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Healthy Policy Analysis

The Value of Explicit, Deliberative, and Context-Specified Ethics Analysis for Health Technology Assessment: Evidence From a Novel Approach Piloted in South Africa



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ABSTRACT

Objectives: This article explores the perceived value, including associated strengths and challenges, of using a context-specified ethics framework to guide deliberative health technology appraisals.

Methods: The South African Values and Ethics for Universal Health Coverage (SAVE-UHC) approach, piloted in South Africa, consisted of 2 phases: (1) convening a national multistakeholder working group to develop a provisional ethics framework and (2) testing the provisional ethics framework through simulated health technology assessment appraisal committee meetings (SACs). Three SACs each reviewed 2 case studies of sample health interventions using the framework. Participants completed postappraisal questionnaires and engaged in focus group discussions.

Results: The SACs involved 27 participants across 3 provinces. Findings from the postappraisal questionnaires demonstrated general support for the SAVE-UHC approach and content of the framework, high levels of satisfaction with the recommendations produced, and general sentiment that participants were able to actively contribute to appraisals. Qualitative data showed participants perceived using a context-specified ethics framework in deliberative decision making: (1) supported wider consideration of and deliberation about morally relevant features of the health coverage decisions, thereby contributing to quality of appraisals; (2) could improve transparency; and (3) offered benefits to those directly involved in the priority-setting process. Participants also identified some challenges and concerns associated with the approach.

Conclusions: The SAVE-UHC approach presents a novel way to develop and pilot a locally contextualized, explicit ethics framework for health priority setting. This work highlights how the combination of a context-specified ethics framework and structured deliberative appraisals can contribute to the quality of health technology appraisals and transparency of health priority setting.

Keywords: ethics, ethics analysis, health equity, health priority setting.

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Introduction

Health priority setting is a morally complex endeavor, with unavoidable trade-offs. Although the ethics challenges policy makers face regarding healthcare coverage decisions are widely appreciated globally, countries continue to grapple with how best to incorporate ethics considerations in decision-making processes. ¹⁻⁴ In recent years, there has been growing exploration of and experimentation with value frameworks and deliberative processes to guide health priority setting, particularly as part of health technology assessment (HTA) in countries moving toward universal health coverage. ⁵⁻⁹ With this increasing global focus and attention to HTA bodies and processes, there are opportunities to

generate evidence on how different approaches to integrating ethics in HTA can influence the decision-making process and resulting policy recommendations.

Ongoing efforts in South Africa to introduce National Health Insurance, including commitments to set up a national HTA agency, 10,11 provided a policy window for the South African Values and Ethics for Universal Health Coverage (SAVE-UHC) Project [https://save-uhc.org] to conduct research on a novel, engagement-driven approach to develop and pilot a context-specified ethics framework for health priority setting. 12 This article reports the findings of the SAVE-UHC Project on the perceived value, including associated strengths and challenges, of using a context-specified ethics framework to guide deliberative

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health technology appraisals as part of the broader set of health priority-setting activities.

Background: Value of Using an Explicit Ethics Framework to Guide Deliberative Health Priority Setting

In assessing the perceived value of the SAVE-UHC approach, we draw upon the work of other scholars to structure our findings around 3 overarching themes in the literature: (1) the quality of the health technology appraisal (as it pertains to comprehensively accounting for relevant values and trade-offs), (2) contributions to transparency and accountability, and (3) benefits for those directly involved in the deliberative process.

