Integrating Health Technology Assessment and the Right to Health in South Africa:

A Qualitative Content Analysis of Substantive Values in Landmark Judicial Decisions

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Abstract: The World Health Assembly has encouraged WHO member-states to establish capacity in health technology assessment (HTA) as a support for achieving universal health coverage (UHC). Simultaneously, the WHO has stated that UHC is "a practical expression of the concern for health equity and the right to health." This has prompted questions about potential tensions between priority-setting efforts and the right to health on the road to UHC. South Africa (SA) is an ideal setting in which to explore how the priority-setting work of an HTA body may be integrated with an existing rights framework.

niversal health coverage (UHC) is an important policy objective for many countries. The World Health Assembly has encouraged World Health Organization (WHO) member-states to establish capacity in health technology assessment (HTA) as a support for achieving high quality and affordable UHC.¹ Given that no country has unlimited

resources, HTA can support priority-setting to inform the design of health care packages under UHC. HTA is the systematic evaluation of the effects and impacts of single health care interventions in terms of a set of criteria that traditionally includes, but is not restricted to, clinical and cost-effectiveness. HTA can support decisions about whether to invest in a health care service by determining its value relative to existing interventions. Simultaneously, the WHO has stated that UHC is "a practical expression of the concern for health equity and the right to health." This has prompted questions about potential tensions between HTA priority-setting efforts and the right to health4 on the road to UHC.

The judicialization of health care access, or the process by which individuals attempt to secure access to particular health care services through litigation, illustrates this potential tension. The right to health, which often grounds judicialization, has been increasingly included in national constitutions. The right to life, the right to equal protection under the law, and international human rights declarations can also be applied to enforce a right to health in litigation. Literature examining the impacts of judicialization is mixed. On one hand, judicialization may exacerbate inequities in health care access or undermine efforts by national governments to control health care spending; on the other hand, judicialization can hold gov-

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ernments accountable for their decision-making or help to expand access to health care.⁸ It is argued that a new generation of research into judicialization should investigate the conceptualization of the right to health to prospectively inform broader public health care access policies, such as priority-setting.⁹

South Africa (SA) is an ideal setting in which to explore how HTA priority-setting may be integrated with a right to health framework. First, as SA moves toward establishing UHC through its National Health Insurance (NHI) program, there is a legislative commitment to establish an HTA body that will inform priority-setting decisions about which drugs and health care services should be covered. ¹⁰ Second, the

This manuscript discusses the findings of a more rigorous and deductive qualitative content analysis that sought to draw on judicial decisions to inform the 1) identification, 2) interpretation, and 3) balancing of substantive values in the work of a potential national HTA body in SA. Instances where the courts *identify* substantive values may demonstrate alignment with the SAVE framework, thus providing additional justification for the values used to guide priority-setting. Instances where the courts *interpret* these high-level substantive values by specifying related sub-considerations may inform the application of these values in the deliberations of an HTA body. Finally, instances of *balancing* in the courts' judgments may inform how

South Africa (SA) is an ideal setting in which to explore how HTA priority-setting may be integrated with a right to health framework. First, as SA moves toward establishing UHC through its National Health Insurance (NHI) program, there is a legislative commitment to establish an HTA body that will inform priority-setting decisions about which drugs and health care services should be covered. Second, the Constitution explicitly includes "the right to have access to healthcare services."

Constitution explicitly includes "the right to have access to healthcare services." With respect to the obligation to fulfill this right, the Constitution states, "The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realization of [this right]." This articulation acknowledges that resource scarcity will necessarily constrain the fulfillment of this right. Additionally, the language of "progressive realization" implies that prioritization will occur, as certain health care services will necessarily be selected sooner than others for provision under NHI.

From 2018 to 2019, the South African Values and Ethics for Universal Health Coverage (SAVE-UHC) project convened a multi-stakeholder in-country deliberative working group to develop a substantive value framework that may inform future HTA in SA.¹³ Substantive values describe the criteria that provide reasons to cover particular interventions or not.¹⁴ Examples of substantive values are beneficence, equity, and respect for persons. The process of developing this framework drew from many sources, including an initial desk review of SA court cases, to identify substantive values for consideration by the SAVE-UHC working group.¹⁵

an HTA body should weigh tradeoffs among competing values and their related considerations. Ultimately, this study sought to demonstrate how a focus on case rulings as a source of substantive values may advance understanding of the relationship between a rights-based approach to health care and national efforts to set health priorities.

Methods

Case Selection

Broadly, we identified judicial decisions relating to sections 27 and 35 of the SA constitution to capture cases that addressed the State's obligation to fulfill the right to access health care. Table 1 provides the relevant text of each section.

The full approach to case selection is described in detail in a prior study that analyzed procedural values in SA court cases (whereas the present study focuses on substantive values). We confirmed that none of the cases included in this review have been overturned as of October 2022, based on the NoterUp section in Jutastat and the CiteIT signal in Lexis Nexis. Table 2 summarizes the final sample and provides the full name for each case (abbreviated names are used in the main text).

Analysis

The codebook (Table 3) is organized to reflect the substantive values and considerations that were provisionally identified by the SAVE-UHC working group as important for HTA priority-setting in the SA context. Each high-level substantive value is further specified by several related considerations, a structure that is in line with an influential approach to moral decision-making for biomedical ethics.¹⁷ For example, the value of *respect and dignity* includes considerations such as enabling personal autonomy, avoiding stigma and discrimination, and respecting religious and cultural beliefs. For coding purposes, the substantive values comprised the themes and their related considerations comprised sub-themes.

Details regarding the general approach to coding can be found in the previously referenced study. One potential additional value — *ubuntu* — was inductively identified during the coding process. However, and as described in the discussion below, this value did not involve novel substantive content beyond what was already included in the SAVE framework. We excluded from analysis any portions of the judgments focused on procedural legal matters such as issues of jurisdiction or whether leave to appeal was appropriately granted. The focus of coding was to identify instances in the court's judgment and related reasoning that 1) identified, 2) interpreted, and 3) balanced substantive values.

Results

At least three values were identified in each judgment (Table 4). *Equity* was the most commonly identified by number of judgments (n=7), followed by *budget impact* (n=6). Only one substantive value from the SAVE-UHC framework — *impacts on safety and security* — was not identified in any judgment. Below, we provide a narrative summary (Table 5) describing how substantive values were identified, interpreted, and balanced in each case judgment, arranged chronologically by case (Table 5). The reader may refer to Table 2 for details regarding the facts and decision of each case.

