South African Values & Ethics for Universal Health Coverage

An ethics framework for health priority-setting

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

This Framework

This framework was developed as part of the project: ***South African Values and Ethics for Universal Health Coverage: Ethics for priority-setting on the path to National Health Insurance***

Working Group

The ethics framework was developed by a multi-stakeholder working group across five meetings. SAVE-UHC Working Group members included, in alphabetical order:

Duane Blaauw, Cassey Chambers, Tobias Chirwa, Nonhlanhla Duba, Liz Gwyther, Mark Heywood, Karen Hofman, Leslie London, Thulani Masilela, Neil McKerrow*, Olurotimi Modupe, Lynn Moeng, Victoria Mubaiwa, Noluthando Nematswerani, Yuri Ramkissoon, Yusuf Saloojee*, Sibongile Tshabalala, Krish Valabhjee, Marije Versteeg-Mojanaga.*

*Served as Chair for at least one working group meeting

Partner institutions

The research supporting the development of this Framework was done by the SAVE-UHC Research Team:

SAMRC/WITS Centre for Health Economics and Decision Science
PRICELESS SA
Karen Hofman*
Aviva Tugendhaft
Sue Goldstein
Atiya Mosam
Ravikanthi Rapiti (former)

Stellenbosch University
Nicola Barsdorf*
Debbie Marais
Cynthia Ngwalo
Sunita Potgeiter

Center for Global Development
Carleigh Krubiner*

Johns Hopkins Berman Institute of Bioethics
Ruth Faden*
Maria Merritt
Michael DiStefano

Imperial College London
Kalipso Chalkidou* (former)
Ryan Li (former)

*Principal Investigators

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Introduction to the South African Values and Ethics (SAVE) for UHC Framework

Background

South Africa's population has multiple diverse health needs. As the government works toward progressive realisation of the Constitutional right to health care and the promises of Universal Health Coverage (UHC), there will be challenging decisions about what health services and health interventions will or will not be covered with a limited budget. As part of ongoing discussions about a National Health Insurance (NHI) scheme, there is a commitment to establishing a health priority-setting process to navigate tough choices about which health services, products, and programmes to publicly funded.

Priority-setting for health raises many ethics questions about how to use scarce resources. Decision-makers must balance the needs of individuals with the broader health needs of the population, while also taking into account equity considerations and the many ways that health interventions impact other aspects of wellbeing.

An ethics framework can help navigate these challenging decisions and tradeoffs, providing a method and structure for exploring morally relevant ethics considerations associated with a decision. When used in the context of health priority-setting it can help ensure that, for every proposed health intervention, consideration is given to:

- Identifying and evaluating relevant social values;
- Acknowledging, discussing, and explaining any trade-offs when a decision involves promoting one social value at the expense of another;
- Transparently explaining and justifying recommendations to the public.

The South African Values and Ethics for Universal Health Coverage (SAVE-UHC) Project developed this Ethics Framework to identify the specific domains and considerations that reflect South Africa's core values for health priority-setting. The framework was shaped by a collaborative, multi-stakeholder South African Working Group of policymakers, civil society and patient group representatives, academics, providers, and payers, drawing upon various sources of literature, policy documents, and the collective experience and perspectives of the Working Group members. [See Appendix A for more details]

The SAVE-UHC Ethics Framework was developed with a specific priority-setting process in mind called "Health Technology Assessment" or HTA [see Appendix B]. HTA is an increasingly popular approach for guiding policy decisions about whether a specific health intervention should be added or subtracted from a health benefits package. It relies on a transparent process in which:

(1) a specific health intervention is identified for consideration;

(2) relevant evidence is compiled about that intervention; and

(3) an appraisal committee reviews and discusses the evidence to systematically evaluate the anticipated properties and expected impacts of the intervention before issuing a policy recommendation.

The Framework was designed to apply after a health intervention is proposed for inclusion or prioritisation and selected for review. It lays out a set of morally relevant considerations to inform the types of evidence that are gathered and guide discussions and deliberations during the appraisal. In line with good practices for evidence-informed decision-making, those using the framework should search for the best available evidence for each domain, assessing the rigour, quality, and relevance of the data to the South African setting, while recognizing that there may be limited or different types of evidence for different kinds of morally relevant considerations.

Although the SAVE-UHC Ethics Framework was designed with HTA in mind, it is likely to be useful for many other kinds of health priority-setting activities. It can be used to help decisionmakers assess investments in health interventions in light of South Africa's core values and ethics, and in line with the principles laid out in the 2017 NHI White Paper.

While this framework can be helpful in supporting ethical and evidence-informed decisions about what types of health interventions should be publicly funded, **it is not intended to do everything.** Evaluating a particular health intervention against the domains raised in the framework is only one part of the larger health priority-setting process. There are many other decisions regarding the design and financing of any public health programme that this framework does not address.

The SAVE-UHC Framework answers the question:

"Once a health intervention is proposed for inclusion under NHI or another health programme, how should it be assessed?"

