Implementation of Medicines Pricing Policies In Sub-Saharan Africa: Systematic Review

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Abstract

Background: High medicine prices contribute to increasing cost of healthcare worldwide. Many patients with limited resources in sub-Saharan Africa (SSA), are confronted with out-of-pocket charges, constraining their access to medicines. Different medicine pricing policies are implemented to improve affordability and availability. However, evidence on the experiences of implementations of these policies in SSA settings appears limited. To bridge this knowledge gap, we reviewed published evidence and answered the question: what are the key determinants of implementation of medicines pricing policies in SSA countries?

Methods: We identified policies, examined implementation processes, key actors involved, contextual influences on and impact of these policies. We searched five databases and grey literature; screening was done in two stages following clear inclusion criteria. A structured template guided the data extraction and data analysis followed thematic narrative synthesis. The review followed best practices and reported using PRISMA guidelines.

Results: Of the 5595 studies identified, 32 met the inclusion criteria. The results showed fourteen pricing policies were implemented across SSA between 2003 and 2020. These were in four domains: targeted public subsides, regulatory frameworks and direct price control, generic medicine policies and purchasing policies. Main actors involved were government, wholesalers, manufacturers, retailers, professional bodies, community members and private and public health facilities. Key contextual barriers to implementation were: limited awareness about policies, lack of regulatory capacity, and lack of price transparency in external reference pricing process. Key facilitators were: favourable policy environment on essential medicines, strong political will, and international support. Evidence on effectiveness of these policies on reducing prices of, and improving access to, medicines were mixed. Reductions in prices were reported occasionally and implementation of medicine pricing policy sometimes led to improved availability and affordability to essential medicines.

Conclusions: Implementation of medicine pricing policies in SSA shows some mixed evidence of improved availability and affordability to essential medicines. It is important to understand country-specific experiences, diversity of policy actors and contextual barriers and facilitators to policy implementation. Our study suggests three policy implications: avoiding ‘one-size-fits-all’ approach, engaging both private and public sector policy actors in policy implementation and continuously monitor implementation and effects of policies.

Systematic review protocol registration: PROSPERO registration number CRD42020178166.

Background

Over the past decade, the cost of accessing safe and quality healthcare has increased rapidly globally, attributed largely to the high prices of medicines (1). Additionally, there are concerns that most of the highly-priced medicines do not necessarily translate into improved health outcomes (2). In response to

high and increasing medicine prices, medicine pricing policies have been implemented to regulate prices of medicine and improve financial access (3, 4) to safe, quality and affordable medicines, one of the sustainable development goals in attaining universal health coverage by 2030 (5–7). A medicine pricing policy, can be defined as a set of written principles or requirements for managing the prices of medicines agreed or adopted by a public institution, a group of purchasing organizations, or individual health services (8).

Various medicine pricing policies exist to regulate supply of essential medicines (8). These policies can be categorised into (a) regulatory framework and direct price control e.g., reference pricing, mark-up regulation, voluntary licence agreement and tiered pricing, (b) targeted public subsides e.g., affordable medicines schemes, (c) generic medicine policy e.g., promoting generic prescribing and use and (d) purchasing policies e.g., pooled procurement. Reference pricing is the practice of benchmarking or referencing a medicine price to the price in one or several countries or purchasing authorities (8). Reference pricing remains a key policy widely employed globally as a regulatory policy (9–13). Mark-up regulation represents the additional charges and cost applied to the price of a medicine along the supply chain and this includes setting a single exit price at the ex-factory level (8). Generic medicine policies are widely recommended and applied in many contexts (14–16) to influence medicine prices through competitions (8). Pooled procurement through a single entity on behalf of individual purchasing authorities promotes competitive prices from manufacturer and suppliers (16–18).