Many scholars have noted that a primary function of an explicit ethics framework is to help ensure that the priority-setting process adequately addresses morally relevant features of health coverage decisions and attends to social values.^{5-7,13-16} An ethics framework increases the likelihood that the process and resulting recommendations take account of criteria that matter deeply to the public or those directly impacted by decisions. HTA practitioners agree that value frameworks—especially when applied through deliberative processes—can enhance quality of HTA.5,6,17 For instance, participants in the 2018 Latin American HTA International Policy Forum agreed that using more comprehensive and inclusive value frameworks could "improve health system effectiveness, efficiency, sustainability, and equity." At the global level, the WHO-INTEGRATE evidence to decision framework 1.0 was developed to reflect broader norms and values, with substantive criteria including "human rights and sociocultural acceptability, health equity, nondiscrimination, societal implications, and feasibility." 17

The literature also addresses how explicit ethics frameworks can support greater transparency and accountability in HTA processes, which in turn can support greater legitimacy of decisions. ^{6,7,13,15,16} Explicit ethics frameworks not only can provide the public with a clear set of decision criteria against which health technologies will be evaluated but they can also help appraisal committees to effectively deliberate and defend their positions as they work toward a final recommendation. ^{6,7,15,16,17} Both of these forms of transparency can support accountability in health decision making. ^{6,15,17} Additionally, Hofmann et al. have discussed the need for greater transparency in how values shape evidence generation, citing the need "to untangle the normative assumptions in the production or presentation of facts and to tease out implicit value judgement in HTA," with ethics frameworks as a means to more transparently address value judgments.

The literature further discusses how participation in deliberative processes may support improved stakeholder engagement and offer benefits to those directly involved. ^{6,7,18-21} Baltussen et al⁷ describe how evidence-informed deliberative processes can improve understanding among stakeholders by sharing diverse perspectives and describing the values supporting their positions. Abelson et al²² emphasize learning opportunities via presentation of balanced facts and information on the health decision under review. Another study in Switzerland simulated health prioritysetting exercises with an adapted version of the Choosing Healthplans All Together tool; when participants were asked what they found most valuable about the exercise, the most common responses were that they had learned something, appreciated hearing the opinions of different people, and understood their own position better.²² Moreover, they valued the opportunity to give their own opinions, consider priority-setting decisions, and influence the process. We build upon these 3 themes in the presentation of our findings.

Methods

The SAVE-UHC approach consisted of 2 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. The working group was 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. Over 18 months, the working group produced the provisional SAVE-UHC ethics framework consisting of 12 domains (see Fig. 1). The methodology for developing the framework and the contents of the domains are detailed elsewhere. 14,23

In phase II, the research team piloted the provisional ethics framework through simulated HTA appraisal committee meetings (SACs). Simulations were necessary as no national HTA agency existed at the time of the study. SACs comprised 8 to 10 participants, recruited through a purposive sampling strategy to ensure various stakeholder perspectives were included: policy makers, civil society, 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 3 provinces to cover different geographical contexts: Gauteng (GT), Western Cape (WC), and KwaZulu-Natal (KZN). The study included 27 participants (Table 1). Ethics approval was granted by the Human Research Ethics Committee of the University of the Witwatersrand (R14/49, ref. no. H1907/11).

Each SAC reviewed 2 case studies of sample health interventions: opioid substitution therapy and either a novel contraceptive implant or seasonal influenza immunization for children younger than 5 years. Cases were selected to include a range of health areas (mental health, family planning, infectious disease) and health interventions (prevention and treatment). Each SAC was tasked with applying the provisional ethics framework to 2 case studies with the intention of producing a coverage recommendation. To enable comparative analysis, all SACs used the opioid substitution therapy case as their second case.

Data collection included an initial questionnaire collecting sociodemographic characteristics (age, gender, stakeholder type, and race) and self-reported data on familiarity with and perceptions of approaches for health decision making; recordings of all appraisal and deliberation sessions; individually completed postappraisal questionnaires after each health technology appraisal; and focus group discussions with each SAC soliciting feedback on the overall approach and its perceived value.¹²

All recordings were transcribed verbatim and the research team analyzed transcripts using thematic content analysis to develop a standardized codebook, with inductive codes emerging from the text and deductive codes related to our primary research questions (see Appendix 1 in Supplemental Materials found at https://doi.org/10.1016/j.vhri.2022.10.003). To improve intercoder reliability, at least 2 team members coded each transcript using MAXQDA (VERBI Software), with regular discussions to address coding issues as they arose. Data analysis of the postappraisal questionnaires included statistical analysis of Likert scale statements and qualitative analysis of open-ended responses.

