

From theory to practice:
**The impact of the NICE Real-World
Evidence framework in health
technology assessment**
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**Natalie Tikhonovsky, Nishit Dhanji,
Benjamin D. Bray, Sreeram Ramagopalan**
Ben.Bray@lcp.uk.com





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We sought to identify and characterise references to the NICE Real-World Evidence framework

NICE real-world evidence framework

Corporate document

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www.nice.org.uk/corporate/ecd9

Rationale and Objective

Since its publication, the extent to which the RWE framework is being invoked in technology appraisals is unknown.

We aimed to identify and characterise references to the RWE framework in NICE single technology appraisals (STAs).

Method

- 1 Double screening of all STA guidance documents for explicit mention of RWE framework
- 2 We used a previously published automated algorithm* to screen accompanying NICE appraisal documentation for keywords



Key aspects of NICE's RWE Framework

- ✓ Guidance on conducting quantitative RWE studies
- ✓ Assessing data suitability
- ✓ Methods for RWE studies of comparative effects

Despite the increased use of RWE in NICE STAs, the RWE framework has been sparingly mentioned

Analysis of **all NICE STAs (n=115)** published* between **23 June 2022-31 January 2024** found:

Mention of the RWE framework

7% of the STAs (**8/115**) made at least one reference to the framework, with **5** mentioning it multiple times for a **total of 15 mentions**

Source of mentions

8

Mentions by the manufacturer, remaining 7 from other stakeholders**

NICE recommendation

4

STAs out of the 8 received a positive reimbursement recommendation

Inclusion of RWD

8

STAs out of the 8 included RWD to estimate treatment effectiveness‡

**External stakeholders, NICE committees, or the External Assessment Group

RWE trends

The inclusion of RWE **increased from 45% to 63%** in the 12 months **before vs. after the framework.**† Among the STAs post-framework including RWE, only **6 cited the framework.**

Conclusion

Although limited direct references does not necessarily indicate the framework's under-utilisation, there is opportunity for further transparency in its use to provide learnings for all stakeholders involved in HTA.

*Excluding those withdrawn, terminated, or replaced.

†32 out of 71 STAs included RWE during the period 22 June 2021-22 June 2022 and 53 out of 82 during the period 23 June 2022-23 June 2023.

‡4 used external control arms, 1 used an indirect treatment comparison, and 3 provided real-world effectiveness of the technology under consideration

Abbreviations. HTA, health technology appraisal; NICE, National Institute for Health and Care Excellence; RWD; real-world data; RWE, real-world evidence; STA, single technology appraisal