The implementation of medicine pricing policies is influenced by multiple contextual barriers or facilitators of implementation approaches and processes. The facilitators include increased competition, skilful negotiations, pragmatic supply management and bulk purchasing (19). Medicine pricing policies are challenged by the prevailing market conditions in a particular context, including proximity to particular medicines, quantities purchased and functionality of regulatory framework (20, 21). There is, however, limited published evidence summarising influences on the implementation of medicines pricing policies across low- and middle-income countries (LMICs).

Most medicine pricing policies have been implemented in high income countries, but there is paucity of empirical data/evidence on implementation policies in LMICs, especially sub-Saharan Africa (SSA). Understanding medicine pricing policy implementation is particularly important as implementation of these policies can be a major challenge in LMICs where many patients with extremely limited resources need to provide out of pocket payments, thus impeding their access to medicines and putting them at further risk with increasing prices (11, 22).

With this backdrop, we conducted a systematic review on available medicine pricing policies in SSA, their implementation processes, contextual influences and impacts on prices and access to essential medicines. We addressed the main question: what are the key determinants of implementation of medicines pricing policies in sub-Saharan African countries? The review addressed four interrelated questions: (1) Which medicines pricing policies have been implemented in SSA and what are their key elements? (2) How have these policies been implemented (in relation to implementation approaches,

processes, involvement of actors, and their underpinning evidence)? (3) Which key facilitators and barriers affected implementation of medicines pricing policies, and how? (4) What were the effects of medicines pricing policies with regards to reducing prices and improving access to medicines? We hope that results reported in this paper, will be of interest and relevance to health policy analysts, implementation science scholars and decision-makers who are engaged in improving access to medicines in LMIC settings.

Methodology

The review was conducted as part of a study on 'Improving equitable access to essential medicines in Ghana through bridging the gaps in implementing medicines pricing policy, which involved collaboration between University of Ghana, Ghana Health Services and University of Leeds, with funding from the National Institute for Health Research (NIHR), UK. The review follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement (23). The review protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO, reference: CRD42020178166) and published (24).

Search strategy

The literature search was initially run in April 2020 to identify studies covering implementation of medicine pricing policies in SSA. We updated and re-ran the searches on 25th May 2021 in Ovid MEDLINE(R) ALL 1946 to May 24, 2021, EMBASE (Ovid) 1996 to 2021 Week 20; Global Health (Ovid) 1973 to 2021 Week 20, Web of Science Core Collection, Scopus (Elsevier B.V), and African Index Medicus (via WHO Global Health Index Medicus). We also searched for grey literature in the Institutional Repository for Information Sharing (WHO) (25) and the World Bank Open Knowledge repository (26). For additional French-speaking articles we searched the Erudit (University of Montreal) (27) and Cairn International (Cairn Info) databases (28).

Search strategies were developed using the major concepts: sub-Saharan African countries, medicine pricing, medicine policy and implementation. Database subject headings and free text words to search titles and abstracts were identified by the Information Specialist and project team members. The search terms and strategy were peer-reviewed by a senior Information Specialist using the PRESS Checklist (29). The searches were not limited by language but were restricted to studies published since 2000. This date was chosen following the introduction of the Millennium Development Goals (MDG) in 2000, which included a global focus on improving access to medicines and services. However, we did not search DFID or contact experts for additional papers as envisaged in the original protocol. Full search strategies are available in Additional file [see Additional file 1].

The results of the database searches were stored and de-duplicated in an EndNote X9 library. Further relevant studies were added by citation searching of the included studies from the following reviews (13,

30-33).

Screening

A screening decision flowchart was agreed within the review team, which followed inclusion and exclusion criteria [see Additional file 2]. We included all empirical studies (RCTs, quasi-experimental studies, cross-sectional and cohort studies) and reviews in English or French possessing the following criteria: a focus on medicine pricing policies to improve the affordability of medicines in the country; a focus on how the policy processes were implemented; a SSA context, published since 2000 with relevant information available for analysis.