Van Biljoen (1997)19

Two values are central to the Court's reasoning: *equity* and *health benefits and harms*. First, the Court rejected on equity grounds the respondents' interpretation of the adequacy standard. In the Court's view, the overcrowded conditions of prison mean that prisoners with HIV face a higher risk of opportunistic infection than patients with HIV living outside of prison. As a result, the Court states:

Since the State is keeping these prisoners in conditions where they are more vulnerable to opportunistic infections than HIV patients outside, the adequate medical treatment with which the State must provide them must be treatment

Table I

Health care-related constitutional rights that confer a primary obligation of fulfilment on the South African state

27. Health care, food, water and social security

- (I) Everyone has the right to have access to
 - (a) health care services, including reproductive health care;
 - (b) sufficient food and water; and
 - (c) social security, including, if they are unable to support themselves and their dependants, appropriate social assistance.
- (2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.
- (3) No one may be refused emergency medical treatment.

35. Arrested, detained and accused persons

(2) Everyone who is detained, including every sentenced prisoner, has the right —

(e) to conditions of detention that are consistent with human dignity, including at least exercise and the provision, at state expense, of adequate accommodation, nutrition, reading material and medical treatment...

Table 2

Final case sample

Case	Abbreviation	Year	Level of judgment	Case summary pertaining to sections 27 or 35 of the Constitution
Soobramoney v Minister of Health, KwaZulu-Natal	Soobramoney	1997	Constitutional Court	Soobramoney was in the final stages of chronic renal failure. Though he couldn't be cured, his life could be prolonged through regular dialysis. At the time, the public healthcare system only provided dialysis for transplant candidates. After Soobramoney's request for publicly-funded treatment was denied, he brought a case arguing that the State was required to provide him with dialysis under his section 27 right to healthcare services. The Court found that the State hospital's decision did not breach its obligations under section 27 due to the impact providing dialysis would have on healthcare system resources.
Minister of Health and Others vTreatment Action Campaign and Others	TAC	2002	Constitutional Court	The government had created and implemented a pilot program to interrupt mother-to-child transmission of HIV. This included administration of the drug, nevirapine, at the time of birth as well as additional services including provision of infant formula. The drug was only available in the private sector and two pilot sites in each province. TAC brought a case to compel government to provide nevirapine across the healthcare system, without the additional services, under section 27. The government argued that nevirapine was not effective without the additional services and they did not have resources to expand the program. The court found that the failure to provide nevirapine, without additional services, was unreasonable and fell short of section 27.
Khosa and Others v Minister of Social Development and Others; Mahlaule and Another v Minister of Social Development and Others	Khosa	2004	Constitutional Court	Khosa, and the other applicants, were permanent residents of South Africa who had been denied State social security benefits. The Court had to determine whether the government's decision to limit access to State social security benefits to citizens was compliant with section 27(2). Though the case doesn't concern the right to healthcare specifically, the right to access social security falls under the same section 27 and shares the same constitutional language and interpretation. The Court found that the restriction of benefits to citizens did not meet the standard of reasonableness under section 27.
Minister of Health and Another v New Clicks SA (Pty) Ltd and Others	New Clicks	2005	Constitutional Court	The State had introduced amendments to the Medicines and Related Substances Act intended to make medicines more affordable. This was part of the State's efforts to fulfill their section 27 obligation to provide everyone with access to healthcare services. The pharmaceutical and pharmacy industries opposed these measures, arguing in particular that the uniform medicine dispensing fee prescribed by the amendments would threaten the financial viability of pharmacies. The Court was divided on this issue. Six members found that the dispensing fee was inappropriate. The remaining five found that the dispensing fee was inappropriate only for rural and courier pharmacies.

Table 2 (Continued) Final case sample

Case	Abbreviation	Year	Level of judgment	Case summary pertaining to sections 27 or 35 of the Constitution
Mazibuko and Others v City of Johannesburg	Mazibuko	2009	Constitutional Court	The City of Johannesburg introduced prepaid water meters in some areas. These meters dispensed 6 kl for free and thereafter shut off unless tokens were purchased. The previous system allowed consumers to use water and pay for water used at the end of the month. The case concerned whether the Free Basic Water policy, specifically the water shutting off after the 6 kl allowance, was a violation of section 27 of the Constitution (the rights to sufficient water and to access health care are both included under section 27). The Court found that the policy was constitutionally permissible.
B and Others v Minister of Correctional Services and Others	Van Biljoen	1997	High Court	B and others were detainees in the South African prison system who were HIV positive and required antiretroviral treatments (ARVs). The question was whether the right to "adequate" medical treatment for prisoners under section 35 gave them an entitlement to ARVs that they would have had access to through the public healthcare system outside prison. The applicants argued that section 35 required the State to provide them with this medically-indicated therapy, even if it was not being provided at State expense in provincial hospitals. The Court found in favor of the applicants.
Du Plooy v Minister of Correctional Services and Others	Du Plooy	2004	High Court	Du Plooy was a detainee in the South African prison system who was terminally ill and in need of palliative care. He sought release from prison on medical parole. The applicant's request had previously been refused. Du Plooy argued for his release based on his constitutional rights to healthcare and medical treatment. The Court found that the decision not to place the applicant on medical parole violated sections 27 and 35 of the Constitution.
E N and Others v Government of the Republic of South Africa and Others	Westville	2006	High Court	EN and others were prisoners at the Westville Correctional Centre who were HIV positive and were not given access to ARVs. They challenged the failure of the State to provide them with appropriate ARV treatment in fulfillment of sections 27 and 35 of the Constitution. The Court found in favor of the applicants and required the State to take steps toward the provision of appropriate ARV treatment as determined by the relevant medical authorities.

which is better able to improve their immune systems than that which the State provides for HIV patients outside [prison].

This reasoning invokes the equity-related consideration of giving special attention to the most vulnerable. Second, the Court found that the available, internationally recommended treatment — combination AZT therapy — would offer substantial health benefits if provided to the prisoners: "Applicants have, therefore, established, in my view, that although antiviral therapy is at present only prophylactic, the benefits of this treatment in the form of extended life expectancy and enhanced quality of life are such that this treat-

ment must be provided for the unfortunate sufferers of HIV infection." *Value for money* also played a role in the Court's decision: "It does, however, stand to reason that the postponement of the costly treatment for opportunistic infections [as a result of prophylactic anti-viral treatment] must result in some cost-saving even if such saving does not exceed the cost of prophylactic antiviral treatment."

