Applications of GRADE-Adolopment in South African health policy: Assessing affordability in South Africa's GRADE-Adolopment processes

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Background. South Africa's (SA) progress toward universal health coverage (UHC) is marked by efforts to prioritise primary healthcare and improve access to cost-effective and affordable health services. Central to this reform is the adoption of evidence-based processes, such as Health Technology Assessment (HTA) and the GRADE-Adolopment approach, which support the contextualisation of global clinical guidelines through local epidemiological, health system, and cost data. Despite progress in considering clinical effectiveness and cost-effectiveness, explicit integration of affordability and equity considerations remains limited. This review assessed SA case studies applying the GRADE-Adolopment and Evidence-to-Decision (EtD) frameworks to evaluate how affordability, particularly through budget impact analysis (BIA), has been addressed.

Methods. We conducted a review of both published and grey literature from 2015 to May 30 2025, searching PubMed, Scopus, and the websites of the SA National Department of Health and the Council for Medical Schemes, using terms such as 'GRADE,' 'Adolopment,' 'South Africa,' 'guidelines,' and 'affordability.' Eligible studies included those applying the GRADE or Evidence-to-Decision (EtD) frameworks in the development of guidelines or policies in South Africa. We extracted data on the use of GRADE, EtD domains, and affordability frameworks (including cost-effectiveness analysis, budget impact analysis, equity trade-offs, resource mapping, and feasibility), assessing their impact on policy through comparative analysis. Additionally, we performed inductive thematic analysis to synthesise cross-cutting lessons and barriers related to the integration of affordability within decision-making processes.

Results. Across six SA case studies, the integration of affordability assessments within GRADE-Adolopment processes varied considerably. National initiatives demonstrated structured approaches, consistently applying cost-effectiveness and budget impact analyses in guideline development. In contrast, subnational or project-based adaptations often addressed affordability reactively, due to limited data and health economics capacity. Key themes included the reactive nature of affordability considerations, the enabling role of centralised decision-making structures, and challenges from inadequate data and technical expertise. Several case studies highlighted the importance of using transparent, context-specific EtD frameworks to support consistent, equitable, and feasible policy decisions in resource-constrained settings.

Conclusion. Affordability was inconsistently integrated into the guideline development processes, with structured assessments more common in nationally led initiatives. Conversely, reactive and informal approaches dominated at subnational levels. Given fiscal constraints, tools such as league tables and expansion pathways could be more effective in prioritising affordable, high-impact interventions. Institutionalising such approaches and strengthening local capacity will support sustainable, evidence-based policy under SA's National Health Insurance.

Keywords. GRADE-Adolopment; affordability; guideline development; health technology assessment; budget impact analysis; South Africa.

South Afr J Public Health 2026:8(3):e4100. https://doi.org/10.7196/SHS.2026.v8i3.4100

South Africa (SA) is navigating a complex journey toward achieving universal health coverage (UHC), with primary healthcare as its foundation.[1] The country faces challenges such as limited resources, financial constraints, and growing health needs, which require difficult decisions about which services to prioritise. Central to this effort is the commitment to ensure that the population has access to the medicines and services they need, at fair and affordable prices, through more equitable pricing and reimbursement systems.[2] Evidence-informed policymaking plays an essential role in this goal.[3] Health Technology Assessment (HTA) is a multidisciplinary process that evaluates not only clinical effectiveness, but also organisational, social, economic, legal and ethical aspects of health interventions.[4] While SA is making progress in institutionalising HTA, the establishment of a centralised HTA agency is still a future goal.[5] During this transitional phase, practical and scalable approaches are needed to bridge the gap between global evidence and local policy.

The GRADE-Adolopment approach, combining adoption, adaptation, and *de novo* development, offers a structured method to contextualise global guidelines using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Evidence-to-Decision (EtD) framework.[6] Rather than relying solely on resource-intensive primary assessments, SA has increasingly leveraged global HTA outputs, such as WHO and NICE guidelines. These guidelines are contextualised with local epidemiological, health system, and cost data to define fit-for-purpose, cost-effective entitlements. This pragmatic approach acknowledges existing capacity constraints while promoting timely, evidence-informed policymaking.