We excluded studies that were: opinion pieces or conceptual/theoretical publications; policy analyses which focused solely on the agenda-setting and development stages; conducted two plus years prior to 2000 but published after 2000 as this predates the MDG and Sustainable Development Goals (SDG) agenda; in languages where we were unable to resource translation or where full text was unavailable. French articles were screened, translated and data extracted by native French speakers on the research team.

Screening was conducted in two stages using the review management software Rayyan (34). The first stage screening focused on the titles and abstracts and the second on full texts. To ensure consistency across the team, the initial titles, and abstracts of 50 records were independently screened by eight researchers and the results were discussed to reach consensus and standardise approach and calibration. The remaining records were then randomly allocated (295 each) for independent screening. One researcher (TM) screened the remaining records and co-screened 20% of the records from each reviewers' subset for consistency. In the second stage, full text articles were independently reviewed by two researchers (AC, LB) against the inclusion criteria. Discrepancies were resolved in discussion between these members and with involvement of two further reviewers (AK & TM).

Quality Assessment

Quality assessment on the included studies was performed independently by two researchers (AC, LB) using the relevant critical appraisal checklists from the Joanna Briggs Institute. Results of quality assessment are presented in Additional file [see Additional file 3]. Three quality assessment tools for cross-sectional analytical studies, cohort studies and qualitative studies from the Joanna Briggs Institute Tools were used. The checklist criteria were not modified but interpreted flexibly to reflect our focus on the implementation of medicines pricing policies. For cross-sectional analytical studies, a total of 23 out of the 24 studies reported a clearly defined inclusion criteria for the recruitment of participants and description of outcomes to be considered for the study. The studies provided sufficient information of the study settings and population. However, only six studies provided information to indicate how potential confounding factors were identified or accounted for and similarly, little information existed on how

confounding factors were addressed. For the narrative synthesis, most studies did not report information on the philosophical perspective, making it difficult to establish congruity with the research objectives and methodological approaches adopted. However, congruity was established between the research methodology and the analysis and interpretation of the results. Lastly, for the cohort studies, the nature of the studies did not permit quality appraisal of the three included studies due to limited information. Nonetheless, little or no information was provided on how potential confounding factors were identified and dealt with to minimize bias. There was information on the follow-up period out of the 3 studies reported that the two groups had similar characteristics, but measurement of exposures was not done uniformly across both exposed and unexposed populations thus the risk of bias was unclear. However, statistical analyses adopted in the studies were relevant and reported results addressing the study objectives. Overall, on the cohort studies, there was limited information to sufficiently appraise the studies, thus further increasing ambiguity and risk of bias of the included studies.

Data extraction

Two authors (AC, LB) extracted the data from all the 32 studies using Microsoft Word template. The forms were designed to include publication details (author, date, country, study design; date study conducted); medicines pricing policy (key elements, effects on prices, effects on healthcare access); the policy implementation approach (processes, actors, evidence use) and any facilitators and barriers to policy implementation and their effects.

Data Analysis and Synthesis

Due to the heterogeneous nature of medicines pricing policies, and the countries involved, we conducted a thematic narrative synthesis of the data (35), which followed the four review questions. Extracted data were coded in identifying the main themes emerging as shown in Table 1. The findings were synthesized, organized, and reported around the main themes and subthemes.

Table 1: Themes and subthemes

Themes	Subthemes
Medicines pricing policies implemented	Targeted public subsides
	Regulatory framework
	Generic medicines policies
	Purchasing policies
Policy implementation approach	Use of private distributors
	Regulatory framework
Use of evidence in the policy implementation design	Type of evidence used
Actors involved in policy implementation	Government
	Retailers
	Wholesalers
	Manufacturers
	Professional bodies
	Donor agencies
	Public and private health facilities
Barriers to policy implementation	Contextual factors serving as barriers at micro level (i.e., individual/personal)
	Contextual factors serving as barriers at meso level (i.e., organizational)
	Contextual factors serving as barriers at macro level (i.e., national systems)
Facilitators to policy implementation	Contextual factors serving as facilitators at micro level (i.e., individual/personal)
	Contextual factors serving as facilitators at meso level (i.e., organizational)
	Contextual factors serving as facilitators at macro level (i.e., national systems)
Effectiveness of implemented policies	Control or reduce medicine price
	Improve access to healthcare i.e., availability and affordability

