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Developing and piloting a context-specified ethics framework for health technology assessment: the South African Values and Ethics for Universal Health Coverage approach

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Abstract

Objectives: While ethics has been identified as a core component of health technology assessment (HTA), there are few examples of practical, systematic inclusion of ethics analysis in HTA. Some attribute the scarcity of ethics analysis in HTA to debates about appropriate methodology and the need for ethics frameworks that are relevant to local social values. The "South African Values and Ethics for Universal Health Coverage" (SAVE-UHC) project models an approach that countries can use to develop HTA ethics frameworks that are specific to their national contexts.

Methods: The SAVE-UHC approach consisted of two phases. In Phase I, the research team convened and facilitated a national multistakeholder working group to develop a provisional ethics framework through a collaborative, engagement-driven process. In Phase II, the research team refined the model framework by piloting it through three simulated HTA appraisal committee meetings. Each simulated committee reviewed two case studies of sample health interventions: opioid substitution therapy and either a novel contraceptive implant or seasonal influenza immunization for children under five.

Results: The methodology was fit-for-purpose, resulting in a context-specified ethics framework and producing relevant findings to inform application of the framework for the given HTA context.

Conclusions: The SAVE-UHC approach provides a model for developing, piloting, and refining an ethics framework for health priority-setting that is responsive to national social values. This approach also helps identify key facilitators and challenges for integrating ethics analysis into HTA processes.

Method

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Priority-setting on the path to Universal Health Coverage (UHC) is morally complex with unavoidable trade-offs, especially in resource-constrained settings. Over the past few decades, there has been increasing interest in health technology assessment (HTA) to support national health decision-making in countries pursuing UHC policies (1). HTA has been defined as a process for systematically evaluating the properties, effects, impacts, and overall value of a health intervention in order to inform decision-making in support of an equitable, efficient, and high-quality health system (2). While ethics has long been articulated as central to HTA—alongside clinical effectiveness, safety, costs, and economics—there are still few examples of practical, systematic inclusion of broader ethics analysis in HTA processes (3–7). Lack of consensus about how to conduct ethics analyses, approaches to ethics analysis being ill-suited to those without philosophy backgrounds, and existing frameworks not being adequately specified or responsive to particular social contexts have all been cited as reasons why ethics has lagged behind the other core components of HTA (4;8–11).

South Africa's ongoing process to introduce National Health Insurance (NHI) presented an opportunity to develop a methodological approach for early integration of nationally relevant ethics analysis into priority-setting (12;13). The journey toward NHI over the last decade has focused largely on addressing the inequalities and inefficiencies of the two-tiered, public–private health system. Over 70 percent of South Africans rely on an underfunded public sector

while the wealthy minority are covered by private medical aid schemes that account for more than half of the country's total health expenditure (12). The NHI White Papers and subsequent NHI 2019 Bill state explicitly that NHI should redress structural imbalances in the health system that hinder equal access to quality health services, and commit to establishing a national HTA agency to guide priority-setting for the NHI benefits package (12;13). The White Paper also outlines eight principles underlying NHI: the right to access health care, social solidarity, equity, health as a public good, affordability, efficiency, effectiveness, and appropriateness. Developing and delivering a comprehensive package of health services consistent with these principles requires more explicit guidance on how these principles should be translated in the context of HTA and applied to the assessment of particular health interventions. These expressed commitments by the South African Government to advance specific ethics objectives, beyond economic efficiency, created an opportunity to model how ethics assessment could be operationalized as an integral part of HTA.

The South African Values and Ethics for Universal Health Coverage (SAVE-UHC) Project was designed as a proof-of-concept study of an approach to develop and pilot a context-specified ethics framework for health priority-setting. The project was implemented in South Africa, with the potential to guide other countries in exploring how to integrate systematic and explicit ethics analysis into evolving HTA practices. The approach relies on two assumptions: that an ethics framework developed through active engagement of local stakeholder representatives will enhance its applicability, relevance, and legitimacy; and that broader ethics analysis in HTA contributes substantively to the policy recommendations produced.