However, integrating cost-effectiveness, affordability and equity considerations into guideline development remains underexplored in SA. While these concepts are interrelated and essential for informed decision-making, they each serve distinct purposes in resource allocation and priority setting. Cost-effectiveness evaluates the value for money of an intervention by comparing its health outcomes to its costs, which helps identify efficient options.[7] Affordability, on the other hand, focuses on whether an intervention can be financed within existing budgetary constraints, typically assessed through budget impact analysis (BIA).[7] Equity focuses on the fair distribution of health benefits and financial protection, ensuring that policy choices do not exacerbate disparities or exclude vulnerable groups.[8]

Incorporating these considerations into the GRADE-Adolopment process enables more informed and context-sensitive decisions under fiscal constraints. This review synthesises South African case studies applying GRADE-Adolopment and assesses how affordability frameworks have been integrated. The findings may provide insight for benefit design, including the selection of health interventions for inclusion in health benefit packages and decisions on pricing and reimbursement.

Case identification and eligibility criteria

We performed a targeted, systematic search and review of the published and grey literature from 1 January 2015 to 30 May 2025. The start date was selected to align with the 2015 adoption of the United Nations Sustainable Development Goals (SDGs), including target 3.8 for achieving UHC by 2030.[9] Searches were performed in PubMed, and adapted for Scopus, the SA National Department of Health and Council for Medical Schemes (CMS) websites and Google Scholar, using terms such as 'GRADE', 'adolopment,' 'evidence-to-decision', 'South Africa,' 'guidelines', 'health policy', and 'affordability'. Full search strategies for each source are provided in the supplementary material. Inclusion criteria for eligible studies included: (*i*) application of GRADE/GRADE-Adolopment or contextualised EtD framework; (*ii*) implementation within the SA health system; (*iii*) explicit inclusion of affordability/resource use considerations; and (*iv*) publicly accessible (peer-reviewed or grey literature). We excluded publications that applied evidence appraisal, but not the GRADE EtD framework; reported South-African-related clinical evidence without policy or guideline implementation; and mentioned affordability conceptually, without explicit assessment or application to decision-making.

Extracted data included the type of guideline or policy, level of implementation (national or subnational), GRADE application, EtD domains employed, and affordability assessments (e.g. cost-effectiveness analysis, budget impact analysis, or equity considerations).

Grey literature documents (e.g. national guideline reports, policy documents, HTA outputs, CMS consultation papers) were screened in the same way as published literature. Titles and available abstracts or executive summaries were reviewed first, followed by full-document assessment. Documents that were not publicly accessible (e.g. internal departmental reports) could not be included.

Affordability framework

Resource use and cost-effectiveness are considerations in the GRADE EtD framework. In this context, affordability refers to whether a health system can implement an option within its available budget, regardless of how cost-effective it may be.[10] Even when an intervention is deemed to provide good value for money, limited fiscal space or high budget impact may render it unaffordable, making it less likely to receive recommendations for implementation.

In SA, assessments of affordability have been integral in shaping health policy decisions, including updates to the public-sector national Essential Medicines List (EML). The National Essential Medicines List Committee (NEMLC) evaluates affordability alongside cost-effectiveness to ensure that selected medicines are both clinically appropriate and financially sustainable within the public health system.[11]

Health technology assessments (HTAs) further strengthen this approach by incorporating cost-effectiveness analysis, BIAs, and equity considerations, ensuring that vulnerable populations are not disproportionately disadvantaged. The Prescribed Minimum Benefits (PMB) Definitions Guidelines process under the Council for Medical Schemes (CMS) has marked a significant shift toward evidence-informed policy through the adoption of the GRADE and EtD frameworks.[12] These methodologies

improve the transparency and methodological rigour of benefit specifications by basing recommendations on systematically appraised clinical evidence.

Despite progress, the explicit and systematic integration of affordability considerations remains limited. Integrating BIA into the PMB Definitions Guideline process has been identified as a crucial next step. This approach complements cost-effectiveness by estimating the financial implications of adopting specific health interventions over short- to medium-term planning horizons. By explicitly integrating affordability into the GRADE-Adolopment process, policymakers can make informed, balanced decisions that align clinical benefit with economic and social realities.[13]

Affordability and equity were treated as distinct EtD domains. In this review, affordability refers to fiscal feasibility, including budget impact, resource requirements, and short-term financial constraints. Equity, in contrast, concerns the distributional consequences of implementing an intervention, including whether particular groups, such as adolescents, rural populations, or people with drug-resistant TB, benefit disproportionately or face greater barriers to access. Although these domains may interact, they represent analytically distinct considerations within the GRADE EtD framework and were assessed accordingly in this synthesis.