Results

The findings from the postappraisal questionnaires demonstrated general support for the SAVE-UHC approach and content of the framework, high levels of satisfaction with the

Figure 1. Snapshot of the SAVE-UHC ethics framework.



SAVE-UHC indicates South African Values and Ethics for Universal Health Coverage.

recommendations produced, and general sentiment that participants were able to actively contribute to the appraisals (see Table 2).

Through the analysis of the qualitative transcripts and postappraisal questionnaires, several themes emerged that were consistent with discussions in the literature regarding perceived or actual value of using an explicit ethics framework to guide deliberative health priority setting, as well as a set of challenges associated with the approach.

Influences on the Quality of the HTA Appraisal and Recommendation

A consistent theme across all 3 SACs was the sentiment that the framework supported wider consideration of and deliberation about morally relevant features of the health coverage decisions, particularly those that would otherwise be overlooked in decision making.

...having served on a body that's making similar decisions ..., I think this forces one to look at a broader range of issues. We've always been focused very much on benefits and harms, with maybe some attention to equity... A number of your elements we have never raised. And bringing that ethical side into the debate I think is very useful.— KZN_FGD

I think having the twelve points was helpful ... I think the first point, cost effectiveness and burden of diseases, that's not enough ... the other

points enabled us to have a, to pause and look at those issues and consider them...—WC_FGD

In the postappraisal questionnaires in GT after the assessment of flu vaccination for children under 5, participants expressed how the framework enhanced deliberation:

The approach impacted positively on the deliberation because it guided our thinking and critical engagement on the topic both ethically and realistically.—GT-203242_PAQ.Flu

Our deliberations were richer and broader which was good – spurred on by the use of the framework.—GT-769510_PAQ.Flu

Additionally, because the framework was developed specifically for the South African context, many felt it helped address the specific nature of the health condition and how implementation of a health intervention could play out within this national setting, both in the assessment of particular domains and in deliberations:

... this [domain of "Safety & Security"] was developed given the context where there are a lot of violent encounters and unsafe situations, so that it doesn't get lost amongst many other harms. Because that is often a major contextual issue in our setting.—WC_Framework Feedback

Some participants discussed how a context-specified ethics framework like this could enable a priority-setting process that better addresses local priorities, even as global initiatives might be driving adoption of interventions that may or may not align with countries' current priorities or capabilities:

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Table 1. Characteristics of participants in simulated appraisal committees.

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

...a lot of our decisions are based on international agreements or international recommendations, WHO, ILO, whatever, ... everything ratified, everything we accept, but this allows us to take that recommendation within our context and say, yes, it is a good global recommendation...but, within our context and having considered this, this, this, this, and this, not now, or... not at this time. So, yes, we are taking our lead from international leaders and those organisations. but this allows us with evidence to be able to say WHO or ILO, not yet.—GT_FGD

Contributions to Transparency and Accountability

In addition to supporting broader considerations, wider perspectives, and context-specified considerations in the priority-setting process, a number of participants also expressed their views on how an explicit ethics framework could contribute to transparency and accountability. This theme was particularly salient in the focus group discussion of the GT SAC:

...it also introduces transparency in terms of how priorities are actually done, but it really, really begins to say let us consider all these particular things and arrive at a decision—GT_FGD

I think it reduces on the gates of political interference, it is one way of doing so which is really good and I think it also ties to the mainstream factors that would not ordinarily be considered when decisions are being made—GT_FGD

These quotes illustrate how this process can support transparency through clear explication of the value-based decision criteria and justifications based how a health intervention performs across them. Participants at the other 2 SACs similarly noted that this process could "improve transparency" and ensure more than "personal opinions" inform decisions. One participant also discussed how this process could facilitate broader engagement and accountability to stakeholders by proactively addressing concerns that may otherwise only factor in later when civil society groups challenge a decision.

