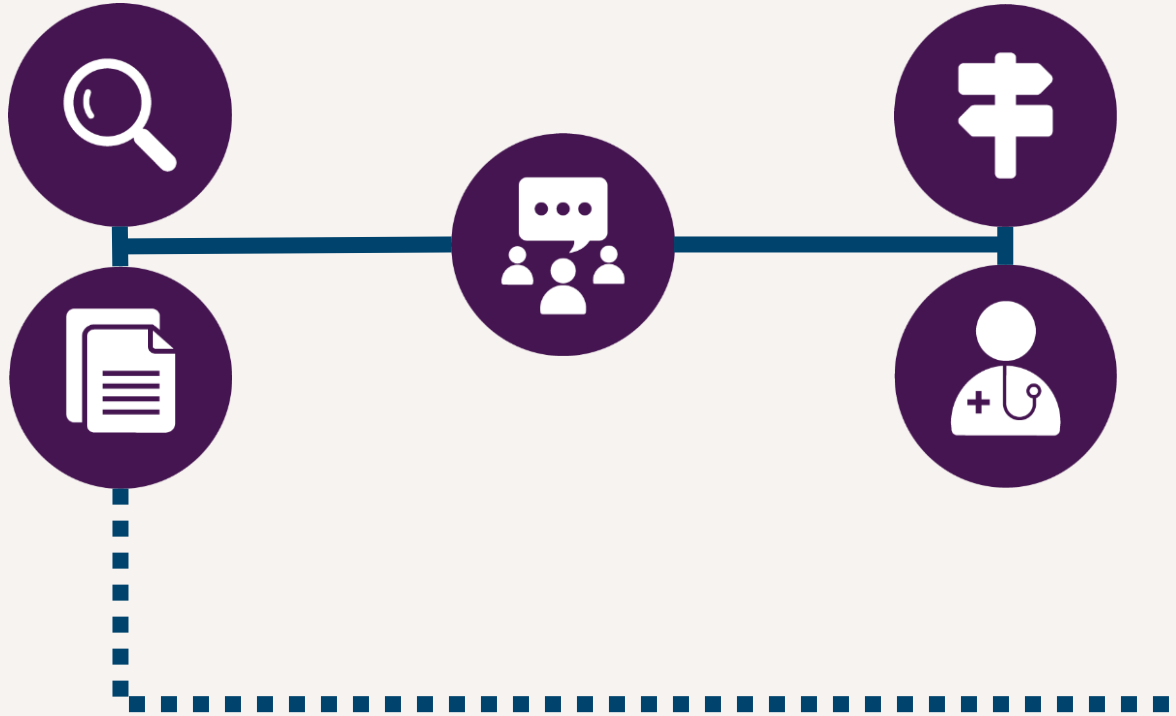
NICE

NICE is committed to using RWE for decision making

Typical NICE guidance development process

RWE has already informed NICE's decision making



How we've used RWE

- Characterising conditions, interventions, pathways, patient outcomes & experience
- Estimating economic burden, resources & costs
- Population baseline event rates and characteristics
- Transition probabilities between health states
- Extrapolation of short-term data
- Test validity of RCT results in UK patients
- Identifying and characterising health inequalities
- Measuring test accuracy
- Estimating medtech failure rates
- Impact on service delivery & decisions

NICE is trying to raise the quality of RWE it receives

NICE real-world evidence framework

Corporate document
Published: 23 June 2022
www.nice.org.uk/corporate/ecd9

- Real-world data can improve our understanding of health and social care delivery, patient health and experiences, and the effects of interventions on patient and system outcomes in routine settings.
- We developed the real-world evidence framework to help deliver on this ambition. It does this by:
  - identifying when real-world data can be used to reduce uncertainties and improve guidance
  - clearly describing best-practices for planning, conducting and reporting real-world evidence studies to improve the quality and transparency of evidence.
- The framework aims to improve the quality of real-world evidence informing our guidance. It does not set minimum acceptable standards for the quality of evidence.