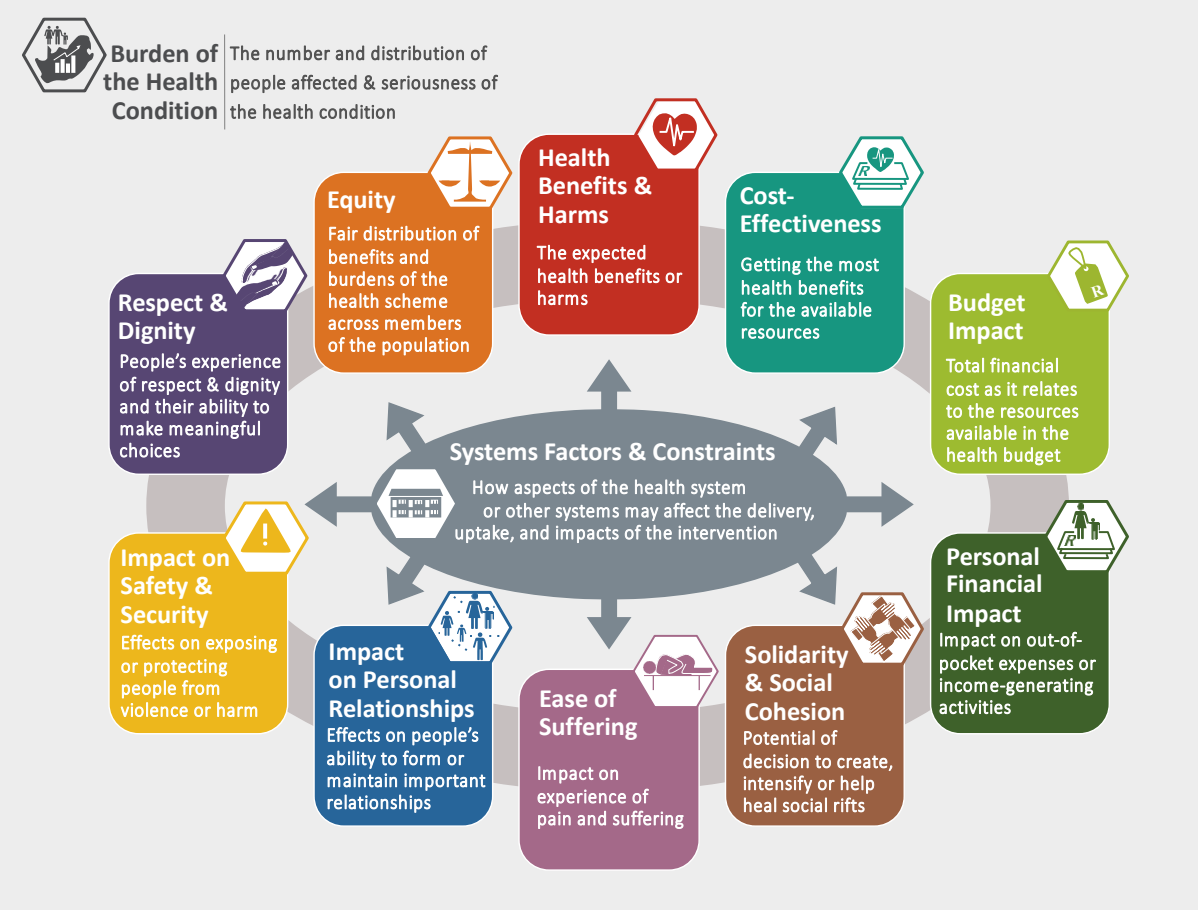
This framework focuses on the substantive ethical considerations that should be taken into account when evaluating health interventions. It does not directly address ethical considerations in the decision making process, including issues of **transparency, participation and representation, and minimising conflicts of interest.** The framework supports these procedural values by establishing a clear set of evaluation criteria, giving the public greater insights into what is taken into account in decision-making and giving decision-makers a way to publicly communicate and justify policy positions.

Orientation to the ethics framework

The SAVE-UHC Ethics Framework has 12 domains that should be considered when assessing whether a particular health intervention should be included under a government-run health scheme. Figure 1 below provides a snapshot of these 12 domains.

In the pages that follow, we present more details on the 12 domains and the specific considerations to inform analysis, deliberations, and decision-making about health interventions in a health priority-setting process.

Figure 1: SAVE-UHC Ethics Framework Snapshot



As indicated in the figure, two of the domains in the Framework operate somewhat differently from the other 10, and those are presented first. **Systems Factors & Constraints**, in the centre of the diagram, shows that context-specific features of the health system and broader infrastructure can have cross-cutting implications for how the delivery of the health intervention may play out — decisionmakers should think about this real-world context when assessing the other domains. Because this domain is cross-cutting, affecting considerations under other domains, the general considerations are laid out first, then more specific "Systems Factors & Constraints" considerations are identified throughout the Framework under each domain using this icon:

The **Burden of the Health Condition** provides the backdrop for deliberating about any health intervention. This domain addresses how serious the health condition is, with details about how many and who within the population is affected, setting the scene for how the proposed health intervention may help address that burden.

Following this, we then present the domains that are most commonly used in a health priority-setting or HTA process: **Health Benefits & Harms**, **Cost-Effectiveness**, and **Budget Impact.** These are followed by the expanded set of domains and morally relevant considerations identified specifically for the South African Values and Ethics Framework: **Equity, Respect and Dignity, Impacts on Personal Financial Situation, Impacts on Personal Relationships, Ease of Suffering, Impacts on Safety and Security, Impacts on Solidarity & Social Cohesion** (see Figure 1).

The SAVE-UHC Ethics Framework does not assign specific importance or weighted scoring to any particular domain. That is because one domain may be really important when assessing a certain type of health intervention, and much less important when looking at a different type of intervention. For example, a new type of contraceptive may raise important ethical considerations that relate to promoting **Respect & Dignity**—including women's reproductive rights and personal choices around pregnancy intention—as well as **Impacts on Personal Relationships**. These domains and related considerations may feature much more centrally in decisions about adopting new family planning interventions, while other types of health interventions may not raise serious issues around meaningful personal choices and effects on families.