Results

Study characteristics

The final searches identified 5505 records, and citation searches identified a further 90 records. Once duplicates were removed there were 2528 records. Screening by titles and abstracts identified 134 records for full text review and 32 studies were eligible for inclusion, data extraction and analysis. Studies were excluded based on wrong outcome (n=57), population (n=5), not SSA (n=2), study type (n=28), publication type (n=4), background article (4) or duplicate (2) and these are detailed in the PRISMA flow diagram (Figure 1).

The characteristics of studies included in the review are listed in Table 2.

Medicine pricing policies implemented in sub-Saharan Africa.

In this section, we report results based on the four review questions.

Types of medicine pricing policies implemented in SSA.

The 32 articles identified in the review revealed a total of 14 medicine pricing policies were implemented across SSA countries between 2003 and 2020. These policies represent four domains, shown in Table 3: 1) targeted public subsidies, 2) regulatory framework and direct price control, 3) generic medicine policies and 4) purchasing policies.

Table 3: Distribution of medicine pricing policies according to implementation countries

Domains	Specific medicine pricing policy	Country	Reference
Targeted public subsidies	Affordable Medicines Facility for Malaria	Uganda, Tanzania, Kenya, Ghana, Nigeria, Niger, Madagascar	Fink, 2014 (57), Sabot 2009 (62), Smith, 2011 (63), Tougher 2014 (49), Ye 2015 (48)
	Free medicines scheme	Cameroon, Mali	d' Almeida 2011(39), Ponsar 2011 (61)
	Equity fund	Madagascar	Honda 2013 (59)
	Subsidy schemes	Tanzania, Uganda, Senegal	Ponsar 2011(61), & Tougher 2014 (49)
Regulatory framework and direct price control	State price regulation frameworks	Angola, Botswana, Democratic Republic of Congo, Lesotho, Malawi, Mozambique, Namibia, South Africa, Swaziland, Mali, Tanzania, Zambia and Zimbabwe.	Liu 2017 (40), Maiga 2010 (53)
	Reference-based pricing systems	South Africa	Casar & Suleman 2019 (46), de Jager & Suleman 2019 (56), Rothberg 2004 (44), Steyn 2007 (45)
	Single Exit Price (SEP) policies	South Africa	Steyn 2007 (45), Moodley & Suleman 2019a (41) and Moodley and Suleman 2019b (42), Bangalee and Suleman 2016 (37), Bangalee and Suleman 2019 (38)
	Pharmacy and Poisons Act	Sudan	Ali and Yahia 2012,(52)
	Tiered pricing and voluntary licencing	Egypt, Ethiopia, Nigeria, Democratic Republic of Congo. Cameroon, Rwanda and South Africa	Assefa 2017, (36)
	Reimbursement schemes	Ghana	Ashigbie 2016, (64)
Generic medicine pricing policies	Generic medicine pricing policies	South Africa, Mali, Kenya	Bangalee and Suleman 2016 (37), Bangalee and Suleman 2019 (38), de Jager and Suleman 2019 (56), Maïga 2010 (53), Nicolosi 2009 (43), Ongarora 2019 (54) and Wilson 2012 (65)
	Cost recovery and generics	Mali	Maïga 2003 (67)

Domains	Specific medicine pricing policy	Country	Reference
Purchasing policies	Public–private partnership	South Africa, Tanzania, Egypt, Ethiopia, Nigeria, Democratic Republic of Congo and Cameroon, Rwanda	Assefa 2017 (36), Walwyn 2018 (47), Wiedenmayer 2019 (50)
	Revolving Drug Fund Policy	Sudan, Kenya	Ali, 2009 (55) and Tran et al 2020 (66)

Medicine pricing policies were reported from 25/46 countries in SSA, with 12/32 reported from South Africa (36-47). As shown in Figure 2, most were single-country studies, but a few were based on a multi-country data (36, 40, 48, 49).