Because we would make these decisions without considering some of the ethical issues raised in the domains and it would then become the voices of civil society that then begin to say, 'but what about this? But what about this? But what about this? But because those voices often come after the decision has been made, we are almost on a collision course. It becomes them against us, you understand. And it creates a problem. So, I think this is a good thing... as long as we get the right people.—KZN_FGD

Although these were raised as positive contributions of the approach, including for perceived legitimacy and acceptance of HTA recommendations, the caveat about having "the right people" and adequate representation and participation was a common theme raised in all SACs and is presented below and will be further detailed in a forthcoming publication.

Perceived Benefits for Those Directly Involved in Deliberative Ethics Analysis

Many participants expressed appreciation for the opportunity to be involved in the simulated appraisals. These included statements that they had learned through the process, about the health issues at hand, the priority-setting process, and differing viewpoints.

 \dots I like the fact that all of us had an opinion and voice on the different things.—KZN_FGD

...I think it helped to see how priority setting and costing can be considered on an equal footing as other things, and that was very useful.—GT_FGD

It was a really valuable experience of the potential difficulties and technicalities regarding coming to a consensus on a recommendation as a committee.

-WC-792058_PAQ.OST

There were also several instances of peer-to-peer learning where members of the SACs provided detailed explanations of health interventions or conditions they were more familiar with, shared insights about the logistics of implementation, or gave analogous examples of how situations had played out with other related health interventions. For instance, one participant discussing expansion of flu vaccine coverage explained the concept of herd immunity and how, even if wealthier children disproportionately receive the vaccine, it could improve equity by keeping immunization levels sufficiently high to protect everyone. In that same discussion, another member shared how the timing of vaccine procurement would be critical to assess expected benefit, given the seasonality of flu, given that there had been instances in the past where vaccine supplies came too late to realize their anticipated benefit. There were multiple other instances across all 3 SACs of participants drawing comparisons with other types of familiar diseases or interventions to help convey their point or provoke thoughts among the group.

Participants expressed how they felt their involvement opened their minds to broader viewpoints and, in some instances, led them to change their position:

It's quite heartening actually that I didn't come [out] with my preconceived ideas about what was going to be great and what wasn't going to be good, that it did shift, which was through discussions and through persuasion...—WC_FGD

Challenges in Applying the Approach

Although participants highlighted many positive features of the approach, they also identified various challenges and concerns. These included challenges related to evidence gaps, difficulty in

Table 2. Responses to the postappraisal questionnaires.

(1 = strongly disagree; 5 = strongly agree)	Mean	Median	
I am satisfied with the final recommendation generated by the appraisal committee.			
Gauteng (n = 9) Childhood flu vaccination Opioid substitution therapy* (n = 7)	3.78 4.57	4 5	
Western Cape (n = 8) Contraceptive implant Opioid substitution therapy	4 4.13	4 4.5	
KwaZulu-Natal (n = 10) Contraceptive implant Opioid substitution therapy	4 4.3	4 4	
All sites			
Opioid substitution therapy (n = 25)	4.32	4	
All responses (N = 52)	4.12	4	
The process resulted in a better and or fa	irer recom	mendation.	
Gauteng (n = 9) Childhood flu vaccination Opioid substitution therapy* (n = 7)	4.44 4.43	4 4	
Western Cape (n = 8) Contraceptive implant Opioid substitution therapy	3.13 4.13	4 4	
KwaZulu-Natal (n = 10) Contraceptive implant Opioid substitution therapy	4.5 4.5	5 4.5	
All sites			
Opioid substitution therapy (n = 25)	4.36	4	
All responses (N = 52)	4.21	4	
The SAVE-UHC framework covered the r	elevant etl	nical issues.	
Gauteng (n = 9) Childhood flu vaccination Opioid substitution therapy* (n = 7)	4.22 4.29	4	
Western Cape (n = 8) Contraceptive implant* (n = 7) Opioid substitution therapy	4.00 4.13	4 4	
KwaZulu-Natal (n = 10) Contraceptive implant Opioid substitution therapy	4.6 4.5	5 4.5	
All sites			
Opioid substitution therapy (n = 25)	4.32	4	
All responses (N = 51)	4.31	4	
I was able to contribute to discussions I recommendation and felt heard.	eading to t	the	
Gauteng (n = 9) Childhood flu vaccination Opioid substitution therapy* (n = 7)	4.78 4.71	5 5	
Western Cape (n = 8) Contraceptive implant Opioid substitution therapy	3.88 4.13	4 5	
KwaZulu-Natal (n = 10) Contraceptive implant Opioid substitution therapy	4.9 4.7	5 5	
	continued	l on next page	