Additionally, while most domains will apply to most health interventions, there are some cases where a domain may not be relevant at all. For instance, **Ease of Suffering** may only apply to interventions such as palliative (pain) care, end-of-life care, or in cases where two treatments have similar effectiveness, but a newer one involves a much less painful or unpleasant experience for patients. In these cases, relief of suffering may be a central feature of the intervention. In other cases, however, there may be no special considerations related to **Ease of Suffering** that go beyond what is already reflected directly under **Health Benefits & Harms.**

Rather than assign specific weights or scores to the domains, and acknowledging that not all domains will always be relevant, the SAVE-UHC Ethics Framework is meant to guide deliberative decision-making so that the relevance and significance of particular domains and their considerations can be discussed in the context of a coverage decision. These relevant and significant considerations should be clearly communicated to the public support transparency about how the framework is applied.

Domains of the SAVE-UHC Ethics Framework

Systems factors and constraints

The delivery and uptake of any health intervention will be influenced by a range of systems factors.

Systems factors can include how well the health system is set up to deliver the intervention to the people who need it. Examples of health system facilitators and constraints include having appropriate facilities, healthcare worker capacity and availability, medical equipment, and supplies.

There are other systems factors beyond the health sector that can affect delivery, quality, and uptake of health interventions. These include access to electricity, inadequate or unreliable internet connectivity, access to clean water, transportation and road infrastructure.

While systems factors and constraints may never be perfect for the introduction of a new health intervention, taking stock of them can help shape the overall assessment of expected benefits and harms of an intervention and who experiences them. It can also enable appropriate investments or complementary services that may be needed to support implementation.

When assessing each domain:

- Consider what the health system's existing capacity is, and whether it would be able to deliver the health intervention at a high enough quality and coverage to achieve its intended benefits. This includes:
    - » Do facilities have what they need to provide the intervention, such as trained staff, guidelines, equipment/supplies, diagnostic capacity, medicines and commodities?
    - » Are there enough health workers with the right skills and training to deliver the health intervention?
- Identify and take into account the ways other systems factors and infrastructure may affect how well we can deliver the health intervention.
    - » For example, a medical intervention may rely on access to electricity, clean water, or other telecommunications services. Yet there may not be reliable access to electricity, water supply, or phone/internet services in many parts of the country that are most in need.
- When there are constraints, identify what additional investments are needed to enable adequate implementation.
    - » If additional investments are needed, assess how much they would cost and whether it is possible to get the additional investment. The answer to this might shift whether the intervention is considered cost-effective and what the total budget impact would be.

Burden of the health condition for the country

We use information about the burden of the health condition to think through the size and nature of the health condition the health intervention addresses. This information outlines the need for the health intervention, and whether a decision to adopt it would be in line with broader government priorities for health.

When considering the burden of the health condition, consider the following:

How serious is the health condition for the country?

- How many people are affected by the health condition?
- Which group, or groups, of people are most affected by the health condition? What are their demographics, including data about:
  - » Differences by age or sex
  - » Geographic differences by region or urban vs. rural setting
  - » Differences by socio-economic status (e.g., income or education level)

*Evidence about which groups are most affected by the health condition will inform aspects related to **Equity** (see p. 13)*

How severe is the health condition for the people who are affected by it? For example:

- How does their illness affect their lives? How likely is it that, without intervention, the health condition will cause permanent disability, severe suffering, or death?

What are the trends with the health condition? For example:

- Is the number of people affected going up or down?
- Are new groups of people being affected? If yes, what are the demographics of this group?

*Information about how many people need the intervention and how this may change over time can affect overall cost and **Budget Impact** (see p. 12)*

The size and distribution of burden also relates to the capacity of the health system to meet the demand for related services that are covered.

Social Determinants of Health, Burden of the Health Condition, and Equity

The Burden of the Health Condition is a reflection of the Social Determinants of Health. Health is influenced by the environment in which people are born, grow up, live, and work. Health is shaped by exposure to polluted environments, inadequate housing, and poor sanitation, as well as powerful historical and social forces, such as income inequalities, unemployment, poverty, racial and gender discrimination, and extreme violence. Social Determinants of Health can be a useful way to understand both the underlying burden and health equity issues regarding who stands to benefit most from a new health intervention. It also underscores the limitations of any single health intervention to addressing a particular health condition, and the need for broader strategies to comprehensively address social determinants of illness and health inequalities.

Expected health benefits or harms

Evidence about effectiveness informs us about the health benefits and harms we expect to see if the intervention is provided—both for individuals who receive it and in addressing the broader burden of the health condition for the population. We start with information about the benefits and harms of an intervention under ideal circumstances, like in a controlled research trial. But it is also important to assess benefits or harms based on real-world implementation in the South African context.

To assess expected health benefits or harms, consider:

Expected benefits under ideal and real-world circumstances

How effective is the intervention at preventing or treating disease, improving health and life expectancy, and/or avoiding disability or chronic illness?