Some studies focused exclusively on evaluating effects of a medicine pricing policy on access to healthcare (39, 50, 51), the effect of the policy on prevailing prices of medicines (36, 37, 40-42, 44, 46, 49, 52-54). Others, however, evaluated policy effects on medicine prices and access to medicines (45, 47, 48, 55-64).

How medicine pricing policies were implemented

Approaches to policy implementation

Approaches to policy implementation were described in 10/32 studies. Two main implementation approaches for medicine pricing policies were evident in the data: a) use of private distribution outlets and networks and b) use of government's regulatory frameworks. Three studies (39, 50, 59) described using private distribution outlets and networks to improve financial and geographical access of medicines through pooled procurement and subsided schemes. For example, in Tanzania the government engaged private sector pharmaceutical supplier as the prime vendor to provide complementary medicines needed by public health facilities (50).

The second approach involved the use of regulatory frameworks to guide the sale and distribution of medicines (37, 38, 46, 52, 53, 58, 64). Seven reported on the use of regulatory frameworks. Reduction in reference price was an approach used to set price ceilings for a particular group or category of medicines including generic medicines (46). The implementation of the single exit price (a fixed ex-factory price) policy was also observed in different contexts (37, 38, 41, 42, 45).

Actors in policy implementation

A total of 23/32 studies highlighted seven groups of policy actors who were involved in policy implementation. These comprised: g*overnment* (39, 41, 44-46, 48, 50, 55, 56, 59-61, 63, 65), *wholesalers*

(45, 52, 58, 62), *retailers* (45, 52, 56, 62), *manufacturers* (36, 42, 45, 52, 58, 65), *donor agencies* (48, 55, 57, 61, 63), *professional bodies* (53, 56), *community members* (59), and *public and private health facilities* (50, 53, 58, 60, 64). Information reported in the studies covered largely actors' roles in policy implementation, but did not report actors' interests, agendas, and relative powers.

Evidence to inform policy implementation

None of the studies reported on the use of evidence to inform implementation as well as monitoring and evaluating implemented policies although few studies (3/32) explicitly described evidence use in informing the design of medicine pricing policies. Where it was reported, evidence was sourced from a cross sectional survey (36), review of pharmaceutical pricing policies (51), and a WHO report on medicine access and procurement of medical commodities (47).

Key facilitators and barriers to implementation of medicine pricing policies

Multiple contextual facilitators and barriers to the implementation of the medicine pricing policies in sub-Saharan Africa were identified in this review. These were across the micro (individual), meso (organizational) and macro (national) levels (Table 4). Five studies only reported facilitators (37, 40, 45, 55, 60), seven reported only barriers (36, 38, 46, 52, 54, 56, 57) and 14 reported both barriers and facilitators (39, 44, 47-51, 59-66).

Table 4: Key facilitators and barriers to implmentation of medicines pricing policies