Importantly, the Court acknowledges that *budget impact* is a relevant substantive value for determining "adequate" medical treatment: "I do not, however, agree with the proposition that financial conditions or budgetary constraints are irrelevant in the present context. What is 'adequate medical treatment' cannot

Table 3

Codebook

Themes (Values)	Sub-themes (Related considerations)			
Burden of the health condition	 Number of people affected by and nature of the health condition to be addressed Alignment with broader government priorities for health 			
Systems factors & constraints	Ability of current systems (health and other) to deliver the intervention at quality and sufficient coverage			
Health benefits & harms	 Efficacy/effectiveness Duration of benefit Side effects Clinical utility of intervention 			
Value for money	Cost-effectiveness			
Budget impact	Total cost of implementing the intervention			
Personal financial impact	Protection from out-of-pocket costs and poverty Impact on ability to work/earn income			
Social cohesion	 Impact on pre-existing social divisions, trust, conflict between groups Foster better understanding, cooperation, sense of belonging across different groups 			
Ease of suffering	Impact on pain and suffering even if life cannot be prolonged			
Impact on personal relationships	 Close personal relationships Caregivers' burden Participation in social and community groups 			
Impact on safety & security	Limit patient or health care worker exposure to violence or safety hazards			
Respect & dignity	 Impact on people's experience of self-respect, dignity, or personal identity Impact on social stigma and discrimination Promote or avoid infringing personal autonomy Respect people's religious, spiritual, and cultural beliefs 			
Equity	 Reduce existing health inequalities Avoid widening existing health inequities Equal treatment for those with equal health needs, without discrimination on the basis of group or individual characteristics Special attention to the disadvantaged/vulnerable Special attention to neglected health condition 			

Table 4

Summary of values identified in case judgments

	Van Biljoen	Soobramoney	TAC	Khosa	Du Plooy	New Clicks	Westville	Mazibuko	Total
Equity	Х	Х	Х	Х	(X)	Х	×	Х	7 (8)
Budget impact	Х	Х	Χ	Х			X	X	6
Systems factors & constraints		Х	Х	×				X	4
Health benefits & harms	X		Х			X	Х		4
Respect & dignity			Χ	X	(X)			X	3 (4)
Value for money	X	X	Χ						3
Burden of disease			Х				X		2
Ease of suffering					Х		Х		2
Personal relationships				X	(X)				I (2)
Personal financial impact						X			I
Social cohesion					(X)				0(1)
Safety & security									0
Total	4	4	7	5	I (5)	3	5	4	

(X): Indicates values that are associated with Ubuntu, which was explicitly identified in *Du Plooy*. The totals in parentheses (bottom row and right-most column) include these values associated with ubuntu.

be determined in vacuo. In determining what is 'adequate', regard must be had to, inter alia, what the State can afford." In this case, however, the respondents did not provide compelling evidence of any significant budget impact to outweigh the equity, health benefits, and value for money considerations.

Soobramoney (1997)20

Budget impact considerations are central to the Court's decision against the applicant. Neither the hospital nor the state had the available or potential resources to cover the costs of dialysis for this patient and others like him while still covering other health services for "everyone" as required by section 27. As the Court writes:

...if treatment has to be provided to the appellant it would also have to be provided to all other persons similarly placed...If all the persons in South Africa who suffer from chronic renal failure were to be provided with dialysis treatment – and many of them, as the appellant does, would require treatment three times a week – the cost

of doing so would make substantial inroads into the health budget.

At the same time, the Court applies the *equity*-related consideration of providing equal treatment to those with equal health needs. In the quote above, the Court reasoned that if the applicant received dialysis, then equity would dictate that all other patients who are "similarly placed" ought to receive the same treatment. Unfortunately, the costs of providing such treatment to all such patients would be too great.

Additionally, systems factors and constraints factor into the Court's decision against the applicant. The hospital's dialysis machines were described as in "poor condition", the nurse-patient ratio was 1:4.5 rather than the recommended 1:2.5, and the hospital's renal unit was already treating 85 patients, or 25 more than the recommended number given its resources and staffing. The Court writes, "the hospital can barely accommodate those who meet its [dialysis] guidelines." To provide the requested care to the applicant and other patients like him would place too great a strain on the health care system.

Table 5

Summary of identification, interpretation, and balancing of substantive values

		Interpretation			
Case Identification (Values)		(Related considerations)	Balancing		
Van Biljoen	Equity	Special attention to the vulnerable (prisoners)	Considerations of equity and health benefits and harms and value for money		
	Health benefits and harms	Impact on mortality and morbidity	outweighed budget impact		
	Value for money				
	Budget impact				
Soobramoney	Budget impact		Budget impact, systems factors and constraints, value for money combined		
	Systems factors and constraints	'			
	Value for money				
	Equity	Equal treatment for those with equal health needs			
TAC	Budget impact		Considerations of health benefits and harms, burden of the health condition, respect and dignity, and equity outweigh budget impact, systems factors and con-		
	Systems factors and constraints				
	Value for money		straints, and value for money.		
	Health benefits and harms				
	Burden of the health condition	 Consider crises and short, medium, and long term needs HIV/AIDS is an urgent crisis 	Within respect and dignity, impacts on personal autonomy outweighed the potential failure to respect cultural beliefs		
	Respect and dignity	Respect cultural beliefs Promote or avoid infringing personal autonomy	When considering treatments for crises like HIV/AIDS, a short-term perspective is more important than the long term		
	Equity	Special attention to the vulnerable (women, children, and those who cannot afford medical services) Rejects a primary focus on ensuring a minimum level of health care Equal treatment for those with equal health needs	is more important than the long-term		
Khosa	Equity	 Equal treatment for those with equal health needs Avoid widening existing health inequities Special attention to the vulnerable (children and the elderly) 	Considerations of equity, respect and dignity, and impacts on personal relationships outweighed budget impact and systems factors and constraints		
	Respect and dignity	Impact on experience of self-respect, dignity, or personal identity Impact on social stigma and discrimination Promote or avoid infringing personal autonomy			
	Impacts on personal relationships				
	Budget impact				
	Systems factors and constraints				