- How large are the expected health benefits of the intervention?
  - For individuals who benefit, how large is the effect size? If only small health improvements are likely, how clinically meaningful are they for people with the health condition? For example, people with a severe disease or disability may experience minor improvements in their health and how they can function, but these improvements could have significant benefits to their experience of health and overall wellbeing.
  - What percent of people with the health condition are likely to experience these benefits/respond well to the intervention?
- How long-lasting are the benefits? Does the intervention require ongoing or consistent use to experience the health benefits?
  - Does this intervention have advantages over existing options that may improve ease of use, adherence, and overall effectiveness?
- How severe would the consequences be if the intervention is not covered, for affected individuals and for the population?
- What are the overall expected benefits of health intervention for the broader population in reducing the burden of the health condition?
  - Beyond the total direct benefits for people receiving the intervention, are there additional indirect health benefits for the population, like herd immunity or reduced virus circulating in communities?

The known side effects of the intervention

To the extent there are any negative side effects for those using the intervention:

- How frequent and severe are the known side effects of the intervention?
- Are any of the side effects long-lasting or permanent?
- Are there ways to avoid or reduce the impact of the side effects?
- Will the nature of the side effects reduce overall uptake or effectiveness?
- How do the side effects of this intervention compare to other interventions for the condition?

Expected benefits or harms given ***Systems Factors & Constraints***

The real-world context of the health system

- Do health system factors related to quality, availability, and capacity enable effective delivery of the health intervention or could they limit the intervention's effectiveness?
- How might these factors affect the likely benefits and/or harms we would expect to see from offering the intervention?

Consider:

» the capacity of our health care workforce to implement the intervention

» the facilities and equipment we need for the intervention to be successful

» the quality of the services, products, and care

The real-world context of other systems factors

- Does the intervention rely on other systems factors, such as reliable access to clean water, electricity, data sources, or internet to work properly?
- How might these factors affect the likely benefits and/or harms we would expect to see from offering the intervention?

Because systems factors naturally vary across different parts of the country and for different population groups, see more under ***Equity*** as to how systems factors may affect the distribution of who benefits or is harmed by introducing the intervention (see p. 13)

Cost-effectiveness

With a limited health budget, the Government will have to choose carefully about how to spend public resources. For any new health intervention proposed, it is worth assessing how much health benefit can be gained for the additional costs, in Rand spent and resources allocated. How do the costs and health gains associated with this intervention compare to alternative options that the Government could fund instead?

Standard principles about how governments should spend public resources for health include:

- Choosing health interventions that produce the greatest health benefits for the costs
- Avoiding high-cost interventions that provide limited health benefits

These standards are often measured using a cost-effectiveness threshold:

Cost-effectiveness analysis and thresholds

Cost-effectiveness analysis (CEA) is a common type of economic evaluation used for HTA analysis. It helps us understand the comparative cost per unit of health gained for different medicines, vaccines, and health services. CEA looks at different options and tells us how much more health benefit we can buy if we invest in one type of health intervention versus another option.

There are two parts of the equation:

» **Health Benefits** gained or lost (usually measured in QALYs or DALYs[1])

» Changes in **Costs** (also called incremental costs)

We use this information to calculate the cost per unit of health gained for a given intervention. Then we compare that number to a standard, country-specific "Threshold" that tells us the highest cost per unit of health gained that would be considered cost-effective.

The cost-effectiveness threshold is meant to help decisionmakers compare how one health intervention compares with the wide range of possible health interventions that could be covered.

1. QALYs are "Quality-Adjusted Life Years" and DALYs are "Disability-Adjusted Life Years." Both are common summary measures used by health economists to help quantify health benefit across different kinds of health interventions with a standard unit of measurement. While these and other summary measures for health are important for the purposes of health policy & planning, there have also been criticisms that these measures can discriminate against those living with disabilities and the elderly in ways that could raise Equity concerns. As such, cost-effectiveness must be considered alongside other relevant domains.

There are a few additional ways to think about cost-effectiveness:

Comparing interventions for the same health condition

- Does the proposed intervention secure more health benefits for the cost than what is currently available for the health condition?
- Are there any other interventions for the health condition not currently offered that could provide similar health benefits for a lower cost?
    - » For example, if the proposed intervention is a new medicine for asthma that is very expensive, could a different, cheaper asthma medication be offered that would achieve the same health benefit?

Comparing health interventions for the same target population:

- Is the intervention cost-effective compared to other interventions that address the same population group's other health needs?
    - » For example, with a specific child health intervention, we ask how the cost-effectiveness of this intervention compares to other interventions for promoting children's health.

Other ways to improve cost-effectiveness in providing the intervention

- Are there ways to deliver the health intervention more efficiently to reduce costs and / or improve associated health gains?
    - » For example, could a diabetes intervention offer group counselling on diet and exercise instead of individual counselling to reduce costs for provider time?

Cost-Effectiveness gains given ***Systems Factors & Constraints***

In the real-world context of the health system & other factors

- Will the expected health benefits be lower than projected?
- Are there additional costs, not already accounted for, that may be needed to effectively deliver this intervention and ensure appropriate uptake?
- How might the changes in expected benefits and/or costs affect the assessment of the intervention – and would it still meet the cost-effectiveness threshold?

Budget impact

With a limited health budget, the total costs to the Government of implementing the health intervention will need to be assessed to determine whether the Government can afford it within the available resources.

To assess budget impact and how affordable the intervention is, consider:

- How much is the total cost for the Government to cover the intervention for all people who are eligible in the target population? Is it a large or small share of the total public budget available for covering health services?
  - » Some interventions may be very expensive, but because they are needed by only a small number of people, they might have a smaller budget impact.
  - » Other interventions may be relatively cheap, but because they are needed by a lot of people, they might have a larger budget impact.