Table 2. Continued

(1 = strongly disagree; 5 = strongly agree)	Mean	Median
All sites		
Opioid substitution therapy (n = 25)	4.52	5
All responses (N = 52)	4.54	5
CAVELILIC indicator Courth African Values and	Ethics for I	Iniversal Health

SAVE-UHC indicates South African Values and Ethics for Universal Health Coverage.

applying a greater number of considerations, and concerns about how stakeholder representation and participation could sway deliberations. These findings are described below, with further detail to be presented in a forthcoming complementary article on implementation considerations for HTA in South Africa.

Sufficient and appropriate evidence

A highly salient theme among participant discussions was the need for evidence and how an expanded set of domains increases the demand for different types of information that may not always be readily available. Others noted that information on certain domains or subconsiderations may be difficult to quantify, including impacts on Social Solidarity and Cohesion or Respect and Dignity.²⁴ One participant discussed how certain domains may require different kinds of evidence, including the role of different qualitative data and inputs from patients and providers. Another participant worried that a lack of evidence on certain domains could allow deliberations to be unduly swayed by theoretical considerations, even when there might be good evidentiary support for a different decision:

...there is the risk that the elements for which there is the least evidence and most subjectivity could become dominant and you forget about the bits which you've actually got very good evidence about, and that's still the challenge to the decision-making process—KZN_FGD

The final recommendation from one of the opioid substitution therapy deliberations centered on improving evidence through tailored pilot studies that address key questions and evidence gaps for the relevant domains. Multiple comments during the KZN deliberation on the contraceptive implant noted that a decision to introduce an intervention does not preclude further research to examine questions about its use and impacts:

You also have opportunities for programmatic Pharmacovigilance so you can say in a number of sites in the country we will have enhanced data collection ... taking from programmatic data and reading more information and being able to reflect on it.—KZN Contraceptive Implant Deliberation

One participant noted how the need for evidence underscored the importance of a well-resourced HTA body that enable evidence-informed decision making, particularly with multiple domains to consider:

I think what we've seen these two days is how complex and how difficult it is to make decisions of this nature..., so what I think which is very, very important is one needs a proper institution that does this type of work that can provide the type of evidence that you require.— WC_FGD

^{*}Indicates some responses missing, with adjusted sample size.

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Cognitive load: applying and balancing multiple considerations

Many participants commented that the comprehensiveness of the framework added to the complexity of the decision-making process, with the committee having to assess and balance the importance of varying considerations.