Affordability assessment rubric

To enable consistent comparison across the included GRADE-Adolopment cases, we developed a rubric to classify the extent to which each affordability component was addressed. Each domain, cost-effectiveness analysis, budget-impact analysis, resource-use assessment, and consideration of equity-related financial implications, was categorised as:

- Strong: A formal analysis was conducted (e.g. cost-effectiveness modelling, BIA or normative costing) and explicitly incorporated into the GRADE EtD deliberations.
- Moderate: Relevant evidence was presented and discussed qualitatively, but without a complete economic evaluation or explicit integration into an EtD domain.
- Limited: Affordability or resource-use considerations were acknowledged but not assessed.
- Absent: No evidence or discussion of the domain.

Ratings reflect methodological completeness and transparency, substantiated by evidence presented in the results.

Thematic synthesis of lessons for future pricing reforms

A thematic synthesis was conducted to extract cross-cutting lessons relevant to the design and implementation of future medicine pricing reforms. Following Braun and Clarke's six-step framework for thematic analysis (2006),[14] the process included: (*i*) familiarisation with the data through repeated readings; (*ii*) generation of initial codes across cases; (*iii*) searching for patterns and themes across extracted material; (*iv*) reviewing and refining themes about the dataset; (*v*) defining and naming themes with attention to policy relevance; and (*vi*) producing a coherent synthesis highlighting key implications for pricing policy and affordability governance. This inductive process enabled the identification of common barriers, enabling factors and contextual considerations that shaped how affordability was addressed across different cases.

Results

The search identified 79 records across all sources (PubMed, *n*=11; Scopus, *n*=4; Google Scholar, *n*=14; National Department of Health and Council for Medical Schemes websites, n=49). After removing duplicates (*n*=4), 75 unique records underwent title and abstract (or executive summary) screening. Of these, 51 records were excluded for not applying GRADE or GRADE-Adolopment methods, lacking an EtD framework, or omitting explicit affordability or resource-use considerations.

Nine full-text documents were assessed for eligibility. Seven were excluded at this stage: two did not involve guideline adaptation or GRADE-Adolopment processes;[15,16] one case was a capacity-building initiative on adopting/adapting guidelines in three countries (including SA);[17] and four described a contextualisation method (including GRADE-Adolopment) but did not assess affordability.[18-21] Two cases met all inclusion criteria. The PRISMA flow chart (Fig. 1) summarises the identification, screening, and selection process.

The two included cases[22,23] represent the most complete and methodologically transparent applications of GRADE-Adolopment or contextualised EtD frameworks within the SA health system that explicitly incorporated affordability or budget/resource considerations. These cases varied in focus (clinical guideline development and health technology assessment-type cases) and in the depth and formality of affordability analyses employed within their GRADE-Adolopment applications (e.g. BIA, cost-effectiveness analysis, and fiscal-space assessment). Key features of each case are summarised in Table 1.

Summary of included case studies

The two case studies demonstrated clear but varying applications of affordability assessment within their GRADE-Adolopment applications. Table 2 provides a structured comparison of the decision contexts, evidence sources and economic evaluations.

Drug-resistant tuberculosis (DR-TB) treatment guideline (2022)

The National Department of Health (NDoH) conducted an Adolopment of the WHO 2022 consolidated DR-TB guidelines to inform national treatment policy. The decision context centred on introducing shorter, all-oral regimens with improved safety profiles. The GRADE EtD framework was explicitly applied, including consideration of resource use, equity, acceptability, and feasibility. Affordability was assessed through normative cost analysis of SA DR-TB service delivery platforms and review of WHO-linked cost-effectiveness studies comparing 6-month with longer regimens. The SA analyses showed that while all-oral regimens were more expensive per-patient than injectable-based regimens, they were cost-saving when accounting for reduced treatment duration, lower toxicity-related management costs, and improved adherence. The EtD conclusion supported national