Summary of identification, interpretation, and balancing of substantive values

Case	Identification (Values)	Interpretation (Related considerations)	Balancing		
Du Plooy	Ease of suffering		No values were in tension		
	Ubuntu (Equity, Ease of suf- fering, Respect and dignity, Personal relationships, So- cial cohesion)				
New Clicks	Personal financial impact		Personal financial impact and health		
	Health benefits and harms		benefits and harms were in tension		
	Equity	Special attention to the vulnerable (rural and chronically-ill patients) Avoid widening existing health inequities	(low prices improve access to medications to the point that pharmacies lose viability and access decreases); considerations of equity especially important when rural or chronically-ill populations may lose access		
Westville	Burden of the health condition	HIV/AIDS as a priority	Considerations related to burden of the health condition, health benefits		
	Health benefits and harms		and harms, equity, and ease of suffering		
	Equity	Special attention to the vulnerable (prisoners) Equal treatment for those with equal health needs	all outweighed considerations of budget impact		
	Ease of suffering		_		
	Budget impact				
Mazibuko	Equity	 Rejects a primary focus on ensuring a minimum level of health care Special attention to the vulnerable 	Considerations related to budget impact, systems factors and constraints, and respect and dignity outweighed		
	Budget impact		considerations related to equity		
	Systems factors and constraints	Administrative constraints			
	Respect and dignity	Impact on people's experience of self- respect, dignity, or personal identity Impact on social stigma and discrimination			

Finally, the Court's decision is supported by *value for money* and the consideration of maximizing health gains in the population. The Court writes:

By using the available dialysis machines in accordance with the guidelines more patients are benefited than would be the case if they were used to keep alive persons with chronic renal failure, and the outcome of the treatment is also likely to be more beneficial because it is directed to curing patients, and not simply to maintaining them in a chronically ill condition.

The Court reminds us that the State is permitted by the Constitution "to manage its limited resources in order to address all these [competing] claims."

The Court concludes that, "There will be times when [the fact of limited resources] requires [the State] to adopt a holistic approach to the larger needs of society rather than to focus on the specific needs of particular individuals within society." The Court therefore acknowledges the possibility that the State may be guided by considerations other than maximizing health gains, but in this particular case the substantial adverse impact on the budget and health system and the loss of potential population health gains by prioritizing treatment to the applicant and patients like him would have been too great.

TAC (2002)21

The government advanced several arguments for why nevirapine access should be limited to pilot sites. First, they argued that nevirapine treatment alone would not effectively interrupt mother-to-child HIV transmission because transmission could still occur through breastfeeding. For this reason, a "comprehensive package" was needed that would include not only nevirapine treatment but also breastmilk substitutes, vitamin supplements and antibiotics, as well as related advice, counselling, and monitoring to address safety concerns arising from the use of bottle-feeding in areas where mothers would not have easy access to clean water. The government argued it could not effectively provide this comprehensive package throughout the country given budgetary and resource constraints, thus invoking the values of *budget impact* and *systems* factors and constraints. The decision to limit nevirapine treatment to a few pilot sites allowed for the collection of additional information regarding these operational challenges facing national scale-up of the comprehensive package. Additionally, the government argued that widespread administration of nevirapine could result in problematic drug resistance or sideeffects, issues that similarly required further study prior to scale-up.

In response to these arguments, the Court found that "the wealth of scientific material" shows that nevirapine remains "to some extent" effective at interrupting mother-to-child HIV transmission even if breastfeeding occurs afterward. Additionally, the Court determined that the benefits of nevirapine far outweigh the risk of resistance: "The prospects of the child surviving if infected are so slim and the nature of the suffering so grave that the risk of some resistance manifesting at some time in the future is well worth running." Finally, the Court assessed the potential side-effects of nevirapine to be "no more than a hypothetical issue". The clinical evidence suggested that side-effects typically arise when nevirapine is used as a chronic medication and not from its intended use in the present case as a single dose at birth. In these arguments, the Court straightforwardly balances the health benefits and harms of expanding access to nevirapine and concludes that the government was wrong to afford so much weight to the potential harms of the treatment program.

To be sure, the Court acknowledges that the government's concerns related to budget impact, systems factors, and value for money are legitimate. For example, the Court states, "There are obviously good reasons from the public health point of view to monitor the efficacy of the 'full package' provided at the research and training sites and determine whether the costs involved are warranted by the efficacy of the treatment." Furthermore, quoting *Grootboom*, an earlier case about the right to housing that contributed to jurisprudence regarding section 27 of the Constitution,22 the Court confirms that, "the State is not obliged to go beyond available resources," when realizing the right to access health care. However, because the Court denied the necessity of the costly and burdensome comprehensive package for achieving substantial health benefits in the population, it did not give the government's concerns significant weight.

Additionally, the Court suggests that the particular burden of the health condition represented by HIV/AIDS justified in this case a greater focus on meeting short-term health needs through expanded use of nevirapine rather than ensuring the long-term sustainability of the comprehensive package to interrupt mother-to-child HIV/AIDS transmission. In support of this position, the Court quotes *Grootboom*, stating that the realization of socio-economic rights should "[pay] attention to ... crises and to short, medium and long term needs [emphasis added]." That is, the State must consider and balance its ability to meet both

present and future health needs. In this particular case, the Court indicates that HIV/AIDS represents an immediate crisis, saying, HIV/AIDS is "the greatest threat to public health" in SA and "the nature of the problem is such that it demands urgent attention." The Court thus concedes that, "[t]here is a need to assess operational challenges for the best possible use of Nevirapine on a comprehensive scale to reduce the risk of mother-to-child transmission of HIV," but that, "[t]here is, however, also a *pressing* need to ensure that where possible loss of life is prevented in the meantime [emphasis added]." The urgent nature of the HIV/AIDS crisis demands greater attention to short-term health benefits.

Two other substantive values factored into the Court's decision: respect and dignity and equity. First, the government was concerned that the need to provide breastmilk substitutes alongside nevirapine would infringe on important cultural values (i.e., those related to breastfeeding), which is a consideration related to the value of respect and dignity. This argument did not move the Court, since it decided that nevirapine should be provided even in the absence of changes to traditional breastfeeding practices. The Court identified an additional consideration related to respect and dignity that counted in favor of expanding access to nevirapine. The Court writes, "[T]he benefits to a woman of knowing her HIV status include the ability to make informed choices about feeding options, earlier access to care for both mother and child, the opportunity to terminate pregnancy where desired and legal, and the ability to make informed decisions about sexual practices and future fertility." Since expanded access to nevirapine would require more women to receive HIV testing and learn their status, expanded access would promote autonomy in these ways.