The SAVE-UHC project approach had two phases: (i) collaborative and engagement-driven development of a Provisional Ethics Framework to guide coverage decisions under NHI and (ii) piloting of the Provisional Ethics Framework through simulated health technology analyses and appraisals. The primary research objectives of the piloting stage were to inform refinement of the Framework, to assess the perceived value of deliberative ethics appraisal using the Framework, and to provide insights and recommendations regarding its implementation in the context of HTA processes. This paper describes the methodology as applied in South Africa and reflections on how this approach could be adapted.

The methodology

Phase I: Developing the Provisional Context-Specified Ethics Framework

Phase I focused on developing a provisional South African Ethics Framework to guide HTA analysis and appraisal. The Framework was developed by a multistakeholder South African Working Group (WG) purposively recruited to include representatives from national and provincial health departments, other government departments, patient advocacy groups, medical associations, civil society organizations, private insurers, and academic institutions (see Supplement 1). The WG was supported by the research team, with expertise in ethics, public health, and health policy. The framework development process was iterative and consensus-driven, occurring over three meetings (see Figure 1). To support WG activities, the SAVE-UHC research team conducted relevant desk research and development of four brief case studies to assess the applicability and comprehensiveness of the provisional framework using hypothetical health interventions (see Figure 2 and Supplement 4).

Note that framework development concentrated on substantive ethics considerations for evaluating health interventions and did not directly address procedural ethics considerations, such as issues of transparency, participation and representation, and minimizing conflicts of interest. However, the framework should indirectly support these procedural values by establishing a clear set of evaluation criteria, giving the public greater insights into the decision-making process and decision-makers a way to publicly communicate and justify policy positions.

Developing a Menu of Principles and Ethics Considerations

Before the first WG meeting, the research team reviewed several health priority-setting and HTA ethics frameworks (14–21) to develop a worksheet that the WG members could use to identify the candidate's high-level principles and more specific ethics considerations under them for potential inclusion in the SAVE-UHC Framework (see worksheet in Supplement 2). The worksheet begins with the principles laid out in the NHI White Paper, followed by additional principles and considerations from the literature. This handout supported a facilitated exercise in WG Meeting 1: WG members independently reviewed and reflected on potential content for inclusion in the Framework before engaging in a group exercise to identify the most salient ethics considerations for inclusion and whether any principles or specific considerations needed to be added.

After WG Meeting 1, to support a consensus-driven approach and guide later discussions and refinement of the Provisional Framework, the research team surveyed WG members' opinions of the relative importance of the proposed ethical principles and considerations.

Over WG Meetings 1–3, successive iterations of the worksheet supported discussions on the content of the Provisional Ethics Framework. The WG debated several issues including whether and how the Framework should address concepts of "hope" and "rescue" and whether interventions for "extreme circumstances" or those "addressing harms caused by the health system" fit under the scope of HTA for NHI. Discussions also centered on the inclusion of "burden of the health condition," the reframing of "solidarity" to encompass impacts of an intervention on "social cohesion," and the explicit inclusion of "systems factors" as a standalone domain. Recognizing that not all sets of relevant ethics considerations could be conceptualized as principles (e.g., "burden of the health condition" which is an epidemiological concept), the resulting Framework refers to the sets of ethics considerations as "domains."

Reviewing Policy Documents and Judicial Precedent

Development of the Worksheet also included a review of explicit and implicit ethics commitments in the NHI White Paper, with a specific focus on aspects relevant to coverage decisions and priority-setting for the benefits package (see Supplement 3). At a WG member's suggestion, the research team reviewed relevant Constitutional Court cases (22) to ensure that the Framework would cohere with judicial interpretations and precedents related to the constitutional right to health (see Supplement 4).

Brief Cases with Hypothetical Health Interventions

Each of the WG meetings used brief hypothetical case studies to move from discussions of abstract concepts and considerations