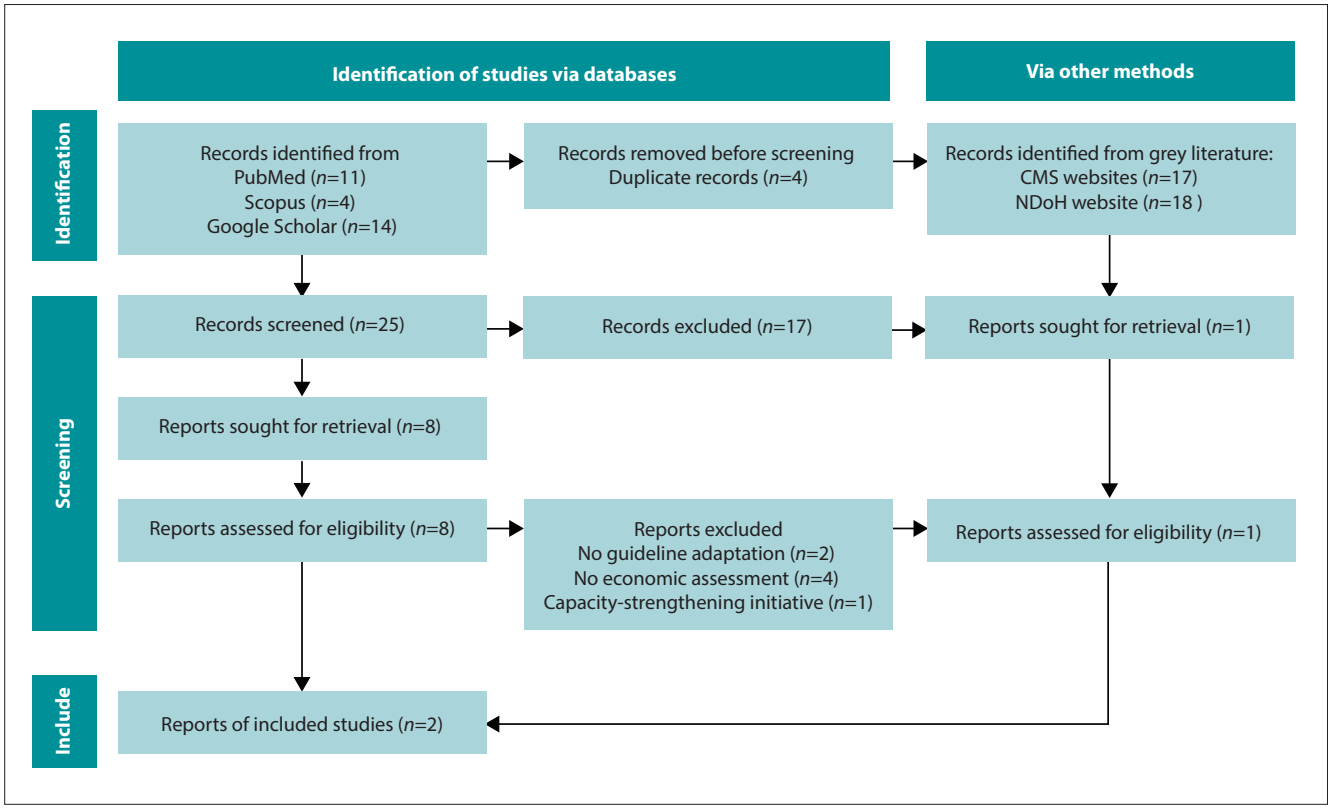

Fig.1

Table 1. Summary of GRADE-Adolopment case studies in SA

Case	Decision context	GRADE-Adolopment process	Evidence use	EtD criteria applied	Affordability/ economic assessment
1. DVR for HIV PrEP[22]	Assessment of whether the DVR should be included as a female-controlled HIV-prevention option in SA public-sector guidelines	Structured appraisal of global evidence for local relevance; Consideration of contextual factors (equity for adolescent girls and young women, acceptability, feasibility of delivery); Guidance developed to inform national HIV-prevention policy deliberations	Systematic review of clinical effectiveness and safety; SA HIV incidence and demographic data; Evidence on acceptability, uptake, and user preferences	Benefits/harms, Cost, Acceptability, Feasibility, Equity	SA-specific cost-effectiveness analysis incorporating local HIV incidence patterns; BIA estimating national rollout costs under different targeting strategies; Overall conclusion: DVR is cost-effective in high-incidence populations and has moderate budget impact when offered as part of a choice-based prevention package
2. SA Adolopment of WHO DR-TB Treatment Guidelines[23]	Updating national DR-TB treatment policy by assessing WHO-recommended shorter, all-oral regimens to replace longer injectable-based regimens	Full application of GRADE EtD domains (benefits/ harms, resource use, equity, acceptability, feasibility); Explicit adoption and adaptation of WHO recommendations to the SA context; Structured decision-making within the NEMLC	WHO evidence profiles and systematic reviews on efficacy and safety; South African programmatic data on toxicity, adherence, and implementation feasibility; Local clinical-expert input	Benefits/harms, cost, acceptability, feasibility, equity	SA normative cost analysis comparing the existing DR-TB regimen to shorter all-oral regimens; Review of WHO-linked cost-effectiveness modelling, showing improved value for money; Overall conclusion: shorter all-oral regimens are cost-saving when considering treatment duration, toxicity, and improved adherence

SA = South Africa; GRADE = Grading of Recommendations Assessment, Development and Evaluation; EtD = evidence-to-decision ; DVR = dapivirine vaginal ring ; BIA = budget impact analysis; PrEP = pre-exposure prophylaxis; DR-TB = drug-resistant tuberculosis; WHO = World Health Organization; NEMLC = National Essential Medicines List Committee.

Table 2. Affordability assessment across included GRADE-Adolopment cases

Affordability domain	DR-TB Guideline (2022)	Dapivirine vaginal ring (2024)
Cost-effectiveness analysis	Strong: Formal analysis incorporating WHO-linked and local contextualised models showing improved value for money of shorter all-oral regimens.	Strong: SA-specific model demonstrating cost-effectiveness in high-incidence populations.