- Will covering the intervention be affordable and sustainable?
  - » Will costs of the intervention go up or down?
  - » Will the number of people in need of the intervention go up or down?

Changing trends in Burden of the Health Condition can help you assess how the total cost of covering the intervention may change over time

- Is the size of the overall health budget likely to go up or down in coming years?

Budget Impact given ***Systems Factors & Constraints***

In the real-world context of the health system & other factors

- Are there new investments needed in facilities, infrastructure, or other systems factors that will increase the total cost to deliver this intervention?
- Are these costs "one-time" investments that only apply at the introduction of a health intervention, or will there be ongoing budget implications for as long as the service is provided?

Equity

Equity is about fairness — about how health benefits and harms are distributed across the population and about addressing unfair inequalities in health. The idea is to ensure that everyone has a fair chance to benefit from the health system and to address disadvantages related to health. A key goal for equity is to reduce or eliminate unfair differences in health care and health outcomes across population

Considering how to promote equity includes:

- ways to narrow or reduce existing health inequities. This means selecting interventions that will improve the health of people who belong to disadvantaged groups that are more likely to experience less health or face greater risks for bad health outcomes than advantaged groups
- avoiding health coverage decisions that will create or widen existing health inequities between the advantaged and disadvantaged
- ensuring that certain services are provided to all people who experience the same health need, without discrimination by group or individual characteristics

Addressing current health inequities

- Does the health intervention address specific health needs of population groups who are disadvantaged, underserved or particularly vulnerable in their health needs and status? For example:
    - » Does the intervention help meet the needs of priority populations, such as: children, women and girls, the elderly, people with disabilities, the poor, people with mental illness, people living in informal settlements and rural areas, the homeless, migrants, and refugees?
    - » Does the intervention help reach underserved communities and groups that previously had suboptimal coverage?
- Does the health intervention address a condition that is currently neglected, or has been historically overlooked for various reasons? For example:
    - » Does the intervention address tropical diseases, rarer diseases, mental health, or other conditions that have not been prioritised in the past?

Avoiding new or worse health inequities

- Is covering the intervention likely to create any new health inequities, widen existing health inequities, or contribute to future potential inequities? In other words, is the intervention more likely to benefit only those who are already better off or make things worse for groups that are already disadvantaged?
- Consider how this may relate to:

Out-of-pocket costs or lost wages needed to access the intervention (see Personal Financial Impacts p. 17)

Differential impacts on members of the household and care-giver burden, including gender equity (see Impacts on Personal Relationships p. 18)

There are also some health services that should be provided to everyone, regardless of whether they belong to a disadvantaged group. When assessing if a health service that should be considered for all, consider:

- Is this the type of intervention that should be guaranteed to everyone in society, regardless of their circumstances?
  - » For example, emergency medical transport and trauma services for serious injuries that all people need equally.

Equity in light of ***Systems Factors & Constraints***

In the real-world context of the health system & other factors

- Does the intervention require access to certain types of health facilities, equipment, or specialist health providers that will be harder to reach for certain members of the population (e.g., those in rural areas) – in ways that may make health inequities worse?
- Does the intervention require certain types of infrastructure or technologies – such as internet access, mobile phones, clean water, electricity – that may not be reliably available in underserved areas or for disadvantaged populations?
- Does implementing the intervention rely on other sectors that do not equitably serve different groups, with the result that inclusion of the intervention may reinforce disadvantages for populations who already underserved by those systems? If so, how would provision reinforce existing inequalities by gender, age, income, or geography)?
  - » Are there feasible and affordable ways to bridge these gaps, e.g., through transport services, mobile clinics, or new investments in underserved areas?
- Conversely, does this intervention have advantages over existing health service offerings that make it easier to access, deliver with sufficient quality, or use by

Respect and dignity

Human dignity and equal moral status are basic principles underlying human rights and are important to consider in health priority-setting. There are various ways in which health coverage decisions can demonstrate respect for human dignity and peoples' equal moral status in the health system. There are also health interventions that help preserve or promote people's sense of dignity and respect. These include respect for people's personal preferences, values and traditions, and considerations of choice and privacy.

Promoting respect and dignity includes considering:

Self-respect

- In what ways might this intervention either positively or negatively affect people's experience of self-respect, dignity, and personal identity? For example:
  - » Does the health intervention enable people to be more independent in self-care activities like bathing?
  - » Does the intervention enable people to participate in activities that improve their self-esteem?

Enabling environment for personal choice

- Will this intervention affect people's opportunities to make meaningful choices and decisions about their wellbeing in line with their personal values, beliefs, and life plans?
  - » Some health interventions may relate to very personal decisions about how a person manages their health condition.
  - » Certain interventions may improve health in ways that enable people to pursue other important goals.
  - » Some interventions may give people a greater sense of control over their lives and how they experience the health condition addressed.
  - » Other interventions may undermine people's sense of control or intrude on their privacy, such as when close monitoring or supervision is required to take a medication.

Social stigma and negative discrimination

- Might the intervention make people vulnerable to stigma and discrimination?
- Could the intervention make existing stigma and negative discrimination even worse?
- Are there ways to deliver the intervention that would help protect people from possible sources of social stigma and discrimination?
- Might the intervention proactively prevent or alleviate stigma and negative discrimination relating to the health condition addressed?