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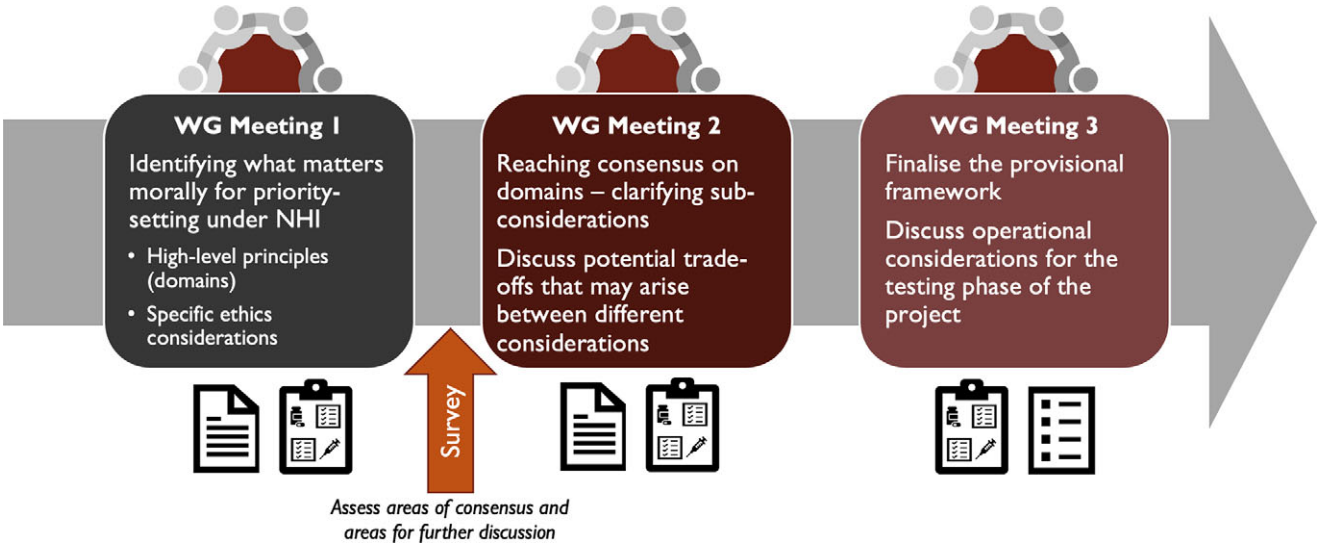


Figure 1. Process to develop the provisional framework across three working group meetings.



Figure 2. Inputs to the development of the provisional ethics framework.

to concrete exercises more akin to an HTA appraisal. This allowed WG members to deliberate the relevance and importance of various Framework domains and surface new considerations as needed using realistic examples. The brief case studies were expanding coverage of the human papillomavirus (HPV) vaccine beyond girls ages nine and ten; introducing rubella-containing vaccines, specifically moving from measles only to measles, mumps, and rubella (MMR) vaccines; covering cochlear implants for children under five with profound hearing loss; and providing laparoscopic sleeve gastrectomy for morbidly obese people living with diabetes. To pressure-test the adequacy of the evolving Framework, case studies were selected to capture both a range of health conditions and associated interventions as well as a range of relevant ethics considerations. The format of these case materials summarized available evidence in sections corresponding to the evolving ethics domains of the Provisional Framework.

Through this collection of activities, the WG finalized the Provisional Ethics Framework (see Figure 3), which was professionally edited for plain language to increase accessibility for all stakeholders and people whose first language is not English. This was then piloted in Phase II.