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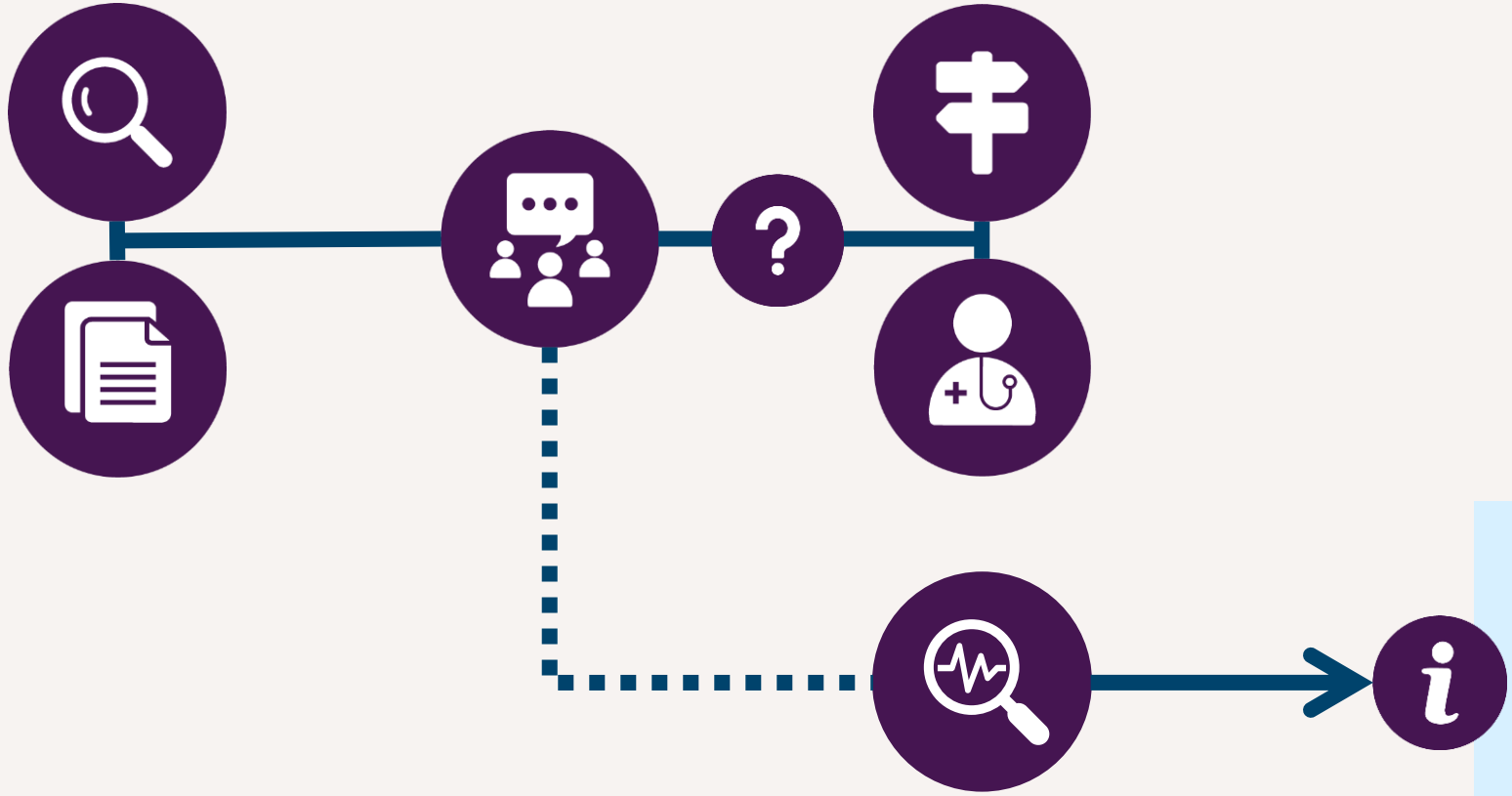
Sometimes NICE asks for new research to fill identified evidence gaps



Do NICE research recommendations ask for **RWE studies**?

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Research recommendations

https://www.nice.org.uk/about/what-we-do/science-policy-research/research-recommendations

As we develop guidance, we identify gaps and uncertainties in the evidence base which could benefit from further research. The most important unanswered questions are developed into research recommendations. Read our process and methods guide (PDF).

Browse the list below to find a topic of interest. Only research recommendations made from 2011 onwards are shown. Please contact us if you need more information.

