

Background

- In November 2023, the Institute for Clinical and Economic Review (ICER) published an update to its Value Assessment Framework implementing key updates to their methods and procedures.¹ One of the updates was the adoption of a new “non-zero” approach to analyses. Using this approach, cost-effectiveness models will have “non-zero” inputs for impacts on patient and caregiver productivity, even when direct data are lacking.¹ In effect, this update ensures the reflection of a societal perspective in all evaluations.
- The National Institute for Health and Care Excellence (NICE) 2022 Methods Guide update did not recommend a societal perspective as part of their appraisals.²

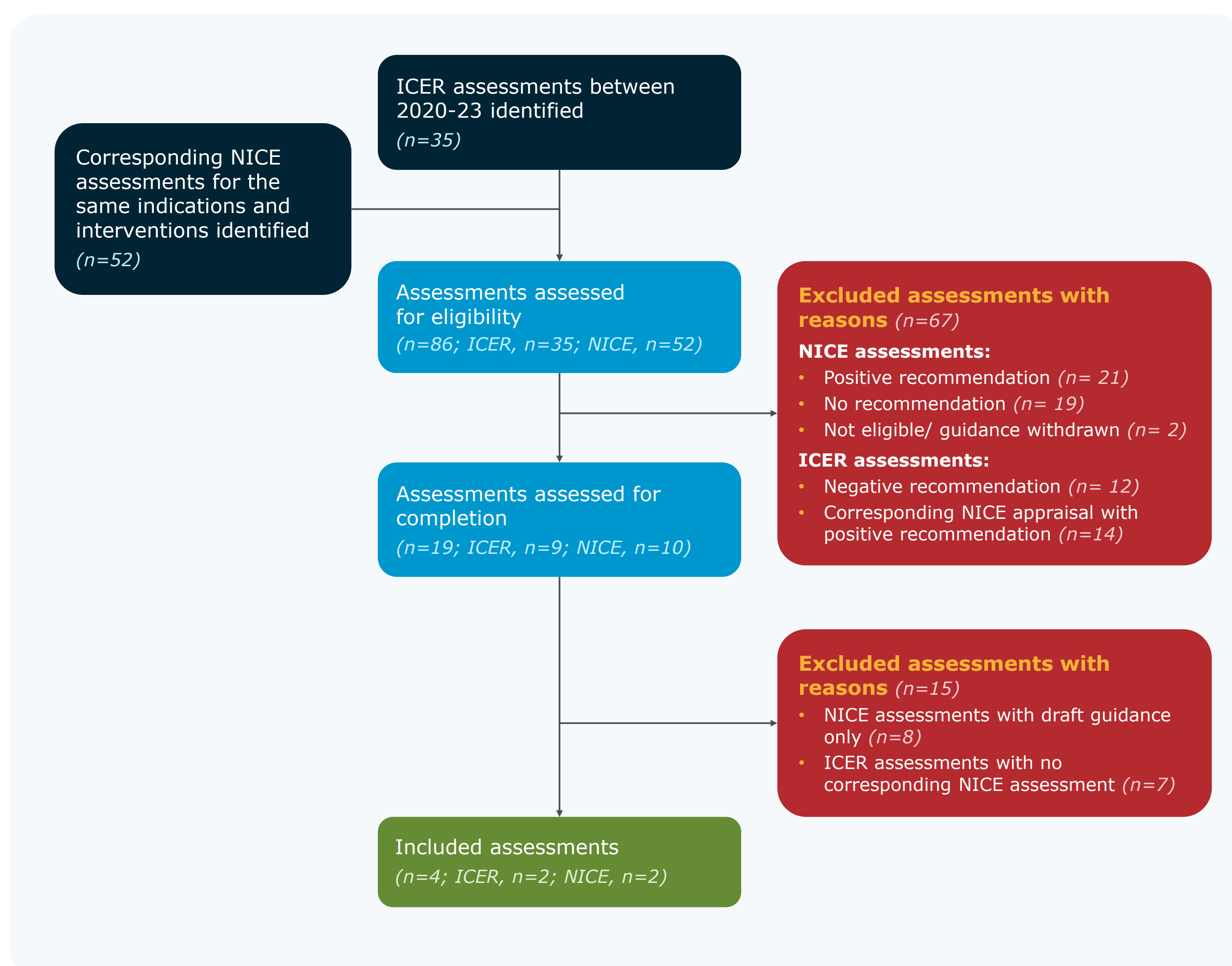
Objective

The aim of this study was to identify the potential benefits of the societal versus health service perspectives recommended by ICER and NICE, and to evaluate what value implementation of a societal perspective in NICE assessments could have.