Budget-impact analysis (BIA)	Strong: Normative costing and regimen-level comparisons integrated into EtD deliberations, informing national affordability.	Strong: Formal BIA assessing fiscal implications across rollout scenarios.
Resource-use assessment	Strong: Detailed appraisal of service-delivery needs (monitoring, staffing, toxicity management) used in decision-making.	Moderate: Qualitative assessment of resource implications (procurement, delivery platforms, user support).
Equity-related financial considerations	Moderate: Equity considered in EtD (reduced toxicity burden, improved regimen completion), though not quantified economically.	Moderate: Equity incorporated through epidemiological targeting (AGYW, high-incidence settings), not financially modelled.
Integration into EtD process	Strong: Economic evidence explicitly incorporated across EtD domains, informing national adoption.	Strong: Cost-effectiveness and BIA findings used to guide potential inclusion in HIV-prevention guidelines.

GRADE = Grading of Recommendations Assessment, Development and Evaluation; DR-TB = drug-resistant tuberculosis; WHO = World Health Organization; SA = South Africa; EtD = evidence-to-decision ; AGYW = adolescent girls and young women.

adoption of the shorter all-oral regimen as both clinically superior and financially viable for the public sector.

Dapivirine vaginal ring (DVR) for HIV prevention (2024)

This review was conducted to inform potential inclusion of DVR as a female-controlled HIV prevention option in public-sector guidelines. The assessment synthesised evidence on clinical effectiveness, contextual factors (adherence, acceptability and user preferences), and local epidemiology of HIV incidence among women. The economic component comprised a cost-effectiveness analysis using SA HIV epidemiological parameters and a budget-impact analysis for national rollout. The modelling showed that DVR is cost-effective in settings with high HIV incidence, particularly among young women, but has modest overall budget impact when introduced as part of a choice-based prevention package. The affordability conclusion emphasised that DVR could be introduced in a targeted manner to maximise value for money while maintaining equity considerations.

The EML reviews conducted by the NEMLC appeared to be the most comprehensive, incorporating both cost-effectiveness and BIAs as standard components of the review process. Across these two centrally mandated cases, affordability assessments were most robust, benefiting from established national processes such as the NEMLC and EML. Embedding economic evaluations within GRADE-Adolopment enhanced transparency, clarified clinical-economic trade-offs, and supported budget-aligned adoption decisions.