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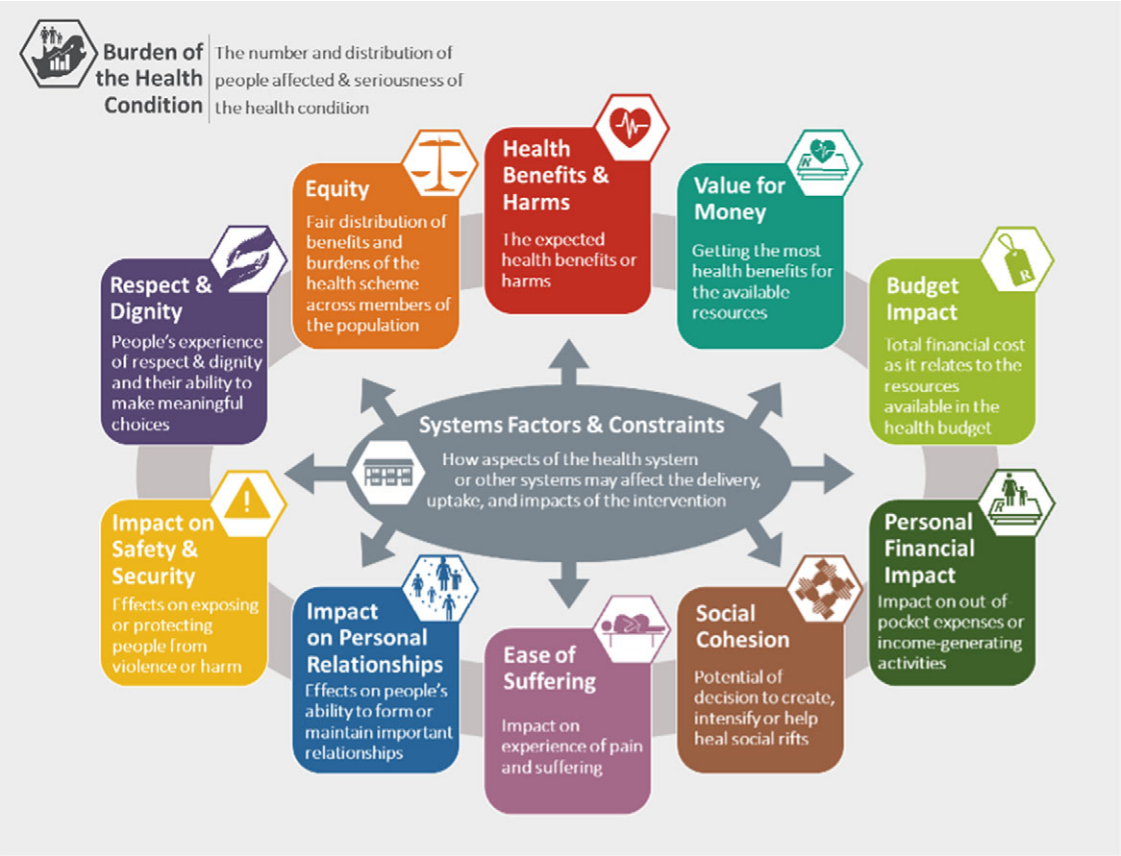


Figure 3. Snapshot of the provisional ethics framework piloted in phase II.

Phase II: Piloting the Framework through Simulated HTA Analysis and Appraisal

In Phase II, "Simulated Appraisal Committees" (SACs) used the Provisional Framework to guide deliberations and recommendations about whether particular health technologies should be covered under NHI. SACs were necessary as there was no national HTA agency nor appraisal committee at the time of the study. SACs were comprised of eight to ten participants, recruited through a purposive sampling strategy to ensure various stakeholder perspectives were included in the committees, including policymakers, civil society representatives, patient groups, public health practitioners, healthcare providers, health economists, and bioethicists. Recruitment also aimed at representation across different gender, race, and age groups. SACs were conducted in three selected provinces to cover different provincial contexts: Gauteng, Western Cape, and KwaZulu-Natal. The study planned to include an SAC in rural Mpumalanga province, as well as an SAC with national policymakers, but these were canceled because of COVID-19 (see Table 1 for participant characteristics).

Before the SAC meetings, the research team prepared detailed case studies on three types of health interventions, synthesizing the relevant and available evidence corresponding to each domain of the Provisional Ethics Framework for each of the proposed health interventions. Cases were selected to include a range of health areas (mental health, family planning, and infectious disease) and health interventions (prevention and treatment). They were opioid substitution therapy, influenza immunization for children under five, and a novel contraceptive implant (see Supplement 5 for an example case write-up). Each SAC was tasked with applying the Provisional Ethics Framework to two case studies with the intention of producing a recommendation. To enable comparative analysis, all SACs used the opioid substitution therapy case as their second case.

The research team again worked with communications experts to edit case study materials for plain language to ensure accessibility to all participants.

Procedures and Data Collection

Demographics and Baseline Data Collection. At the start of each SAC meeting, participants completed a questionnaire collecting information on sociodemographic characteristics (age, gender, stakeholder type, and race as well as self-reported data on familiarity with and perceptions of approaches for health decision-making). Note that the collection of race as a variable was done to facilitate recruitment of SAC members aimed at representation across different racial identities, as well as genders and age groups, in line with SA Department of Health ethics guidance for research.