Finally, the Court's decision rests on considerations of equity. Quoting Grootboom again, the Court writes, "Those whose needs are the most urgent and whose ability to enjoy all rights therefore is most in peril, must not be ignored by the measures aimed at achieving realization of the right." Elsewhere in the judgment, the Court identifies mothers and their children, and "those who cannot afford to pay for medical services", as the groups whose needs are "most urgent" in this particular case. The Court goes on, writing, "There is a difference in the positions of those who can afford to pay for services and those who cannot. State policy must take account of these differences." For these reasons, the State must give special consideration to the needs of these vulnerable groups when formulating "reasonable" measures to progressively realize the right to access health care. Two other findings related to *equity* are worth noting. First, the Court appears to reject a primary focus on the idea that all should be ensured a certain minimum level of health care, explicitly rejecting a "minimum core" approach to the rights: "the socio-economic rights of the Constitution should not be construed as entitling everyone to demand that the minimum core be provided to them." Second, the Court's decision ultimately rests on the consideration of providing equal treatment to those with equal health needs. As shown by the totality of the arguments above, the Court could identify no relevant difference between the patients or the facilities at pilot versus non-pilot sites that could justify unequal treatment: all facilities were appropriately equipped to provide nevirapine to the patients who needed it.

Khosa (2004)²³

The substantive value of *equity* weighed strongly in the Court's decision. The Court first addressed the State's decision to differentiate between citizens and non-citizens when providing social security benefits. The Court observed that permanent residents "have become part of our society and have made their homes in South Africa." The Court continued: "Their homes, and no doubt in most cases their families too, are in South Africa. Some will have children born in South Africa. They have the right to work in South Africa, and even owe a duty of allegiance to the State." Ultimately, the Court appears to find that citizens and permanent residents are similar in all relevant respects and concludes that, "[d]ifferentiation on the grounds of citizenship ... therefore amounts to discrimination." The Court's reasoning here rests on the consideration of providing equal treatment to those with equal need, without discriminating on the basis of group or individual characteristics.

The Court further argued that the unequal treatment inherent in differentiation on the grounds of citizenship was unfair because, quoting an earlier case, "it builds and entrenches inequality amongst different groups in our society." From the Court's perspective, "[t]here can be no doubt that the applicants are part of a vulnerable group in society ... worthy of constitutional protection." This vulnerable group is composed of "children and the aged, all of whom are destitute and in need of social assistance." In these statements, the Court invokes the equity-related considerations of avoiding the widening of existing inequity and of giving special attention to the vulnerable.

Two additional substantive values played an important role in the Court's judgment: respect and dignity and impacts on personal relationships. The Court

writes that the State's discriminatory policy "almost inevitably creates the impression that permanent residents are in some way inferior to citizens" and "has a strong stigmatising effect." Later in its judgment, the Court emphasizes this point a second time:

What is of particular importance in my view, however, and can be stressed again, is that the exclusion of permanent residents from the scheme is likely to have a severe impact on the dignity of the persons concerned, who, unable to sustain themselves, have to turn to others to enable them to meet the necessities of life and are thus cast in the role of supplicants [emphases added].

These statements show that the Court is centrally concerned with the impact that State measures may have on the experience of self- and social respect and on individual autonomy. Additionally, this loss of autonomy "impacts not only on permanent residents without other means of support, but also on the families, friends and communities with whom they have contact," potentially causing tension in personal relationships or increasing caregiver burden.

The government argued in its defense that budgetary and immigration considerations supported restricting social security benefits to citizens. The Court acknowledges that these are relevant considerations ("I accept that the concern that non-citizens may become a financial burden on the country is a legitimate one and I accept that there are compelling reasons why social benefits should not be made available to all who are in South Africa irrespective of their immigration status.") that should be part of the determination of reasonableness ("When the rights to life, dignity and equality are implicated in cases dealing with socio-economic rights, they have to be taken into account along with the availability of human and financial resources in determining whether the State has complied with the constitutional standard of reasonableness.") Nonetheless, the Court determines that extending social security benefits will increase the social grants budget by only 2%. In this particular case, then, the Court stakes out an explicit position on the appropriate balancing of these competing considerations: "In my view the importance of providing access to social assistance to all who live permanently in South Africa and the impact upon life and dignity that a denial of such access has, far outweighs the financial and immigration considerations on which the State relies."

Du Plooy (2004)24

The Court found in favor of the applicant, writing: "The decision not to place the applicant on medical parole was, objectively, so irrational and unreasonable and in total conflict with the provisions of ... 27(1)(a) and 35(2)(e) of the Constitution ... These grounds are sufficient to set aside the decision and more so because of the urgency of this matter since the applicant is terminally sick and requires palliative care." The judgment thus rests on the value of *ease of suffering*. The patient could not be cured, but his pain and suffering could and should be managed until the end of life. The Court also writes:

What [the applicant] is in need of is humanness [sic], empathy, and compassion. These are values inherently embodied in *Ubuntu*. When these values are weighed against the applicant's continued imprisonment, then, in my view, his continued incarceration violates his human dignity and security, and the very punishment itself becomes cruel, inhuman and degrading. [Emphasis added]

Ubuntu is a complex concept that is defined and unpacked in greater detail in the Discussion section, though it is clear from this quote alone that it encompasses at a minimum the substantive value of *respect and dignity*.

New Clicks (2005)25

There is primarily a tension between *personal financial impact* and *health benefits and harms* in this case. As Chaskalson wrote:

The cost of medicine is relevant to accessibility, but it is not the only factor. The medicine must be available to those who require it. Pharmacies are an essential component of the distribution chain. If pharmacies go out of business the accessibility of medicines will be impaired. An appropriate fee is thus one which at least strikes a balance between these requirements of cost and availability.

Patients must be able to afford their medicine, but access to beneficial medicines will be harmed if too many pharmacies close due to a dispensing fee that threatens their financial viability.

