Medical Technology Guidance: A Review to Identify the Evidence Gaps and Data Needs

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INTRODUCTION

- Medical Technology Guidance (MTG) plays a crucial role in the adoption of medical technologies by providing recommendations to the National Institute for Health and Care Excellence (NICE) on use in the National Health Service (NHS).[1]
- External Assessment Centre (EAC), an independent organization that critically appraises the sponsor's submissions for NICE provides objective and rigorous assessments of clinical evidence and economic evaluation for new and existing healthcare technologies.[2]
- The EAC assessments helps to ensure that NICE's guidance is evidence-based and impartial, and decisions about the use of medical technologies are made in the best interest of patients and the NHS.[2] The critical parameters for MTGs and recommendations in NICE includes evaluation of the safety, clinical efficacy, and cost-effectiveness of medical technologies.[1]
- Understanding data gaps limiting the acceptance of MTGs has potential implications for decision-making on the inclusion of such medical technologies in current guidance.

OBJECTIVE

- To characterize the final recommendations and evidence supporting the acceptance of medical technologies presented in MTG reports and to evaluate the trends and data gaps raised by EAC limiting the acceptance of these medical technologies.

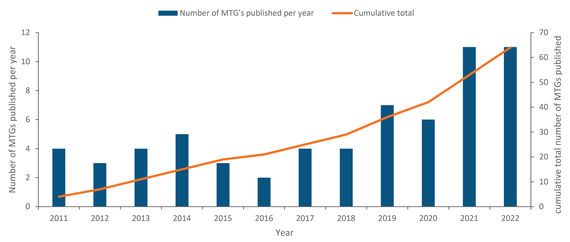
METHODS

- All MTGs published from July 2011 to December 2022 were identified and reviewed using the NICE electronic database. Details of data extraction across MTGs were captured using a pre-specified data extraction template.
- The MTGs were accessed on 29 December 2022 and documented based on their technology class (treatment or diagnostic), disease specialties, clinical evidence, economic evidence, and real-world evidence.
- The decision outcome of the NICE Committee for each assessment was recorded, and the requirement for real-world data (RWD) in the MTGs was also investigated.

RESULTS

- A total of 64 MTGs which were published between July 2011 and December 2022 were assessed, the number of MTGs produced annually increased steadily from 4 to 64 during this period **(Figure 1)**.

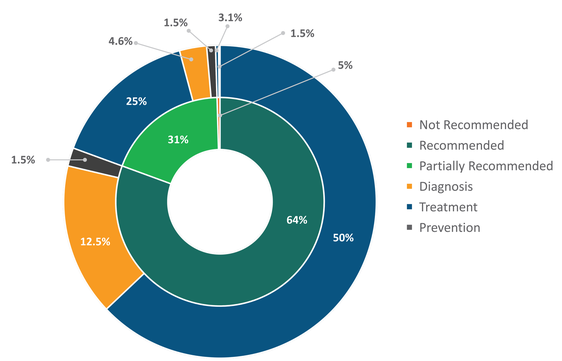
Figure 1. Number of MTGs published from 2011 to 2022



RESULTS

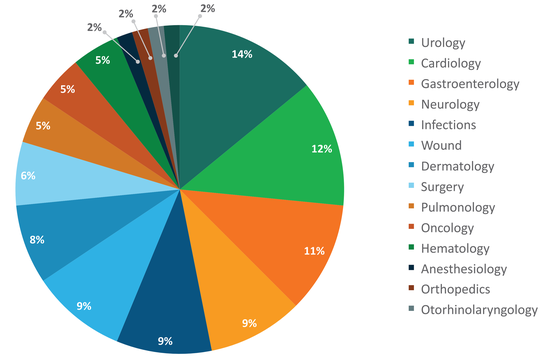
- NICE fully recommended the adoption of medical technology in 64% (*n=41*) of MTGs, 31% (*n=20*) were partially recommended, and 5% (*n=3*) were not recommended. Most of the published MTGs were related to treatment (75%), followed by diagnosis (17%) and prevention (3%) categories **(Figure 2A)**.

Figure 2A. NICE recommendation on adoption of MTGs



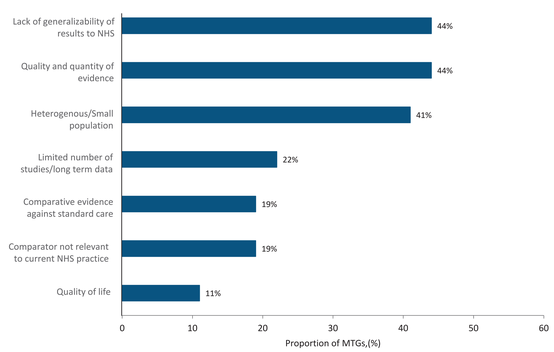
- The MTGs were primarily pertaining to indications in urology 14% (*n=9*), followed by cardiology 12% (*n=8*), gastroenterology 11% (*n*=7), neurology 9% (*n*=6) and infections 9% (*n*=6) **(Figure 2B)**.