I think having the twelve points was helpful \dots [but] twelve is a lot, and weighing therefore becomes an issue \dots -WC_FGD

The downside to that, however, is that in some aspects it kind of encourages a fragmented thinking about the issue and so sometimes one gets too caught up in sort of the specific domains rather than looking at the bigger picture, which I think it sometimes complicates reaching the decision.—KZN_FGD

Conversely, 2 participants in KZN SACs noted how the broad framework helped structure thinking on a complex decision with various considerations, with one saying:

For me what is good about it is that it allowed me, in the process of thinking you know, slicing an issue into smaller portions to allow me to explore each domain, taking it individually...It's helping me.—KZN_FGD

Participation and stakeholder engagement

Across all 3 SACs, participants raised questions about how to ensure appropriate inclusion of different stakeholder perspectives in consideration of the domains and deliberations. Comments included how to ensure that evidence presented to an appraisal committee would be accessible to all those involved as well as other ways to mitigate various power dynamics that may shape the deliberative process.

So the one part that I worry about is participation ... where is the voice of the community, where is the voice of the patient... and also even in the room, if you are a community health worker, how well you'd be able to engage with this material and first of all feel confident enough to give your views...—WC_FGD

It is about who is in that meeting. how strong your voice are and how well you can argue, ... in another committee where the cost was this high for such an intervention, another person could have been very strong to say, no, you know, and we might have all been swayed.— GT_FGD

Discussion

These findings suggest that the SAVE-UHC approach, which produces a context-specified ethics framework for deliberative HTA, can contribute to various dimensions of improved health priority setting on both substantive and procedural grounds.

The piloting demonstrated how a context-specified ethics framework could support broader consideration of morally relevant features of health interventions. Participants described how the framework expanded or challenged their thinking on specific interventions, in some cases leading them to change their position. They noted how the domains addressed issues that were particularly important in the South African setting. After each appraisal, participants gave high ratings when asked if the framework covered the relevant ethical issues.

The SACs also showed how structuring deliberative HTA appraisals around a context-specified framework could pave the way for public reasoning and justification. In theory, more explicit communication about HTA decision making should enhance the legitimacy of an HTA body with potential impacts on acceptability of its recommendations. Many participants said that, in their

experience, it was often unclear how health decisions were made, and a process like this could support greater transparency about the decision criteria used and rationales supporting the final positions. Our findings add to the literature suggesting that a framework drawing upon local social values—applied systematically to synthesize evidence, guide deliberations, and communicate back to the public—would support HTA that coheres with core elements of procedurally just decision making.^{24,25}

Participants reported high satisfaction with the recommendations reached through the use of the framework in deliberative appraisals, with 45 of 52 responses "agreeing" or "strongly agreeing" that they were satisfied with the final recommendation. The average satisfaction scores increased across all sites between the first intervention appraisal and the second. Although our data analysis was not powered for statistical significance, it suggests that familiarity with using the framework may have a positive effect on satisfaction and that adoption and use by a standing HTA committee or appraisal body would support enhanced comfort with the approach, potentially increasing satisfaction with positions reached over time.

Additionally, self-reported benefits for the participants themselves, such as greater appreciation of the priority-setting process and peer learning among a diverse group of participants, suggest at least 2 ways in which the SAVE-UHC approach could be leveraged in support of strengthening HTA. First, it offers insights regarding the ideal composition of an HTA body, with members comprising a diverse range of stakeholders with differing perspectives and experiences.²⁴ Second, across other settings exploring the establishment of HTA, the SAVE-UHC model could inform development of an ethics framework while simultaneously building understanding around HTA processes, ethics, and evidence-informed decision making for health.

Some of the challenges in applying the SAVE-UHC approach, such as having adequate evidence and finding appropriate ways to engage stakeholders, are longstanding issues in HTA that are not exclusive to incorporating an explicit ethics framework. At the same time, these findings showcase how a clearly defined ethics framework can encourage generation of evidence on issues that are important to coverage decisions but are frequently overlooked, both at initial appraisals and with further data collection after implementation. Appropriate stakeholder engagement throughout the HTA process could also contribute meaningfully to the assessment of certain domains, particularly those that may be more difficult to quantify.

