NICE National Institute for Health and Care Excellence

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Exploring evidence gaps in National Institute for Health and Care Excellence early value assessments.

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Background

The Early Value Assessment (EVA) program within the National Institute for Health and Care Excellence (NICE) enables a more rapid assessment of digital products, devices and diagnostics for clinical effectiveness and value for money. Evidence generation plans (EGPs) are published alongside conditional recommendations for early use of technologies in the NHS. The EGPs specify the evidence gaps (essential or supportive), the key outcomes needed for assessing cost-effectiveness in the future, and relevant study approaches for data collection with relevant time frames.

Aims

To explore the evidence gaps, technology types and recommended study approaches described in the evidence generation plans in NICE's EVA program.

What we did and why

NICE EVAs published between 1st July 2022 and 1st July 2024 were reviewed. Summary statistics were used to describe the common themes in the evidence gaps and the recommended study approaches outlined in the EGPs. The evidence gaps were classified as 'essential' or 'supportive' gaps in the EGPs.

Outcomes and impact

Fourteen published EGPs were reviewed in total. These included a total of 57 technologies, of which 77% were patient-facing technologies (n=44). Clinician-facing therapeutic tools accounted for 19% of technologies (n=11) and clinician facing diagnostic tools for only 4% (n=2, data not shown). Figure 1 shows that most technologies are an "app or online tool for communicating about health and care" (n=6, 37%). Evidence gaps were categorised into 9 groups (table 1).

Figure 1. Classification of technology types

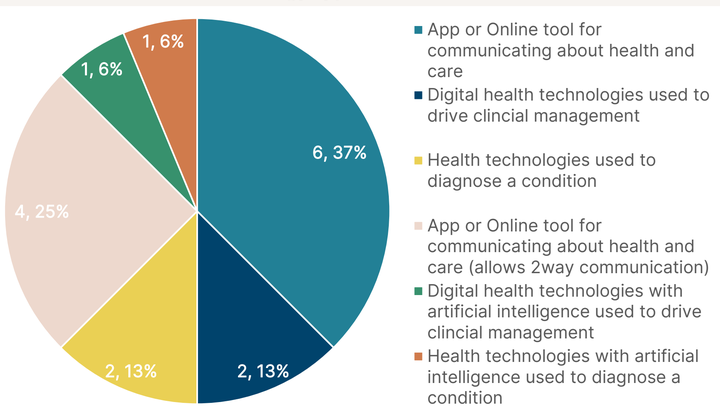
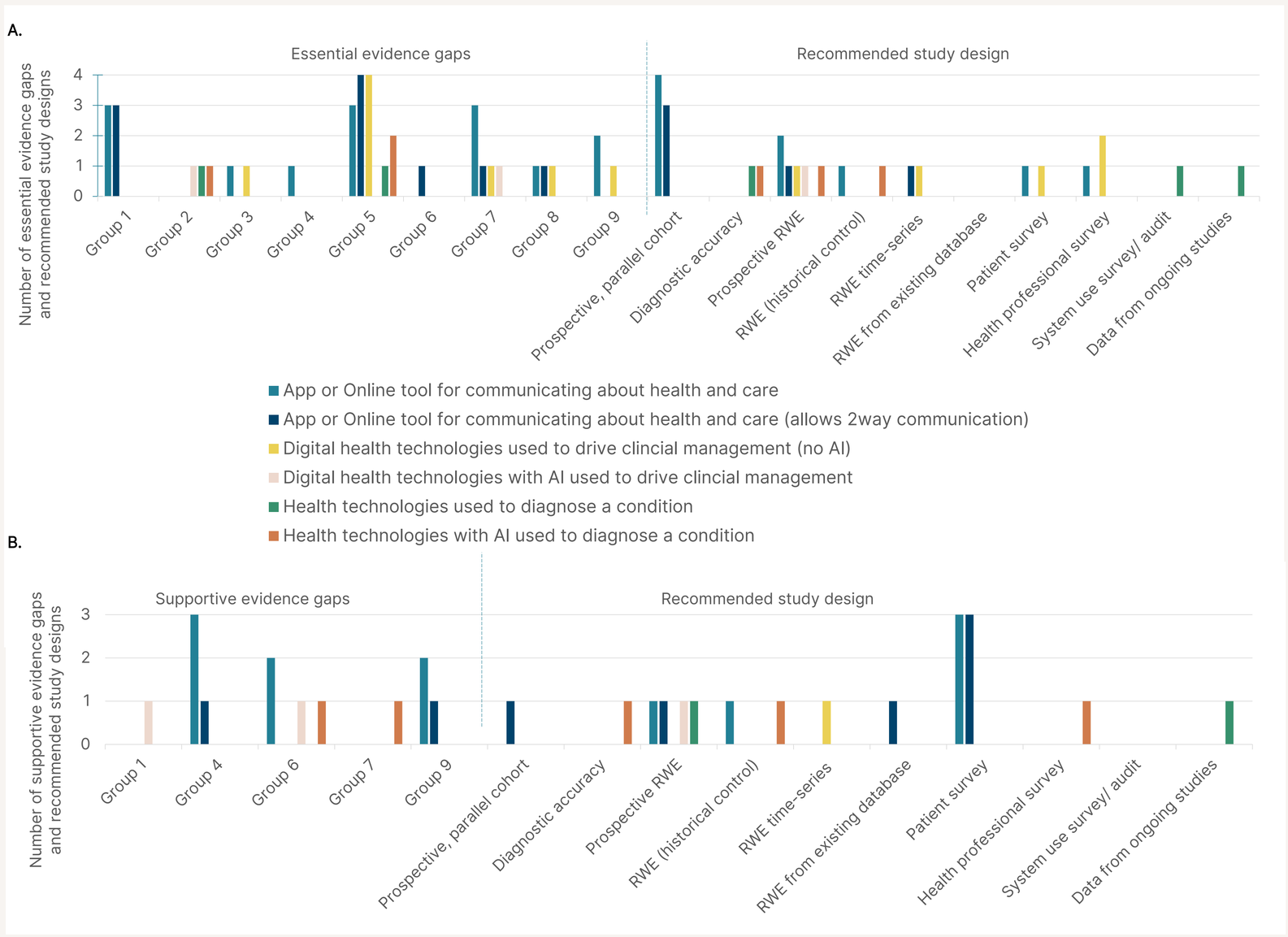