Respect for people's religious, spiritual, and cultural beliefs

- How acceptable, in general, will the health intervention be in the light of people's values, religious beliefs and other cultural norms?
  - » Are there any groups for whom the intervention will be perceived as disrespectful of their values? An example of this is religious / spiritual belief systems that do not allow for certain medical procedures such as blood transfusions or organ transplants.
  - » Are there any ways an intervention could be adapted to make it acceptable? If not, are there any reasonable alternatives that can be offered to meet the needs of people who find the current options unacceptable?

How might people's religious, spiritual, or cultural belief and practices effect the expected health benefits or harms of the intervention?

When there are concerns about Respect and Dignity, consider:

- Are there reasonable alternatives that can be offered where there is a clash between people's values and the nature of the intervention?
- Will there be additional costs for communication, or outreach, to address concerns relating to people's self-respect, dignity, personal identity or personal autonomy, or their cultural or religious / spiritual acceptance of a health intervention?

Consider how these costs may affect Budget Impact & Cost-Effectiveness

Respect & Dignity as it relates to ***Systems Factors & Constraints***

In the real-world context of the health system & other factors

- Are there special considerations related to how, where, and by whom health services are offered that relate to respect and dignity for patients? For example:
  - » Does the gender of the provider matter based on their personal values or religious and cultural practices, such as for certain women seeking sexual and reproductive health services?
  - » Are the facilities equipped to protect the privacy of patients, particularly those who may have a stigmatized condition?
- Does the intervention raise or address any issues related to respect and dignity of the health providers? For example:
  - » If the intervention is going to be delivered by community health workers, could it help or harm their social standing or self-respect?
  - » Is the intervention likely to raise any issues of religious or cultural importance from the provider perspective?

Impacts on personal financial situation

A health intervention may have a financial impact on individuals and families. People may have to pay out of pocket costs to receive care. A core principle of Universal Health Coverage, by which we are guided, is that every person in the country should be able to access quality health care without having to suffer financially for it. A health intervention may also reduce financial hardship if illness or disability keeps people from being able to work and earn income.

To assess whether covering an intervention will change individuals' or their families' financial circumstances, consider how covering of an intervention can result in:

Direct out-of-pocket expenses for individuals and their families

- If the intervention is covered, would it result in a significant impact on the person and their family's experience of poverty? For example:
  - » Does the intervention address a chronic health need requiring frequent out-of-pocket payments, which may be keeping individuals or families stuck in poverty?
  - » Is the expense associated with health intervention so high that, if not covered, it would drive most into poverty?

*High out-of-pocket costs also raise **Equity** considerations as some poorer individuals or households may choose not to seek care at all, while the wealthy are able to pay*

Indirect financial benefits on individuals and their families

- If the intervention is covered, how would it change the ability to earn a living for those affected or their family members?

*There are often links between **Respect & Dignity** and people's experience of poverty or their ability to work. Interventions that reduce poverty or enable people to earn a living likely also have related positive impacts on Respect & Dignity.*

Personal Financial Situation and ***Systems Factors & Constraints***

In the real-world context of the health system & other factors

- Does the intervention have any specific advantages or disadvantages based on systems factors and constraints that are relevant to out-of-pocket payments for those seeking care, such as changes in required frequency, distance, or cost of transport?
- Do the underlying systems factors and constraints impact how the intervention may increase or decrease the ability of patients to participate in income-generating activities, including the time needed to seek and receive services that could otherwise have been spent working?

Forming and maintaining important personal relationships

People's ability to form and maintain personal bonds with others is essential to wellbeing. A person's health status can dramatically affect their personal relationships and the ways in which they interact with others.

When making health coverage decisions, consider how a health intervention may impact personal relationships, for better or worse.

Considering impacts on personal relationships includes:

Impacts on important personal relationships

- Would the health intervention change a person's ability to form and maintain important personal relationships, such as with people they consider as family members, partners, spouses, and friends? If yes, how?

Caregivers' burden

- Would the intervention change the burden on personal caregivers, such as family members, friends, and other social supporters, who help people with the health condition manage their illness, disability, or chronic care needs? If yes, how?

Participation in social groups

- Would the intervention affect a person's and / or their family's ability to participate in social and community groups that are important to them? If yes, how?

Personal Relationships and ***Systems Factors & Constraints***

In the real-world context of the health system & other factors

- Does the intervention have any specific advantages or disadvantages based on systems factors and constraints that are relevant to forming and maintaining personal relationships?
    - » For example, if a new health intervention required fewer visits to a clinic or drug dispensary, would this have meaningful impacts on people's ability to spend time with family, friends, and community members?
- Do the underlying systems factors and constraints impact how the intervention may increase or decrease the burden on caregivers?

Ease of suffering

There are circumstances in which people will not be able to improve functioning, return to "their best possible" health, or extend time before death. Even when people cannot be cured, there may still be ways to reduce the pain or suffering they experience. Here we look at any special benefits, beyond what is counted in the health benefits section, that relate to easing pain and suffering.

Many measures used to quantify health benefits focus more narrowly on years of life gained or lost. Sometimes these measures are adjusted to take account of disability or the quality of those life years. However, there may be other types of benefits specific to how people experience physical pain or other types of suffering that are not well captured in the summary measures used to assess ***Health Benefits & Harms*** or ***Cost-Effectiveness***.