Limitations

Because there was no national HTA body, we relied on simulations to generate evidence around the deliberative application of ethics framework. This limited our ability to assess impacts of the approach on actual health coverage decisions by a standing HTA body. Using a simulated HTA committees also required upfront training on core HTA concepts to establish baseline understanding critical to deliberation, which constrained time for training on the ethics framework itself. Although we initially planned to collect data from 2 additional sites, one in a rural province and another with national policy makers, we were unable to complete these SACs because of the COVID-19 pandemic. Nevertheless, this limitation was partially mitigated by having some participants in the working group and SACs who sit on national level committees and some from a rural health advocacy organization to offer insights. Finally, although the postappraisal questionnaires offer some quantitative insights on sentiments toward the framework and the process and outcomes of deliberations, they were not designed to produce findings of statistical significance.

Conclusion

Priority setting for health is inherently value laden, with complex ethics questions arising as policy makers decide which health interventions will or will not be included in health plans. As many countries move to implement or strengthen HTA, failure to explicitly attend to the wider range of morally relevant considerations can undermine efforts to enhance evidence-informed decision making and fulfill the broader aims of universal health coverage. The SAVE-UHC approach presents a novel way to develop and pilot a locally contextualized, explicit ethics framework for HTA, as one piece of broader health priority setting. To the best of our knowledge, this is the first time in South Africa that an ethics framework has been codeveloped with stakeholders and piloted through simulated HTA appraisal exercises and one of the few examples in the HTA literature of an approach for structured deliberation that explicitly incorporates ethics considerations and moral reasoning.⁴ Moreover, this work highlights how the combination of a context-specified ethics framework and structured deliberative appraisals can contribute to the quality of health technology appraisals and transparency of health priority setting.

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REFERENCES

- Assasi N, Schwartz L, Tarride JE, O'Reilly D, Goeree R. Barriers and facilitators influencing ethical evaluation in health technology assessment. Int J Technol Assess Health Care. 2015;31(3):113.
- Hofmann B, Lysdahl KB, Droste S. Evaluation of ethical aspects in health technology assessment: more methods than applications? Expert Rev Pharmacoecon Outcomes Res. 2015;15(1):5–7.
- Legault GA, Béland JP, Parent M, et al. Ethical evaluation in health technology assessment: a challenge for applied philosophy. Open J Philos. 2019;9(3):331–351.
- Legault GA, Gagnon H, Parent M, et al. Integration of ethical considerations into HTA reports: an analysis of integration levels using a systematic review. Int J Technol Assess Health Care. 2021;37(1):e61.
- Oortwijn W, Sampietro-Colom L, Habens F. Developments in value frameworks to inform the allocation of healthcare resources. *Int J Technol Assess Health Care*. 2017;33(2):323–329.
- Pichon-Riviere A, Garcia-Marti S, Oortwijn W, Augustovski F, Sampietro-Colom L. Defining the value of health technologies in Latin America: developments in value frameworks to inform the allocation of healthcare resources. Int J Technol Assess Health Care. 2019;35(1):64–68.
- Baltussen R, Jansen MPM, Bijlmakers L, et al. Value assessment frameworks for HTA agencies: the organization of evidence-informed deliberative processes. Value Health. 2017;20(2):256–260.
- Gopinathan U, Ottersen T, Cyr PR, Chalkidou K. Evidence-informed deliberative processes for HTA around the globe: exploring the next frontiers of HTA and best practices; Comment on "Use of Evidence-informed Deliberative Processes by Health Technology Assessment Agencies Around the Globe". Int J Health Policy Manag. 2021;10(4):232.
- MacQuilkan K, Baker P, Downey L, et al. Strengthening health technology assessment systems in the global south: a comparative analysis of the HTA journeys of China, India and South Africa. Glob Health Action. 2018;11(1): 1527556
- National Health Insurance for South Africa. Towards Universal Health Coverage (The White Paper). Republic of South Africa National Department of Health. https://serve.mg.co.za/content/documents/2017/06/29/whitepaper-nhi-2017compressed.pdf. Accessed June 16, 2021.
- National Health Insurance Bill. Government Gazette, Republic of South Africa. https://www.gov.za/sites/default/files/gcis_document/201908/national-health-insurance-bill-b-11-2019.pdf; 2019. Accessed June 16, 2021.
- Krubiner CB, Barsdorf NW, Goldstein SJ, et al. Developing and Piloting a Context-Specified Ethics Framework for Health Technology Assessment: The South African Values and Ethics for Universal Health Coverage (SAVE-UHC) Approach. Int J Technol Assess Health Care. 2022;38(1):e26.
- Baltussen R, Marsh K, Thokala P, et al. Multicriteria decision analysis to support health technology assessment agencies: benefits, limitations, and the way forward. Value Health. 2019;22(11):1283–1288.