	Facilitators	Barriers
Micro level factors	Knowledge of implementation status [Honda 2013, Cohen 2013 and Maiga 2010] (51, 53, 59)	Limited awareness about the policy implementation process and the various components of the policy [Assefa 2017](36)
	Village with a drug shop [Smith 2011](63)	Varied prevalence of Hepatitis C affected uniform pricing [Assefa 2017](36)
	Alternative drugs that are less effective but cheaper preferred by public [Cohen 2013](51)	Long distance travel by individuals (Ye 2015, Tran et al 2020)(48, 66)
Meso level factors	Drug and therapeutic committee to regulate prices at the facility level [Ashigbie 2016] (64)	Limited access to medicines, frequent stock outs [Fink 2014, Honda 2013, Ye 2015, Smith 2011](48, 57, 59, 63)
	Pooling resources and buying in bulk [Ashigbie 2016](64)	Shortage of trained personnel and lack of resources to scrutinize prices of medicines and information about medicine prices by the pharmaceutical companies [Ali and Yahia 2012, Tran et al 2020](52, 66)
	Lower prices increase access [Cohen 2013](51)	Lack transparency of prices in an External Reference Pricing (ERP) comparison where confidential discounts are negotiated [Cassar & Suleman 2019](46)
	Subsidies/free provision of medicines [Ponsar 2011](61)	Lack of printed retail prices on medicine pack [Ali and Yahia 2012](52)
Macro level factors	Existing national medicine pricing policies [Steyn 2007, Ashigbie 2016](45, 64)	Lack of state capacity to regulate [Ali and Yahia 2012] (52)
	Strong political will from government [Walwyn & Nkolele 2018, Wiedenmayer 2019, Tran et al 2020](47, 50, 66)	Delays in reimbursement of health facilities and supplies [Ashigbie 2016](64)
	Donor agencies and international policies and interventions [Wilson 2012, Ye 2015, Sabot 2009, Ali 2009](48, 55, 62, 65)	Lack of scrutiny on medicine pricing policy by regulators [Ali and Yahia 2012](52)
		Lack of a coherent and well-functioning national medicine pricing policy [Wilson 2012](65)
	Use of essential medicines list [Ashigbie 2016](64), Medicine and related substance amendment Act [Steyn 2007] (45)	Forex fluctuation (depreciation of the local currency) [Walwyn 2018](47)
		Unfavorable reimbursement practices [Ashigbie 2016] (64)

Micro level factors

Three studies cited education and awareness creation where prescribers and users were aware of the medicines and therapies under the new medicine pricing policy as facilitators of successful medicine pricing polices (51, 59, 60). A key barrier to implementation of medicine pricing policies was the long-distance travelled by individuals in order to access medicines (48).

Meso-level factors

Introduction of government subsidies and exemptions of generic medicines, contributed to a decline in the prices of medicines at facility level in Mali (61). Pooling resources and buying in bulk also reduced the prices of medicines in Ghana (64). Shortage of trained personnel and resources to assess and scrutinize prices of medicines and lack of information about medicine prices by the pharmaceutical companies in Sudan (52), and limited access to medicines and frequent stockouts in multiple countries (48, 57, 59, 63) were the main barriers reported.

Macro-level factors

The review showed that the use of national essential medicine lists by health facilities was a facilitator of the implementation of reimbursement schemes in Ghana (64). Other facilitators were funding support from donor agencies (48, 55, 62), international policy interventions such as supporting domestic production of medicines (65) and existing national essential medicines list and medicine and related substance amendment Act (45, 64). Challenges to implementation included lack of scrutiny on medicines pricing information by regulators with medicine prices of certain generics higher than their originators (52). Additionally, unfavourable National Health Insurance Scheme reimbursement practices such as reimbursement delays and lack of price ‘mark-up’ standardization (64), and the lack of a coherent and well-functioning national medicine pricing policy constrains efforts to regulate and ensure better prices for improved access (65).

Effectiveness of implementing medicine pricing policies

Medicine pricing policies sought to achieve two main aims: a) control or reduce the prices of medicines and b) improve access to essential medicines. Some studies reported separate effects on medicine prices (37, 38, 40-42, 44, 46, 49, 54), or improved access to essential medicines (39, 50, 51, 66). However, as shown in Table 3, many studies reported on both effects (45, 47, 48, 55-64).