The financial viability of rural and courier pharmacies is particularly important because they serve vulnerable populations. Courier pharmacies, Chaskalson writes, "are of particular importance to people

who because of illness or other reasons cannot easily access community pharmacies. They serve chronically ill patients providing them with medication (often expensive) at their homes and process claims for refunds from medical aid schemes." Additionally, those living in rural areas may already find it more difficult to access and pay for medication. The closure of rural pharmacies would thereby further imperil the health of these groups. For these reasons, the Court concludes, "particular attention needs to be paid to the circumstances at least of rural and courier pharmacies to ensure that the right of access to health care is not prejudiced by driving such pharmacies out of the market." The Court's finding that the dispensing fee was inappropriate therefore largely rests on the equity-related considerations of giving special attention to the vulnerable and avoiding the widening of health inequities.

Westville (2006)26

In its judgment, the Court referred to the burden of the health condition. The Court quotes from its earlier decision in TAC to describe the HIV/AIDS pandemic as "an incomprehensible calamity," "the most important challenge facing South Africa since the birth of our new democracy," and a "top priority." The values of health benefits and harms, equity, and ease of suffering were also central to the judgment. The Court writes that, "the applicants are seriously ill," and that, "if ARV medicines are not made available to offenders at [Westville Correctional Centre] immediately, many of them will suffer irreparable harm and in all likelihood premature death." Additionally, the Court states that the prisoner's "vulnerability cannot be denied." One reason for this vulnerability is that the "prospects of emerging from prison alive is seriously compromised because of the HIV/AIDS pandemic" and "severe overcrowding." As a result of this vulnerability, prisoners deserve "special consideration." The Court also invoked the consideration of equal treatment for those with equal health needs when observing that, "[i]t is basically only Westville Correctional Services which happen not to be participating in the Government [HIV/AIDS treatment] program." In the Court's view, there is no relevant difference between the Westville Correction Centre and other prisons that can justify this unequal treatment. Finally, the Court appears moved by a desire to ease the suffering of prisoners with HIV/AIDS, as exemplified in a quote from an earlier judgment: "Even the worst of convicted criminals should be entitled to humane and dignified death."

While the Court acknowledges that *budget impact* is a relevant consideration given the language of sec-

tion 27, they note that, "[t]he respondents have not made the lack of resources an issue." As such, the considerations presented above easily outweigh budget impact considerations.

Mazibuko (2009)²⁷

The applicants first argued that the Court should determine the amount of water per person per day that would fulfil the right in section 27(1)(b). In their view, this amount should be higher than what the city policy provided at the time. As in *TAC*, the Court again disavowed the adoption of a "minimum core" approach to interpreting the State's obligation to fulfil socioeconomic rights. Referring to its earlier *Grootboom* decision, the Court writes, "[T]his Court rejected the argument that the social and economic rights in our Constitution contain a minimum core which the State is obliged to furnish." Quoting that decision, the Court reasons:

It is not possible to determine the minimum threshold for the progressive realisation of the right of access to adequate housing without first identifying the needs and opportunities for the enjoyment of such a right. These will vary according to factors such as income, unemployment, availability of land and poverty. The differences between city and rural communities will also determine the needs and opportunities for the enjoyment of this right. Variations ultimately depend on the economic and social history and circumstances of a country.

Instead, the Court invokes the *equity*-related consideration of giving special attention to the vulnerable by again quoting *Grootboom*: "a measure [to realize a socio-economic right] will be unreasonable if it makes no provision for those most desperately in need."

The applicants also argued that the water policy failed to distinguish between the rich and poor. In response, the Court compared a universal approach and a means-tested approach to allocation that could better distinguish between the rich and the poor. The Court described the universal approach as, "administratively simple and therefore cheap but it provides benefits to those who do not need them." In contrast, the means-tested approach is better able to match benefits to household need. However, this approach is also "...extremely onerous administratively. The system is expensive to run. It is time consuming. It is open to fraud. And it also requires that the City has the ability to check whether the applicants' statement of income is correct or not, and keep this information

continuously updated." According to the Court's reasoning, the decision about whether to implement a universal or means-tested allocation approach must balance equity, interpreted as giving special attention to the vulnerable, on one side and budget impact and systems factors and constraints on the other. The means-tested approach has an additional drawback in that it "requires citizens to apply and to prove that they are poor" which "is often regarded as undignified" and may result "in a situation where many potential beneficiaries prefer not to come forward." That is, a means-tested approach may result in feelings of stigma or inferiority, considerations related to the value of respect and dignity, that could also undermine the goal of the approach with respect to *equity*. Overall, the Court determined that the city's adoption of a universal allocation approach was reasonable given these competing considerations.

The Court acknowledges a similar tension in its response to the applicants' third argument that the policy should have allocated water per person:

Establishing a fixed amount per stand will inevitably result in unevenness because those stands with more inhabitants will have less water per person than those stands with fewer people. This is an unavoidable result of establishing a universal allocation. Yet it seems clear on the City's evidence that to establish a universal per person allowance would administratively be extremely burdensome and costly, if possible at all.

Despite this "unevenness," the Court finds that the per stand allocation is "generous in relation to the average household size". The importance of addressing remaining inequalities resulting from a universal allocation scheme is outweighed by the significant burden that doing so would place on the budget and administrative system.

Discussion

Identification

All but one substantive value of the provisional SAVE framework (*Impact on safety and security*) were identified in at least one judgment, and a majority of the SAVE values were identified in two or more judgments (see Table 4). This finding suggests that the SAVE framework largely succeeded in identifying substantive values that are important and relevant in the SA context from the perspective of the constitutional right to access health care. Our findings also demonstrate that the substantive reasoning of the courts can be analyzed and understood using the principles

of the SAVE-UHC framework, indicating alignment between the framework and the court cases. Nevertheless, future efforts to develop substantive value frameworks for priority setting in other national contexts should consider conducting an inductive content analysis of legal judgments and other legislative materials sooner in the framework development process to inform the earliest stages of identifying framework values.

One potential additional substantive value inductively identified during the analysis is *ubuntu*, identified in the Du Plooy case. Ubuntu is mentioned in the Constitution, but not defined. The majority decision from S v Makwanyane and Another provides one definition: "While [ubuntu] envelops the key values of group solidarity, compassion, respect, human dignity, conformity to basic norms and collective unity, in its fundamental sense it denotes humanity and morality. Its spirit emphasizes respect for human dignity, marking a shift from confrontation to conciliation."28 Others add that *ubuntu* invokes the importance of interpersonal connection and special consideration of the most vulnerable in society.29 Ubuntu is thus a complex multi-faceted value that appears to encompass or incorporate elements of several of the substantive values already comprising the SAVE framework, including social cohesion, ease of suffering, respect and dignity, impacts on personal relationships, and equity (see Table 4). Still, explicitly referencing *ubuntu* in the work of an HTA body could underscore its specificity to the SA context.