To assess whether covering an intervention will have additional or special significance in easing people's suffering, consider:

Potential for reducing symptoms, relieving pain, and minimising suffering

- If we cannot cure or improve a person's condition or extend their life, does the health intervention reduce pain or other negative symptoms? For example:
  - » Does the intervention ease pain for people with incurable cancer or organ failure in the last days of life?
  - » Does the intervention address other unpleasant symptoms for people living with chronic, long-lasting health conditions, such as nausea, fatigue, sleeplessness, and stomach upset or bowel problems?

Beyond the direct benefits to patients, consider whether there are also important impacts for caregivers relevant to Impacts on important personal relationships

Note: This domain will not necessarily be applicable to every intervention. An evaluation of "ease of suffering" most commonly arises for palliative and end-of-life care, as well as symptom management of certain illnesses (e.g., chronic illnesses) or disabilities. It is unlikely to apply in the case of preventive interventions, at least with respect to preventing future illness. It may apply if a new prevention option has less pain or fewer side effects than the current options – particularly if these side effects are not well accounted for in the standard measures used to quantify health benefits and harms. There may also be improvements in the way researchers and health economists evaluate summary measures of health to further include these types of outcomes that patients care about. If the measures used for ***Health Benefits*** and ***Cost-Effectiveness*** are broadened to include these measures, you may not need to consider them separately.

Impacts on safety and security

Coverage decisions for some health interventions may have special considerations that relate to people's exposure to unsafe environments or dangerous encounters. Feeling safe and being protected from harms while seeking health services, getting care, or—in the case of health workers—providing care, is important for the broader wellbeing of patients and providers alike. Here we look at whether the health intervention has any special significance for people's safety and security.

To assess whether covering an intervention will have additional or special significance for people's safety and security, consider:

People managing their health needs

- Does the intervention reduce the need for people to travel through unsafe areas?
  - » For example, a mobile clinic or intervention that can be self-administered at home to reduce exposures to harm or harm in transit?
- Does the intervention help address the needs of patients who may be targets of violence, including based on gender or stigmatised health conditions?
  - » For example, is the intervention directly related to prevention or response services for gender-based violence?
- Does the intervention improve safety within the context of receiving care or services? For example:
  - » an intervention that reduces possibility of injury or infection while in health facilities
  - » an intervention that covers childbirth companions or patient advocates to help address possible abuse or mistreatment within the clinical context
- Could the management of the condition lead to fewer unsafe or violent encounters?
  - » For example, a health intervention that addresses a substance use disorder or mental health problem that may put people in unsafe situations

Health workers' delivering the intervention

- Does the intervention have positive or negative impacts on the safety and security of providers? For example:
  - » an intervention that relies on community health workers to deliver services in unsafe areas
  - » an intervention that reduces workplace exposures to harm from infection, contamination, or threats of violence

Note: This domain will not necessarily be applicable to every intervention. It is possible that some elements (such as prevention of infection or injury in care settings) may be captured in the economic evaluation, in which case they may not need to be assessed independently.

Safety & Security and ***Systems Factors & Constraints***

In the real-world context of the health system & other factors

- Many of the considerations relevant to this domain will depend on other systems factors. For instance, the safety and availability of public transport as well as efforts to address crime and violence in communities will affect the kinds of harmful exposures people may face when they seek care. There may be opportunities to improve safety and security through partnerships with other sectors, so that the health intervention can be safely accessed.

- There are also health systems factors that influence safety and security within the care setting, for all interventions. These may need to be addressed through training, changes to facilities, and other quality improvement measures.

Impacts on solidarity & social cohesion

Social cohesion is the commitment of all members of society – whether or not they know each other personally – to cooperate with each other to survive, prosper and have a sense of belonging and trust.

Social cohesion draws on the principle of solidarity. This domain addresses questions about whether an intervention has the potential to unify people within a society or drive them apart. Unlike impacts on personal relationships – which addresses how an intervention may affect people's relationships to their family members, friends, and other close contacts – social cohesion looks at society at large.

To assess features of the health intervention relevant to solidarity & social cohesion, consider:

- Are there any ways that a decision to include or exclude a health intervention from coverage could:
  - » cause pre-existing divisions, distrust, or conflict to get worse?
  - » help foster social cohesion through better understanding, cooperation, and a sense of belonging across different groups of society?

Considerations about the health condition, intervention, and eligibility:

- Are there any attitudes or public perceptions about the **health condition** that are relevant to solidarity & social cohesion, for better or worse? For example:
  - » Some health challenges can bring people together and promote solidarity, such as responding to a national health crisis or a common condition.

  - » Alternatively, if the health condition has negative associations or addressing it could worsen existing tensions between groups, are there ways to addressed or minimise potential harms to solidarity & social cohesion through public communications or engagement activities?

- Are there any features of the **health intervention** that might promote or diminish solidarity & social cohesion? For example:
  - » An infectious disease control intervention, like vaccination, may make people feel like they are doing their part to reduce the overall risk to their community and society.
    - Does the intervention make it easier or harder for people to look after their own health in ways that support public health or preserve limited health resources for the population?
  - » Alternatively, could a decision to cover health intervention could exacerbate existing social rifts or political divides if it is associated with contentious actors or companies, or if the intervention is the subject of public debate?

- To what extent might social cohesion be an issue if the intervention were only covered for a select, **targeted group**?
  - » In the case of offering interventions only to a targeted population group, there may be a trade-off to consider:
  - » On the one hand, a targeted approach may be more cost-effective because it focuses on those who are likely to experience the largest health benefits. Targeting the worst off or most disadvantaged groups may also promote equity.
  - » **But**, groups who are not covered may feel excluded, causing increased tensions between groups with pre-existing conflicts.