Table 1. Classification of Evidence gaps

Category	Evidence gap
Group1	Adverse events measurement
Group2	Diagnostic accuracy
Group3	Generalisability
Group4	Health-related quality of life measurement
Group5	Insufficient effectiveness evidence compared to standard of care and/or at a sufficient time horizon
Group6	Insufficient effectiveness evidence in specific sub-groups and equity concerns
Group7	Insufficient health resource use data including staff training
Group8	Measurement of the appropriate outcomes and settings for the NHS for instance position in the care pathway
Group9	User acceptance, engagement, usability and experience

Figure 2: A) Essential and B) supportive, evidence gaps and recommended study designs for different technology types



- Figure 2 shows the different types of technology, the evidence gaps identified in their assessments, and the proposed study design to address gaps associated with those technologies.
- Figure 2A shows that essential evidence gaps relating to the effectiveness of the technology compared to standard care, and/or at a sufficient time horizon (group 5), are most common (n=15, 29%) and span most of the technology types.
- Figure 2B shows that supportive evidence gaps are largely split between groups 4 and 5 (n=4, 33% for each). Parallel cohort studies are commonly recommended to address essential gaps (n=6, 26.9%), whereas patient surveys are more common for supportive gaps (n=6, 33%). For each of these proposed study designs for essential and supportive evidence gaps, technologies categorised as 'apps or online tools for communicating health and care' with or without 2-way capabilities, were most frequent (fig.2A and 2B).

What we learnt

- The results show that fundamental evidence around the technology's efficacy is often lacking and is common to different technology types.
- The EVA program takes a pragmatic view on gathering evidence to address the gaps by proposing real-word evidence approaches where possible, but the frequency of proposed prospective cohort studies suggest RWE approaches are not always feasible.
- As real-world evidence becomes more readily available, more pragmatic approaches should be taken for generating evidence.

NICE EVA program

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