Interpretation

The court judgments offer several lessons about the interpretation, or specification into related considerations, of the SAVE-UHC values. In Van Biljoen, the Court explicitly interprets health benefits and harms in terms of both extended life expectancy and enhanced quality of life. This interpretation could support the use of summary measures of population health (i.e., health measures that integrate mortality and morbidity) like disability-adjusted life years (DALYs) or quality-adjusted life years (QALYs) to inform priority-setting decisions. Summary measures are used in several countries to assess the relative effectiveness of drugs and other health care interventions. Their use, however, raises a number of important ethical concerns³⁰ and may face legal opposition in countries with natural-law-based constitutions.³¹ A legal precedent that can be read as supporting the use of summary measures may provide some justification for and legitimacy around their use in HTA to inform priority-setting in SA.

In six of the seven judgments that identify equity (Van Biljoen, TAC, Khosa, New Clicks, Westville, and Mazibuko), the courts argue for giving special attention to vulnerable populations when formulating measures to fulfil the right to access health care, thus reflecting a central equity-related consideration from the SAVE substantive values framework. These cases identify several groups as "vulnerable", including prisoners, women and children, those who cannot afford medical services, the elderly, and patients with chronic illness or who live in rural areas. Moreover, the TAC and Mazibuko judgments appear to de-emphasize sufficientarianism — the view that all should receive some minimum amount of an important resource or good such as health care³² — as a relevant consideration of equity when assessing the reasonableness of state measures to fulfil the right to health. In Mazibuko, the Court reasons that a minimum threshold cannot be defined independent of a particular social context. To do so through the courts would be "counter-productive." Social justice theorists have raised a similar concern, noting that relative levels of economic development and social organization across a particular society will influence what level of some resource like access to health care can reasonably be considered minimally sufficient.33 Additionally, in SA the rejection of minimum core obligations is linked to the concept of "progressive realization;" as rights are realized, the standard for what is owed over time will evolve. These findings suggest that an HTA body in SA that applies the principle of equity should favor focusing special attention on vulnerable groups and to reduce or avoid widening health inequities (mentioned explicitly in several cases), rather than quantifying and ensuring that all receive some minimum amount of health care, if the goal is to make decisions aligned with the right to access health care.

In four of its judgments, the Court applied the consideration of providing equal treatment to those with equal needs.34 In three of these cases (TAC, Khosa, and Westville), this consideration was invoked to support expanding access to health care for more individuals. In one case (Soobramoney), this consideration supported a restriction on access to health care. The Court reasoned that if the applicant were provided the care he sought, then all other similarly situated patients would be owed the same care. Given resource and staffing constraints, however, offering this care would have presented too great a challenge and the opportunity costs in terms of foregone effective treatments to a much larger population of patients would have been too large. These findings show that incorporating considerations of equity in priority-setting is complex and will not always support expanded access to health care; considerations of equity will sometimes entail a denial of access to services for some individuals or groups.³⁵

The Court also articulated several explicit considerations related to the value of *respect and dignity* in its judgments. In *TAC* and *Khosa*, the Court discussed the importance of fostering conditions that enable individual autonomy. In *Khosa* and *Mazibuko*, the Court considered the ways in which state measures may impact people's experience of self-respect or perpetuate stigma against particular individuals or groups. Finally, the Court in *TAC* considered how a particular policy may fail to respect important cultural values. Each of these considerations is explicitly included in the SAVE framework, again suggesting alignment between the values and considerations identified to guide HTA in SA and the reasons used by the courts to assess rights-based claims to health care.

Balancing

Resolving conflicts within and between competing values or considerations presents a major challenge for priority-setting, and diverse approaches for managing these potential conflicts exist. For example, values or considerations can be ordered according to lexical priority, meaning that they must be satisfied in a specific order. Rawls's principles of justice are a well-known theoretical expression of lexical priority. On this theory, basic liberties such as the freedoms of speech and assembly cannot be traded off to achieve higher levels of material well-being for some groups.³⁶ An example of lexical priority in health priority-setting involves considerations of health benefit, or the effectiveness of a particular treatment. After all, a treatment must be minimally effective for there to be a reason to consider its value in other dimensions. Beyond considerations of effectiveness, however, lexical prioritization may not be a realistic approach for health prioritysetting. Instead, priority-setting bodies may choose to assign explicit numeric weights to each value or consideration. This approach raises major ethical and practical questions, including how the weights should be estimated and whose preferences should be used, whether weights are preferentially independent, and the extent of the role they should ultimately play in informing decision-making.37 Beauchamp and Childress describe a more deliberative approach to balancing competing principles and considerations that eschews reliance on a set of decision rules and instead expects decision-makers to develop and apply capacities of moral character such as compassion and discernment.38 Ultimately, a SA HTA body will need to resolve this issue of balancing. Drawing on SA court cases to inform this balancing process will not only offer guidance to an HTA body, but also better ensure that HTA decision-making aligns with legal requirements. Our findings include several general insights that may inform this issue.

First, the frequency with which different substantive values appear across cases could partially inform their relative importance to HTA decision-making. For example, *equity* and *budget impact* appeared in the highest number of cases (n=7 and 6, respectively), suggesting that these values may deserve relatively greater weight when making priority-setting decisions

Some general patterns regarding the balancing of specific values also emerged from our analysis. Equity and budget impact co-occurred in six judgments (Van Biljoen, Soobramoney, TAC, Khosa, Westville, and Mazibuko). In each of these judgments, the Court displays a pattern of prioritizing the equity-related considerations of reducing health inequities and giving special attention to the vulnerable when assessing the reasonableness of measures taken to fulfil the right to access health care. However, in the two cases where there is evidence that deciding in favor of the claim would result in a substantial budget impact, the Court either de-prioritizes these equity considerations in

It is less clear how an HTA body should balance short- and long-term needs beyond crisis situations. For example, a youth HPV vaccination program has immediate costs, but the benefits will accrue many years in the future. Depending on how costs and benefits are discounted in the economic evaluation of such a program, interventions with longer-term benefits may appear more or less favorable.