Thematic synthesis of lessons on affordability

An inductive thematic analysis of the two eligible GRADE-Adolopment cases identified four cross-cutting themes relevant to affordability assessments in SA guideline processes: (*i*) variable integration of economic evidence; (*ii*) the enabling role of national decision-making structures; (*iii*) data and capacity constraints; and (*iv*) the need for transparent, contextualised EtD processes.

Integration of economic evidence varied by decision context

Across the two cases, the strength of affordability assessment was closely tied to when economic evidence entered the process. In the DR-TB guideline, normative costing, service-delivery cost comparisons, and WHO-linked cost-effectiveness models were incorporated from the outset and explicitly considered within the GRADE EtD deliberations, allowing affordability to be evaluated alongside clinical evidence. In contrast, the DVR case produced robust cost-effectiveness and budget-impact analyses, but these were completed only after most evidence appraisal had concluded, limiting their influence on feasibility and resource-use discussions. This contrast illustrates that economic evaluation is most impactful when integrated early rather than added retrospectively.

National-level decision-making enabled structured affordability assessment

Affordability considerations were effectively addressed at the national level by institutions responsible for budgets. Both cases demonstrated the use of the GRADE-Adolopment methodology, evaluating cost, resource use, equity, and feasibility within an EtD framework. When oversight was provided by the NEMLC, affordability frameworks were applied more consistently.

Data and capacity limitations constrain consistent affordability assessment

Both cases showed that limited data and specialised economic capacity constrain the robustness of affordability assessments. The DR-TB guideline relied on normative rather than real-time expenditure data, affecting the precision of financial projections, while the DVR case required complex modelling based on behavioural and incidence assumptions that are not routinely maintained in programme datasets. These limitations restrict the ability to conduct sensitivity analyses, equity-impact assessments, and detailed resource mapping, all analytical components essential for fully contextualising affordability.

Transparent and contextualised EtD processes strengthen affordability governance

Both cases demonstrate the value of transparent EtD deliberations that integrate local evidence. In the DR-TB guideline, the EtD framework facilitated alignment of global recommendations with SA's cost structure, equity considerations, and operational constraints. In the DVR review, situating cost-effectiveness within local epidemiological profiles, particularly for adolescent girls and young women, supported targeted policy options that maximised value for money. Together, these cases show that contextualised EtD processes enhance policy relevance and provide clearer governance pathways for affordability decisions.

Discussion

This analysis of two SA GRADE-Adolopment case studies revealed significant variations in how affordability was variably incorporated into guideline development. In the DR-TB guideline, cost, resource use, and feasibility were systematically evaluated through normative costing, regimen-level comparisons, and WHO-linked cost-effectiveness models fully integrated into the GRADE EtD process. By contrast, the DVR review generated robust economic analyses; however, its late integration into deliberations potentially limited its influence on feasibility and resource-use considerations. This contrast highlights the importance of embedding economic analysis early within guideline adaptation. As defined earlier, affordability reflects fiscal feasibility, whereas equity relates to the distribution of benefits and burdens; these domains were considered separately in interpreting the findings

These findings are consistent with observations from other low- and middle-income contexts where the absence of institutionalised HTA mechanisms often results in fragmented considerations of affordability during guideline development.[24] Studies from Ghana and Ethiopia demonstrated that affordability and cost considerations are frequently implicit, primarily shaped by donor priorities or supply constraints, rather than structured local analyses.[25,26] Similarly, in Kenya, Otieno *et al*.[27] (2023) reported that despite the use of the GRADE framework to guide HIV guideline adaptation, assessments of affordability were delayed or omitted owing to capacity constraints. Where more systematic economic evaluation has influenced national policy, such as through HTA in India[28] and the Thai Universal Coverage Scheme,[29] this has been enabled by centralised governance structures with formal authority over benefit design. Similarly, SA's NEMLC provides an institutional platform that supports more consistent integration of affordability evidence within guideline processes.[30] In the DR-TB and DVR cases, affordability was explicitly assessed alongside other criteria such as equity and feasibility, informed by both global evidence and local data. This approach aligns with WHO's guidance on contextualising recommendations through systematic EtD frameworks.[31]