Introduction and Training Session. Each two-day SAC meeting began with a participatory training session to orient participants to the project, the basics of HTA and cost-effectiveness analysis, the content of the Provisional Ethics Framework, and participants' objectives and roles in the simulated appraisal sessions. After participants engaged in small group discussions to familiarize themselves with the Framework, there was a period for questions and answers with the research team prior to starting the simulations. In addition to clarifying aspects of the approach for participants, this enabled the research team to document any aspects of the Framework or training materials that were unclear, confusing, or otherwise in need of refinement.

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Table 1. Characteristics of Participants in Simulated Appraisal Committees

Participants ($n = 27$)	Number (%)
Geography, by Province	
Gauteng	9 (33%)
KwaZulu-Natal	10 (37%)
Western Cape	8 (30%)
Age	
35 yr and under	6 (22%)
>35 yr	21 (78%)
Gender	
Female	15 (56%)
Male	12 (44%)
Affiliation	
Academic	6 (22%)
Civil society representative	4 (15%)
Health provider	6 (22%)
Patient/Public representative	2 (7%)
Policy maker	5 (19%)
Public health practitioner	1 (4%)
Other	3 (11%)
Self-identified race	
Black African	13 (48%)
Asian/Indian	5 (19%)
White	8 (30%)
Other: Declined to specify	1 (4%)

Case Simulations. Each SAC deliberated on two health interventions over the course of the two-day meetings. Case simulations began with a review of the prepared evidence on the intervention. An independent professional facilitator chaired all the simulated committees. Prior to the SACs, the facilitator engaged with the research team in finalizing the materials, methods of facilitation, and the agenda for each SAC. She ensured that all relevant considerations from the Framework were discussed, and encouraged input from all members of the committee, mitigating concerns that the deliberations could be dominated by just a few voices. At various points in the deliberations, the facilitator gauged whether the group was nearing consensus on the coverage recommendation and invited dissenting opinions to be voiced. At the close of each deliberation, the committee was asked to produce a consensus or majority recommendation along with the rationale for their final position.

Postappraisal Questionnaires. Following appraisal sessions for each case intervention, participants completed a short questionnaire (Supplement 6) to collect individual feedback on their experiences as SAC members as well as their perceptions of the value of using the Ethics Framework for informing policy recommendations for health coverage decisions.

Final Focus Group Discussion. At the end of each SAC meeting, the research team conducted focus group discussions (FGDs) (see Supplement 7) to solicit feedback on the overall approach to deliberative ethics appraisal, the perceived value of the approach, and proposed modifications to the Provisional Framework and research approach, as well as HTA implementation considerations. The FGDs also allowed additional input on the content and format of the Framework and case materials. All FGDs, case discussions, and framework feedback sessions were audio-recorded and professionally transcribed.

Analysis

The research team used thematic content analysis to review transcripts from SAC framework discussions, case appraisals, FGDs, and open-ended questionnaire responses. Analysis included an inductive approach to identify emergent themes as well as a deductive approach structured around the primary research objectives: (i) improving the accessibility and applicability of the Ethics Framework, (ii) assessing the perceived value of deliberative ethics appraisal with the Framework, and (iii) generating recommendations for potential implementation of the Ethics Framework in the South African HTA context. The research team developed a standardized codebook (Supplement 8). To improve intercoder reliability, at least two members of the research team coded each transcript using MaxQDA, with regular discussions among the analysis team to address coding issues as they arose. Coded transcripts were used in the refinement of the Ethics Framework later approved by the SAVE-UHC WG members, and in support of other papers on findings of the pilots. For refinement of the Ethics Framework, the research team reviewed all transcript segments coded by domain and with additional codes related to Framework Content, such as Domain Additions, Clarification, Relationships between Domains, Format and Presentation, Context Specificity, and Number of Domains (see Supplement 8). Based on the inputs from the SACs, the research team reviewed and discussed the findings with the WG through two virtual meetings, proposed suggested edits, and circulated the revised draft for final approval (23). The full findings on the perceived value of the approach and its implications for implementation will be reported in subsequent publications.