Call for research studies addressing NICE recommendations

The National Institute for Health Research (NIHR) are seeking applications to address NICE recommendations as part of a rolling research call.

Filter by title or Recommendation ID

observational

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There are calls for RWE from across NICE guidance

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Correct at April 2022

Ophthalmology

NG82: Age-related macular degeneration (Jan 2018)

Evidence gap: When should anti-vascular endothelial growth factor (VEGF) treatment be suspended or stopped in people with late AMD (wet)?

- Anti-VEGF treatment can be inconvenient, risky and costly, and can last for extended periods.
- After successful treatment, AMD can become sufficiently dormant that treatment could be safely suspended.
- After ineffective treatment, there may be no benefit in continuing to treat eyes.

Large retrospective observational research should:

- Establish the point at which benefits of continuing treatment are unclear.
- Involving eyes in which disease has responded well to treatment, and eyes in which pathological appearances or visual acuity suggest that disease is not responding to treatment.
- Be used to establish a protocol for suspending or stopping treatment.
- Provide the ethical basis for a non-inferiority RCT: protocol-dependent stopping rules vs. clinician discretion.

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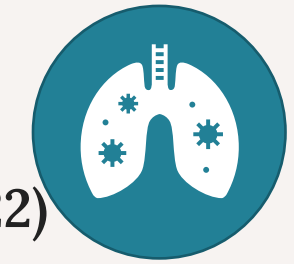
Lung cancer

DG46: EarlyCDT Lung for assessing risk of lung cancer in solid lung nodules (Feb '22)



Evidence gap: A better understanding of the population with lung nodules and current diagnostic pathway is needed.

A large retrospective audit is recommended to:

- Understand how patient and nodule characteristics impact on malignancy prevalence and disease progression.
- Understand current practice regarding clinical management of people with intermediate-risk lung nodules.
- Determine the clinical consequences of CT surveillance, including the likelihood of disease progression during CT surveillance.
- Determine the likelihood and impact of unnecessary biopsy or resection of indolent and benign nodules.

Diabetes

NG17: Type 1 diabetes in adults: diagnosis and management (Aug 2022)
NG18: Diabetes (T1 & T2) in children and young people (June 2022)

Evidence gap: Type 1 diabetes and other diabetes types are treated differently (particularly in terms of insulin use). Misdiagnosis can be harmful. Previously atypical features of type 1 (e.g., high BMI) and uncertain classifications are becoming more common.

What are the best clinical features or combination of features for distinguishing between type 1 diabetes and other types of diabetes?

Evidence gap: The direct effect of continuous glucose monitoring (CGM) technology on the population is not known.

Based on routinely collected RWD, what is the effectiveness and cost effectiveness of CGM devices to improve glycaemic control:

- In adults with type 1 diabetes?
- In children and young people with type 1 and type 2 diabetes?

Medical technologies (1)

MTG68: 'myCOPD' for managing COPD (March 2022)

Evidence gap: Further comparative evidence is needed to address uncertainties about myCOPD's clinical benefits and its effect on healthcare resource use, in people using it to self-manage COPD, and in people referred to pulmonary rehabilitation.

High-quality comparative observational studies designed to minimise bias may provide acceptable evidence:

- For self-management, key outcomes include rates of exacerbations, hospital readmissions and unscheduled care appointments, patient-reported outcomes.
- For rehabilitation, key outcomes include CAT score, 6-minute walk test, rates of exacerbations and hospital admissions.

Real-world data could [also] provide:

- myCOPD uptake rates to inform economic modelling
- qualitative data on patient experience using myCOPD, e.g., preferences and adherence.

Medical technologies (2)

MTG70: 'Sleepio' to treat insomnia and insomnia symptoms (May 2022)

Evidence gap: More research or data collection is recommended on Sleepio for people who are eligible for face-to-face cognitive behavioural therapy for insomnia (CBT-I) in primary care.

- A study based on real-world evidence that collects clinical and resource use data in a population eligible for face-to-face CBT-I, may be appropriate.
- [Identifying] a link between any Sleepio user data and [healthcare] resource use would help address uncertainties in the economic modelling.

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Thank you for listening

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