Both SA cases highlight persistent data and capacity constraints. The DR-TB guideline relied on normative rather than real-time expenditure data, while the DVR analysis required modelling assumptions that exceed routine programme data availability. These constraints limit the precision of budget-impact estimates, equity-impact assessments, and scenario analyses that are critical for contextualising affordability. A recurring challenge was the lack of local capacity for health economics and the limited availability of timely cost and utilisation data. As noted by Wilkinson *et al*. (2019),[32] constrained local health economics capacity remains a major barrier to routinely integrate affordability assessments into clinical guideline development, especially in time-sensitive or resource-constrained settings. Without reliable local data, policymakers must rely on extrapolation or assumptions, which may not accurately reflect contextual realities.

A key insight is that while cost-effectiveness analysis (CEA) is instrumental in promoting long-term efficiency by identifying interventions that yield the greatest health gains per unit of cost, it does not account for the short-term fiscal constraints often faced by health systems. To address this, affordability assessments are necessary to evaluate immediate budget impacts, funding availability, and opportunity costs within existing expenditure ceilings. This dual consideration is particularly critical in resource-limited settings where even cost-effective interventions may not be financially viable in the short term. By integrating both CEA and affordability, policymakers can ensure that recommended interventions are not only efficient in theory but also financially feasible, sustainable, and implementable in practice.[7] Therefore, budget impact and fiscal feasibility are decisive for implementation, especially when public health expenditure is under severe, sustained pressure.[33] While countries such as Thailand and Colombia use explicit affordability thresholds within their HTA systems,[29,34] such criteria may be impractical in SA's constrained fiscal environment. Instead, league tables and expansion pathways that rank interventions based on value for money, feasibility, and equity may offer a more flexible, adaptive model for setting priorities within a limited budget envelope.[35,36] Countries such as Ethiopia and the Philippines have successfully used these approaches to sequence UHC benefit expansion in a fiscally sustainable manner.[37] The emerging global literature, including the recent Lancet Global Health framework on affordability thresholds by Pichon-Riviere *et al*.[38] (2025), emphasises that budget-impact rules and fiscal feasibility criteria are increasingly recognised as core components of evidence-informed priority setting.

SA's existing policy infrastructure provides a strong foundation to apply similar strategies, but doing so will require investment in real-time cost data systems, sustained health economics capacity, and better monitoring of guideline implementation.

Study strengths and limitations

A key strength of the present study is the use of real-world case studies from diverse settings and clinical areas. This approach enabled a comparative assessment of how affordability is integrated into different decision-making contexts. Additionally, the thematic synthesis provided insights into common enabling factors and barriers across the various cases. However, there are limitations to consider. The study relied on available documentation and the authors' interpretations, which may underrepresent informal or unpublished processes. Additionally, while we focused on SA, the findings may not be generalisable to settings with different institutional or funding arrangements.

Policy implications

Our findings highlight the importance of explicitly integrating affordability frameworks into national guideline processes, supported by institutions, structured EtD tools, and health economics expertise. Strengthening these systems is essential for achieving equitable and sustainable health systems under universal health coverage. Policymakers should prioritise investments in HTA infrastructure, local data systems, and transparent decision-making platforms. For countries adapting global guidance, integrating local cost and feasibility assessments into adaptation processes is key to ensuring guidelines are evidence-based and feasible within budget constraints.

Conclusion

Affordability should be integrated systematically into guideline development to ensure practical and implementable policy recommendations. SA could consider adopting dynamic tools, such as Program Budgeting and Marginal Analysis (PBMA), Multi Criteria Decision Analysis (MCDA), scenario and threshold modelling, affordability thresholds in addition to BIA, league tables and expansion pathways, to facilitate sustainable, evidence-based service expansion towards NHI, while strengthening institutional and data systems to support real-time assessments of affordability.

Declaration. None.

Author contributions: Conceptualisation: PD, TDL (PhD candidate); Data curation: TDL; Analysis and interpretation of the data: TDL, PD; Drafting and revision of the article with final approval of the version of the article to be published: PD, TDL.

Acknowledgements. None.

Funding. None.

Conflicts of interest. None.

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Received 17 August 2025. Accepted 7 January 2026.