Results

Application of this methodology yielded a comprehensive, contextualized ethics framework for HTA in South Africa (23). A centerpiece of the SAVE-UHC approach is intensive engagement with and leadership by relevant stakeholders from across South Africa, including local ethicists, in the development and piloting of the Provisional Ethics Framework. The Ethics Framework that resulted, therefore, reflects broad and diverse perspectives about the morally relevant features of a coverage decision for particular health interventions. In the SACs, variation in group composition, dynamics, and the flow of deliberations enabled a broader range of inputs and views, and helped approximately what we expect a multistakeholder HTA body could look like in South Africa. The deep engagement undertaken throughout this approach will hopefully contribute to perceived legitimacy of HTA decisions using the Framework. This inference is supported by responses in the postappraisal questionnaires, in which SAC participants expressed a high degree of satisfaction with the final recommendations (average = 4.12/5) and a perception that the process supported better or fairer recommendations (average = 4.21/5). Scores on whether the Framework covered the relevant ethics considerations were similarly high.

The SAVE approach involved developing various supplementary materials, including training materials and sample case studies

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for simulated appraisals. The training materials and sessions proved to be an important element of the approach, given the diversity of the SAC participants and different background knowledge on priority-setting and key concepts like cost-effectiveness analysis. Over the course of the three SACs, the research team adapted training materials to provide more detailed information on HTA processes, economic evaluation methods and terms, ethics analysis, and the policy context and development of the provisional framework. While the additional time for training would have been desirable, the team recognized the tradeoff of how further time commitments could negatively impact our ability to purposively recruit a diverse range of participants. Those pursuing future applications of this approach may choose to allocate more or less time to training based on the characteristics of the real or simulated HTA committees and what would be most conducive to the dual aims of participation and sufficient baseline knowledge ahead of appraisals with a provisional framework.

The cases selected for simulated appraisals—opioid substitution therapy, childhood influenza immunization, and contraceptive implant—were generally fit for purpose. These cases were selected because they engaged multiple domains of the provisional framework, with evidence to inform key considerations. So designed, the cases allowed SAC members to have rich discussions applying the framework and navigating tensions and trade-offs between domains. The research team also took the decision to artificially set the incremental cost-effectiveness ratios (ICERs) for simulated case interventions just above the cost-effectiveness threshold. We believe that setting each intervention marginally above what would be considered good "value-for-money" in economic terms facilitated engagement with the broader set of relevant criteria to inform appraisals, as compared to more rapid decisions that may have resulted with interventions that were highly cost-effective or ineffective. Additionally, the decision to have different types of interventions (an infectious disease prevention, mental health treatment, and family planning option) that target different population groups (i.e., children, those with substance use disorder, and women of childbearing potential) facilitated discussions about special populations, stigma, disadvantage, past neglect by the health system, and other salient considerations. We also found using a standardized case across all SACs to be helpful in understanding how different groups applied the framework to the same case to assess consistency in deliberations and outcomes. We would recommend the standardized case be used for the second appraisal, to control for improved familiarity with applying the framework between the first and second case. Additional reflections on the findings from appraisals are forthcoming in subsequent results papers.

The piloting approach utilized a professional facilitator to serve in the role of committee chair for the simulated appraisals. In other settings without standing HTA bodies, this approach is advisable to approximate committee dynamics, improve participation amongst participants, and ensure appraisals proceed to a final decision. Based on the SAVE-UHC pilots, it is advisable to develop a facilitator guide to help further standardize the approach across SAC meetings.

Discussion

Many countries are exploring the establishment of new HTA bodies in support of UHC goals (1;24). There is also growing interest in revisiting best practices for deliberative processes for HTA (25;26). The SAVE-UHC project offers a useful approach for developing and piloting a context-specific ethics framework that is responsive to local norms, social values, and laws. In particular, it demonstrates how existing legal documents and judicial precedents can be leveraged in the development of health priority-setting ethics frameworks, as was done with the White Paper principles and Constitutional Court review. The piloting phase also provides an important opportunity to assess key challenges for operationalizing the integration of ethics into HTA, including the kinds and availability of evidence needed and procedural aspects of deliberative appraisal, which will be discussed in further papers resulting from this study.