- 14. Krubiner C, Faden R. A Matter of Morality: Embedding Ethics and Equity in the Health Benefits Policy. In: Glassman A, Giedion U, Smith PC, eds. What's In, What's Out: Designing Benefits for Universal Health Coverage. Center for Global Development. Washington DC: Center for Global Development; 2017:290–326. https://www.cgdev.org/publication/whats-in-whats-outdesigning-benefits-universal-health-coverage. Accessed November 10, 2022.
- Hofmann B, Bond K, Sandman L. Evaluating facts and facting evaluations: on the fact-value relationship in HTA. J Eval Clin Pract. 2018;24(5):957–965.
- Bond K, Stiffell R, Ollendorf DA. Principles for deliberative processes in health technology assessment [published online ahead of print August 4, 2020]. Int J Technol Assess Health Care. https://doi.org/10.1017/S026646232 0000550.
- 17. Rehfuess EA, Stratil JM, Scheel IB, Portela A, Norris SL, Baltussen R. The WHO-INTEGRATE evidence to decision framework version 1.0: integrating WHO norms and values and a complexity perspective. *BMJ Glob Health*. 2019;4(suppl 1):e000844.
- Blacksher E, Diebel A, Forest PG, Goold SD, Abelson J. What is public deliberation? Hastings Cent Rep. 2012;42(2):14–17.
- Denburg AE, Ungar WJ, Chen S, Hurley J, Abelson J. Does moral reasoning influence public values for health care priority setting?: A population-based randomized stated preference survey. Health Policy (New York). 2020;124(6):647–658.

- Jansen M, Baltussen R, Bijlmakers L, Tummers M. The Dutch Citizen Forum on Public Reimbursement of Healthcare: a qualitative analysis of opinion change. Int J Heal Policy Manag. 2020;11(2):118–127.
- Schindler M, Danis M, Goold SD, Hurst SA. Solidarity and cost management: Swiss citizens' reasons for priorities regarding health insurance coverage. Heal Expect. 2018;21(5):858–869.
- Abelson J, Blacksher EA, Li KK, Boesveld SE, Goold SD. Public deliberation in health policy and bioethics: mapping an emerging, interdisciplinary field. J Public Deliberation. 2013;9(1). art5.
- Blaauw D, Chambers C, Chirwa T, et al. The SAVE-UHC Working Group & Research Team. Introducing an ethics framework for health priority setting in South Africa on the path to universal health coverage. S Afr Med J. 2022;112(3):68–71.
- **24.** Daniels N. Accountability for reasonableness: establishing a fair process for priority setting is easier than agreeing on principles. *BMJ*. 2000;321(7272): 1300–1301.
- DiStefano MJ, Abdool Karim S, Krubiner CB. Integrating health technology assessment and the right to health: a qualitative content analysis of procedural values in South African judicial decisions. Health Policy Plan. 2022;37(5):644–654.
- Teerawattananon Y, Painter C, Dabak S, et al. Avoiding health technology assessment: a global survey of reasons for not using health technology assessment in decision making. Cost Eff Resour Alloc. 2021;19(1):1–8.