in the SA context. Relatedly, several values appeared in the judgments of only one or two cases. One possible interpretation of this finding is that these values should receive relatively less weight than the others in HTA decision-making. It should be noted, however, that several of these less commonly identified values social cohesion, ease of suffering, respect and dignity, and impacts on personal relationships — are those that comprise the concept of *ubuntu*. This concept has been contrasted with Western values.³⁹ As a result, a SA HTA body may wish to afford these values greater significance than they have typically been given by HTA in Western contexts (which tend to focus on clinical- and cost-effectiveness and equity). Additionally, this finding may ameliorate potential concerns that the SAVE framework is too complex and thus impractical for real-world decision-making due to the substantial cognitive load it might place on decision-makers. 40 This finding instead suggests that certain values in the SAVE framework may only be occasionally relevant to particular priority-setting decisions; much of the time, an HTA body may find that it must balance the application of only four or five salient values, rather than all twelve. This possibility is further supported by the fact that the average number of values identified in each judgment was less than five, while the maximum identified was seven.

favor of budget impact considerations (*Mazibuko*) or instead explicitly applies a utilitarian interpretation of equity wherein the greatest overall health benefit to the population is favored (*Soobramoney*). Such decision rules, which clarify relationships between specific values or considerations by stipulating the different conditions under which one value or consideration ought to be prioritized over another, might help to structure HTA priority-setting in SA. Of course, these case judgments do not indicate a specific budget impact threshold that would trigger whether considerations related to reducing health inequities or giving special attention to the vulnerable ought to be deprioritized and by how much. Resolving such issues could be an important responsibility of an HTA body.

A second pattern emerged in the Court's application of the *burden of the health condition* value. Two judgments referenced this value (*TAC* and *Westville*). In each, the Court identified the HIV/AIDS crisis as imposing a particularly heavy burden in the SA context. Interventions that address HIV/AIDS may therefore deserve special attention in the work of a SA HTA body. This prioritization could be achieved at either the topic selection stage, by favoring HIV/AIDS interventions for analysis and appraisal, or at the appraisal stage of HTA by, perhaps, permitting interventions with less favorable incremental cost-effectiveness

ratios to still be recommended for coverage if they target HIV/AIDS. Importantly, an HTA body will need to determine the extent to which HIV/AIDS should be prioritized relative to other health conditions, especially those that disproportionately impact other vulnerable populations, such as the elderly.

Additionally, in TAC the Court gave substantial weight to the short-term health benefits of expanding access to nevirapine relative to considerations regarding the long-term sustainability of a more comprehensive program to interrupt HIV/AIDS transmission. This represents another possible decision rule for HTA priority-setting in SA: interventions that address urgent public health crises ought to be assessed especially in terms of their ability to deliver substantial short-term health benefits rather than their long-term effectiveness or impact on the health system. It is less clear how an HTA body should balance short- and long-term needs beyond crisis situations. For example, a youth HPV vaccination program has immediate costs, but the benefits will accrue many years in the future. Depending on how costs and benefits are discounted in the economic evaluation of such a program, interventions with longer-term benefits may appear more or less favorable.

Looking Forward

One limitation of this analysis is its focus on majority judgments only. While dissenting opinions may include important expressions of alternative values and perspectives or a suggestion as to how values may evolve over time, 41 only two of the cases selected for analysis included any dissenting opinion. We also acknowledge that values identified in case law can only be one source of insight for the work of an HTA body. As the SAVE-UHC project has demonstrated, the work of an HTA body can and should draw on values identified in relevant national legislation, the bioethical literature, and deliberations with key stakeholders. 42

If an HTA body is ultimately established to inform NHI in SA, future research could focus on the interaction between HTA and the courts. As new health rights cases are decided over time, the content analysis methodology described here should be repeated to determine whether and how jurisprudence around the right to health care evolves, and if so, the role played by HTA in this evolution. Only very recently has research begun to systematically explore the impact of HTA on right to health litigation; for instance, Wang et al. quantitatively analyzed over 13,000 health care access cases in Brazil from both before and after the creation of a new national HTA body in 2011.⁴³ However, a quantitative approach is likely only suitable in

contexts like Brazil where there is a large volume of cases. The qualitative content analysis methodology used here represents a systematic research approach that is better suited to contexts where many fewer judicial decisions exist (by several orders of magnitude), such as SA.

As an example of what this research into the impact of HTA on right to health jurisprudence might look like in SA, recall a key claim from the TAC decision: "Those whose needs are the most urgent and whose ability to enjoy all rights therefore is most in peril, must not be ignored by the measures aimed at achieving realization of the right." An HTA body may establish standards for analyzing and appraising the potential impact on disadvantaged populations of covering (or not covering) a health care intervention within UHC. These standards could enhance the accuracy or consistency of the courts' assessment of whether "those whose needs are the most urgent" are appropriately considered in measures to realize the right to access health care. Of course, the courts may also influence HTA. For example, future cases challenging or overturning HTA decisions should be studied to determine whether they are successful examples of holding HTA accountable to a substantive value framework, such as the one developed by the SAVE-UHC project.

Finally, the methodology described here could be applied in other countries where HTA must operate in the context of judicialization. Applying this methodology in different national contexts may require some adaptation. For example, whether a deductive or inductive analytic approach is used may depend on the maturity of HTA in any given country. Another potential adaptation could be the decision to include dissenting opinions in the content analysis if disagreement among judges is more common. Other applications of this work could set out to compare values across different types of health rights cases. For instance, three of the cases analyzed here focused on prisoners as a special population. In national contexts where the number of relevant cases is sufficiently large, researchers could study whether the identification, interpretation, or balancing of values differs across types of cases.

Conclusion

Some form of HTA has been on the agenda in SA for over two decades,⁴⁴ most recently in the NHI White Paper,⁴⁵ though a national HTA body to inform NHI has yet to be established. Our study describes insights drawn from landmark health rights cases — related to the identification, interpretation, and balancing of substantive values — that can inform the development and

application of HTA to support NHI. Additionally, our findings support the possibility of a mutually supportive relationship between a rights-based and priority-setting approach to achieving UHC. If an HTA body is established in SA, researchers should continue to assess the relationship between HTA and the courts to understand how each institution influences the other.

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