Figure 2B. Proportion of MTGs by disease area



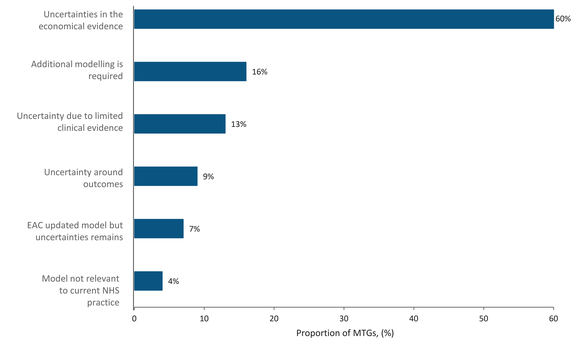
- Across the 64 reviewed MTGs, the clinical evidence submitted by the sponsors utilized randomized controlled trials (RCT) data for 45 MTGs, and the economic evaluation data was available for 19 MTGs. Regarding the economic evaluation of MTGs, the most common modeling approaches used were a combination of the decision tree and Markov model 37% (*n=7*) and the cost analysis model 32% (*n=6*).
  - Insufficient clinical evidence was highlighted in 50% of MTGs in the treatment category while one-third in diagnostics. Inconsistent reported outcomes, small population, lack of generalizability of results to NHS, and the quality and quantity of clinical evidence are the main reason for NICE not issuing a positive recommendation **(Figure 3A)**.

Figure 3A. Data insufficiencies in the clinical evidence of MTGs



- Similarly, uncertainties in economic evidence were observed in 70–75% of technologies overall. The most common reason cited for insufficient evidence was uncertainty regarding economic evidence, uncertainty in the cost model and additional extensive modelling necessitating the need for further evidence **(Figure 3B)**.

Figure 3B. Data insufficiencies in the economic evidence of MTGs



- In the EAC analysis, clinical evidence in 14 MTGs was augmented with the inclusion of new studies, and economic models were revised for 45 MTGs resulting in the recommendation of 14 MTGs by NICE. In the recommended MTGs, compared to new clinical evidence (36%) the rate of new economic models incorporated by EAC is relatively higher indicating a lack of economic evidence (93%) **(Table 1)**.

Table 1: Recommended MTGs after inclusion of additional analysis suggested by EAC

MTG Identifier	Additional analysis by EAC in Clinical Evidence	Additional analysis by EAC in Economical Modelling	Type of study Clinical Evidence	Type of study Economical Modelling
MTG8	No	Revised	-	Most of the evidence are single-arm studies
MTG12	No	Change of model	-	EAC performed two-way sensitivity analysis
MTG13	Yes, new studies were included	Yes, new studies were included	Not specified	Not specified
MTG16	Yes	Yes	Systematic review and meta-analysis	Short and long-term models
MTG17	No	Yes, new studies were included	Not specified, threshold analysis	Threshold analysis, base-case analysis
MTG24	No	Yes, model revised	-	Revised the parameters in the company's model, carried out a one-way sensitivity analysis
MTG27	Yes, new studies were included	Yes, new studies were included	Meta-analysis, carried out further literature search	Re-ran the company's model to address the issues, Meta-analysis
MTG30	No	Change of model	-	Revised the company's relative risk estimates, revised the cost of the surgeries, univariate sensitivity analysis, sensitivity analysis
MTG32	Yes, new studies were included	Yes, new studies were included	Additional literature review	Revised company list price, sensitivity analysis
MTG34	Yes, new studies were included	Yes, new studies were included	Meta-analysis	A multivariate sensitivity analysis, one-way sensitivity analysis
MTG39	No	Change of model	-	Change of time horizon to longer period
MTG42	No	Change of model	-	Calibrated the models to align with the healing outcomes
MTG43	No	Change of model	-	Applied baseline incidence rates, updated the number of PICO and comparator dressings used
MTG59	Yes, new studies were included	No	Meta-analysis	-

- In MTGs with partial recommendation, EAC has encouraged the collection of RWD in ~40% (*n=8*) MTGs to support decision making. The types of RWD suggested by EAC included observational studies, databases (e.g., National database), and registry studies **(Table 2)**.

Table 2: Partial Recommended MTGs for which additional RWD analysis is required

MTG Identifier	Medical Technology	Key parameter suggested by EAC/NICE	Type of RWD source asked by EAC/NICE
MTG56	Alpha-Stim AID	• Long term evidence on clinical benefit • Comparator evidence • Understand treatment landscape • Robust clinical efficacy data	Details not disclosed
MTG44	Curos	• More NHS-based evidence for potential clinical benefits • Robust clinical data	Patient-powered (Patient community) & Observational study (Prospective trial)
MTG60	DyeVert systems	• Long term evidence	Details not disclosed
MTG63	Endo-SPONGE	• Data for understanding patient population • Patient-reported outcome measures • Evidence for comparative cost modelling	Database (National database), Registry data, Observational data
MTG33	ENDURALIFE powered CRT-D devices	• Analysis of data collected to understand patient lifespan outcomes	Registry data
MTG61	Synergo	• Robust evidence of clinical effectiveness • More data on clinical benefit • Outcomes suggested by NICE's interventional procedures audit tool	Observational data (Retrospective analysis)
MTG21	ReCell Spray-on skin system	• Observational data to resolve some of the clinical uncertainties • Comparator evidence • Hospital-based audit data to improve cost model	Database, Registry data
MTG54	VAC Veraflo therapy system	• Data collection from registries to provide confidence in assumptions made in the economic models	Registry data

CONCLUSIONS

- MTGs published between July 2011 and December 2022, showed that the decision outcome in 64% (*n=41*) of the MTGs fully supported the medical technology.
- The main reasons for the NICE not issuing positive recommendations included the quantity or quality of the clinical evidence, inconsistently reported outcomes, uncertainty in the cost model and additional extensive modelling.
- In almost 40% of the MTGs with partial recommendation EAC suggested the collection of RWD along with robust economic evidence.
- Considerable data gaps have restricted the acceptance of medical technologies. Hence, supportive clinical and economic evidence is required for informed decision making and could improve the rate of acceptance of medical technologies in current guidance.

REFERENCES:

1. NICE: Medical Technologies Evaluation Programme: Process guide. In: National Institute for Health and Care Excellence (ed.). (2017).
2. NICE: MTEP Assessment Report In: National Institute for Health and Care Excellence

DISCLOSURES:

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