Methods

- All ICER assessments published in 2020 to 2023 (n=35) and the corresponding NICE appraisals for the same intervention were identified. Most ICER assessments evaluated multiple interventions for the indication of interest, therefore corresponding to several NICE appraisals per ICER assessment.
- This qualitative analysis focused on cases where ICER provided a positive recommendation for the intervention (deemed to have a net health benefit), while NICE’s recommendation was negative due to prohibitively high incremental cost-effectiveness ratios (ICERs). It was assumed that a societal perspective would only improve cost-effectiveness, hence positive NICE recommendations were excluded.
- We explored how utilizing the societal perspective from the ICER framework may have impacted interventions’ cost-effectiveness for NICE. Results were assessed to consider whether the funding decision of these products may have changed.

Figure 1: Included NICE and ICER assessments



Results

- Out of the 35 ICER assessments evaluated, 25 had at least one intervention that was deemed to have a net health benefit, defined as a combination of ratings for comparative clinical effectiveness and comparative value.
- There were 52 corresponding NICE appraisals for the same indication and intervention (Figure 1).
- Of the 23 NICE appraisals where a final recommendation was available, two were not recommended and included in the analysis (Table 1). Of the 29 appraisals in development or awaiting final decision, eight had a draft negative recommendation but were excluded from the analysis due to the immaturity of the decision.

Table 1: Interventions with positive ICER appraisals and negative NICE guidance between years 2020-2023

Intervention of interest	ICER review			NICE appraisal	
	ICER Assessment	ICER without societal perspective	ICER with societal perspective	TA number	ICER
Lumacaftor-ivacaftor	Cystic fibrosis	ICER for intervention plus BSC vs. BSC alone: \$1,480,000	ICER for intervention plus BSC vs. BSC alone: N/A	TA398	£349,000
Naltrexone-bupropion	Obesity management	ICER for intervention vs. lifestyle modification: \$123,000	ICER for intervention vs. lifestyle modification: \$105,000	TA494	£23,750

Discussion

- Obesity, often a chronic disease, is associated with >50 weight-related medical conditions. In the UK, the economic burden of obesity is significant, with estimated costs of £6.1 billion to the NHS and £27 billion to wider UK society,³ and consensus that the available data underestimates the actual financial burden.⁴ ICER’s assessment of naltrexone-bupropion showed a net health benefit and a 14.6% decrease in the ICER when using a modified societal perspective.⁵ NICE did not recommend naltrexone-bupropion due to uncertainty in the committee base-case ICER.⁶ As cited in the final guidance for TA494, the NICE guides to the methods of technology appraisal state that above a plausible ICER of £20,000, the degree of certainty around the ICER must be considered.² If a societal perspective had been considered for this appraisal, while the clinical uncertainties associated with naltrexone-bupropion would remain, it is possible that the ICER may have been sufficiently small to assuage the committee’s concerns.
- Cystic fibrosis (CF) has significant costs to healthcare systems and society, with medications costing the NHS £30 million per year,⁹ and non-health care and indirect costs representing 57% of average annual costs for a cystic fibrosis patient.¹⁰ A societal perspective scenario was not reported for ICER’s assessment of lumacaftor-ivacaftor, however the average ICER reduction for other interventions in the assessment versus the base case analysis was 1.32%. Despite the large societal burden of CF, NICE implementing a wider perspective would be unlikely to make lumacaftor-ivacaftor cost-effective due to the committee’s preferred ICER (£349,000) being considerably higher than normal cost-effectiveness thresholds.¹¹ Inclusion of productivity effects in assessments may bias allocation of health resources towards the working population, favouring younger adults.^{12,13} Therefore, the minimal impact on cost-effectiveness observed when considering a societal perspective for other interventions in the ICER CF assessment further highlights the well-documented challenges of pricing for these products.¹³ This issue has been brought to the forefront once again in the recent negative draft NICE guidance for ivacaftor-tezacaftor-elexacaftor, tezacaftor-ivacaftor and lumacaftor-ivacaftor.^{14,15}

Conclusion

- By introducing a more nuanced perspective, unconsidered costs to society can be accounted for, and NICE may enhance the relevance of evaluations to the lives of the UK general public. However, adoption of a societal perspective would require more resources, necessitating research on valuing non-health benefits and opportunity costs.¹² Results from this analysis showed limited evidence that adoption of a societal perspective would allow for more products to be recommended by NICE.

Abbreviations: BSC, best supportive care; CF, cystic fibrosis; ICER, Institute for Clinical and Economic Review; ICER, incremental cost-effectiveness ratio; N/A, not available; NHS, National Health Service; NICE, National Institute for Health and Care Excellence; SOC, standard of care; TA, technology appraisal.

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