Unlike other approaches to specify and adapt existing frameworks to local contexts, such as those applying the EVIDEM framework (27), this approach is more homegrown, as it begins with local values, legal commitments, and judicial precedent. Moreover, framework application does not rely on quantitative approaches to multicriteria decision analysis with standard weights. Instead, the approach is qualitative and deliberative, with a focus on committee discussion, reasoning, and justifications using the framework. In both these ways, the SAVE-UHC methodology is responsive to past criticisms of top-down ethics frameworks and the failure of weights to account for diverse perspectives of different stakeholders about the relative importance of different criteria in different contexts (28;29).

Using case studies that were relevant to the local setting, and that engaged a number of considerations in the provisional ethics framework, facilitated a productive piloting phase. Cases used in future piloting exercises should aim for similar variation regarding intervention type and key populations affected by the health condition. Future applications could also benefit from similar selection criteria for cases that engage multiple domains of the pilot framework, with ICERs that hover around the cost-effectiveness threshold for that setting.

Lastly, this approach may offer added benefits in settings where HTA is not yet standard practice for health priority-setting or where it may not be widely understood by stakeholder groups outside the government. After attending WG or SAC meetings, a number of participants expressed a deepened understanding and appreciation of health priority-setting, HTA processes, and ethics analysis.

Limitations

Because there was not yet a national HTA or priority-setting body in South Africa, the research team relied on simulated rather than actual appraisal committees for pilot testing and had to make several assumptions about their structure and composition. Even with the same professional facilitator across SACs, there are likely ways that the group dynamics and composition in simulations differ from those of standing appraisal committees, given that standing committees have more time to build rapport and have more experience with technology appraisals. Additionally, the ability of the facilitator or committee chair to engage members in discussions about the framework and its application to the cases could influence the findings.

SAC participants had variable familiarity with approaches to health priority-setting and HTA, and only some of these knowledge gaps could be addressed through the introductory and training sessions. In countries that already have standing HTA bodies, it may be possible to limit training needed for pilot testing to narrowly focus on the novel ethics analysis component. The planned SAC with national policymakers had to be canceled. Although some

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provincial SAC participants serve on national committees, we likely did not fully capture the wider expertise and perspectives of national government stakeholders. The research team hopes to partially address this through ongoing engagement during dissemination and policy translation activities.

The case studies used in the simulated appraisals had to rely on existing publicly available evidence. With many domains of the Ethics Framework covering aspects of healthcare and health interventions that have been traditionally under-researched, including various patient-centered outcomes, there were some evidence gaps and reliance on less generalizable data sources, such as small qualitative studies or pilots, patient advocacy materials, or extrapolation from studies conducted in other settings. While these may be limitations of the pilot phase of this approach, particularly deliberations by SACs, we hope that the formal adoption of an ethics framework for HTA will support greater evidence generation standardized across a set of morally relevant features of health technologies as part of the official HTA process. This approach coheres with the recent call for explicit value frameworks to support evidence-informed deliberative processes for HTA (25), aligning the evaluative criteria used in appraisals with the types of data and evidence generated during analysis so that committees have appropriate information to assess the health intervention.

Lastly, the SAVE-UHC approach is resource intensive, relying on the following: volunteered time from WG members and SAC participants to develop and pilot the framework; a dedicated research team to develop case studies, facilitate the process, and analyze data; and financial resources to administer the project and convene WG and SAC meetings. In some country contexts, supplemental funding may be needed to support application of this methodology beyond what the government is able to commit to standard HTA practice. However, groups interested in using this method may find some efficiencies in considering the materials developed by this project (see Supplementary Files).

Conclusion

Health priority-setting and HTA are inherently value-laden with ethically complex features that sometimes require difficult moral trade-offs. Despite wide recognition of ethics issues as central to the assessment of health technologies and resulting coverage decisions, there are few examples of systematic approaches to embed ethics analysis in HTA processes. This proof-of-concept study demonstrates the development and piloting of a context-specified framework that can guide concrete applications of ethics principles, especially those grounded in national policy documents and legal precedents, in HTA processes and deliberations specific to national values and context.

Supplementary Material. The supplementary material for this article can be found at https://doi.org/10.1017/S0266462322000113.

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Conflicts of Interest. The authors declare that they have no conflict of interest.

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