Note: This domain will not necessarily be applicable to every intervention. Many interventions are likely to be uncontroversial. Also, there may be limited or different types of evidence for assessing this domain. Public engagement activities may be best for determining how and when intervention may impact social cohesion. Public engagement may also be the best tool to address concerns about negative impacts on solidarity & social cohesion.

APPENDIX A: Development of the Framework

How was the ethics framework developed?

Development of the SAVE-UHC Ethics Framework started with the high-level principles outlined in the NHI White Paper in order to translate and apply them to decision-making for specific health interventions.

NHI White Paper Principles

- Right to access health care
- Equity
- Affordability
- Effectiveness
- Social solidarity
- Health as a public good
- Efficiency
- Appropriateness

The project then brought together a multi-stakeholder Working Group to discuss how these principles and other relevant considerations should be included in the HTA process. Drawing on the experience and perspectives of its members—policymakers, civil society and patient group representatives, academics, providers, and payers—the Working Group identified the set of specific domains and considerations that reflect South Africa's core values for HTA.

How was the ethics framework was piloted and refined?

After the SAVE-UHC Working Group developed the *draft* Ethics Framework, the project brought together participants from diverse backgrounds, fields, and perspectives to simulate the process of using the framework for health priority-setting. The project convened meetings across three provinces: Gauteng, Western Cape, and KwaZulu-Natal. At these meetings, participants used the draft Framework to review and discuss two sample health interventions, similar to how a government committee might use a framework like this in the future to decide if a health intervention should be included under National Health Insurance. By simulating the process of a health technology appraisal and soliciting feedback from the meeting participants, the research team was able to identify areas to refine and strengthen the Ethics Framework.

For additional details about the approach taken to develop the SAVE-UHC Ethics Framework, please see the full write-up of the methodology available here: [link]

APPENDIX B: Health Technology Assessment

Health Technology Assessment (HTA) is an increasingly popular process for using evidence to guide policy decisions about what health interventions to include in National Health Insurance schemes and benefits packages.

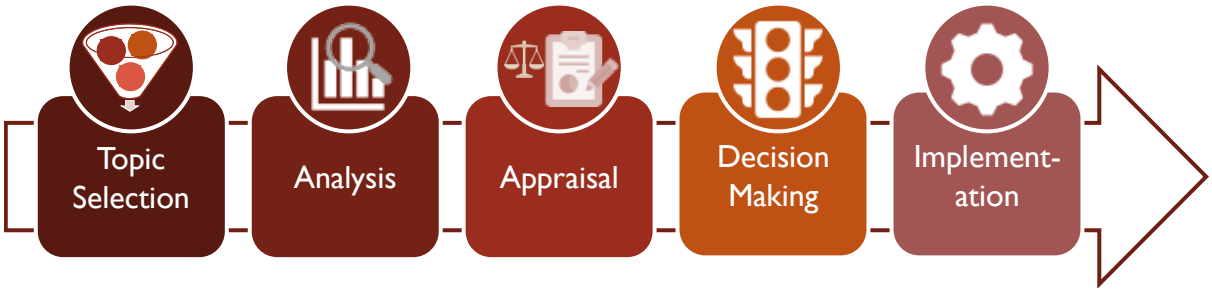
Health Technology Assessment

The systematic evaluation of the properties, effects, and/or impacts of a health intervention, including: medical, economic, social, legal, and ethical considerations.

Health interventions

A health intervention is any service, product, or programme to prevent, diagnose, treat or manage a health condition. For instance, a health intervention could be medication, vaccine, diagnostic test or screening programme, rehabilitation service, medical device, therapy or counselling service, medical transport, and more.

The HTA approach to health priority-setting typically involves five stages:



Topic Selection

A particular health intervention is chosen for an in-depth look at the evidence so that the committee can consider if it should be included under NHI. Sometimes this happens when a new medicine is developed to see if it should be added. Other times an intervention may be selected for HTA when a civil society organisation or advocacy group identifies an unmet health need and proposes an intervention be added to the package.

Analysis

All the relevant evidence on the health intervention is gathered or generated to inform the appraisal committee discussions and recommendations. This traditionally includes an economic evaluation, such as Cost-Effectiveness Analysis, to determine how much additional health can be secured for the money spent on the intervention. Analysis can also include gathering evidence and information on other impacts and criteria that will be relevant to decision-making.

Appraisal

A committee comes together to review and discuss all the evidence and considerations about the health intervention in order to make a policy recommendation about its inclusion under NHI. The committee is not limited to “yes” or “no” recommendations.

They may also advise further collection of evidence, for instance through a small pilot, or a price negotiation to make the intervention more affordable. They can also recommend a targeted approach to reach those who will benefit most while containing overall costs.

These committees often consist of persons with technical expertise in medicine, public health, health economics, epidemiology, patients' rights, as well as lay public representatives. Broader inclusion of different stakeholder groups and disciplinary backgrounds within these committees can help advance procedural values related to participation and representation.

Decision-Making

A formal decision will be made about whether the health intervention will be covered under NHI. In some places, the recommendations from the Appraisal Committee are binding and in other places, policy-makers or payers have the power to make the ultimate decision, even if it differs from the HTA recommendation.

Implementation

The intervention is formally added to the NHI benefits package, with the corresponding funds allocated to cover and provide the service.

The SAVE-UHC Ethics Framework was designed to inform the types of evidence that are gathered in the "analysis" stage, as well as guide deliberations during "appraisals."