Effect on prices of medicines

Overall, implementation of the different medicine pricing policies largely suggests a reduction in the prices of medicines. The results of the review showed that implementation of the tiered pricing (segmented pricing based on targeted markets), voluntary licensing (removing of regulatory barriers) and generic policy (promoting prescribing generic medicines) in seven different countries across Africa led to reductions in generic Direct Acting Antivirals (DAA) from $1200 to between $684 and $750 i.e., the generic medicines were 40% cheaper than the originator prices (52). However, some medicine pricing

policies did not change much or appear to influence the prevailing medicine prices following implementation (42). Although one of the goals of the Pharmacy and Poisons Act (2001) implemented in Sudan was to control prices of the medicines through regulating mark-ups along the supply chain, the evidence generated revealed that the policy did not appear to have an effect in the prevailing medicine prices (52). The weak pharmaceutical price mechanism in Sudan coupled with weak medicine control departments or lack of capacity to regulate activities of importers and retailers were the possible explanation (52).

Effects on improved access to medicines

Fifteen studies reported evidence of policy effect on improved availability and affordability to essential medicines (45, 48, 50, 51, 55-63, 66, 67). In Kenya, implementation of a revolving fund pharmacy model improved the availability of essential medicines from 30% to 40% to over 90% in 15 health facilities (66). In South Africa, when generic reference pricing was implemented, the use of generic rosuvastatin increased from 24% to 63.9% in the subsequent year and to 76.4% a year later (56). In their assessment of the use of artemisinin combination therapy for malaria across different households in Tanzania, the researchers found that artemisinin-based combination treatments increased availability within the retail sector from 31% to 49% and then to 61% (51).

Discussion

This systematic review sought to identify medicines pricing policies implemented in SSA, how these were implemented, which contextual facilitators and barriers affected policy implementation and how effective were these policies. The review revealed 14 different medicine pricing policies reflecting four domains: targeted public subsidies, regulatory framework and direct price control, generic medicine policies and purchasing policies, were implemented across SSA between 2003 and 2020. The medicines pricing policies were implemented in over half (25/46) of SSA countries. The main implementation approaches involved the use of regulatory frameworks and private distribution outlets and networks. The review showed key actors involved in policy implementation were government, wholesalers, manufacturers, retailers, professional bodies, community members and private and public health facilities. The use of evidence to inform policy implementation was not reported in any of the included studies. Key barriers to policy implementation identified included, limited awareness about policies, frequent stock out, lack of capacity to regulate implementation, and lack of price transparency in external reference pricing process whereas key facilitators included, existing national essential medicine policy environment, strong political will, and support from development partners. Evidence on effectiveness of implemented policies on reducing prices and improving access to medicines were mixed. Reductions in prices were reported only in some studies. There was evidence that implementation of medicine pricing policy led to improved availability and affordability to essential medicines.

The categories of medicine pricing policies identified in this study are similar to what were previously reported, which also highlight predominant focus on regulatory measures or direct price control (68).

Although commonly reported in SSA, regulatory measure or direct control is considered highly contentious with no consensus in the literature. For example, opponents from the pharmaceutical sector advocate for a need for free and open market systems, arguing that government control undermines competition and innovation for developing new drugs and limits access in the market to address new medical conditions (69–71). Weak systems for government direct price control may not lead to the required outcome. As revealed in Sudan (52) and Philippines (72), regulation of medicines prices does not guarantee reduction in the prices of essential medicines and improved availability and affordability. It is therefore important to critically examine appropriateness of implementation approaches for achieving outcomes within specific contexts. Adequate capacity to monitor and evaluate policy implementation and understand contextual influences on the implementation is therefore critical.

The use of generic medicines as a strategy to reduce prices and ensure improved access was widely employed in SSA and the effect on price and expenditure favour the use of quality-assured generic medicines (8). A review of generic medicine pricing policies in Europe revealed that policies for implementing generic medicines used different implementation mechanisms such as reductions in reference prices and prescription status of medicines (73). In our review, we found similar approaches for generic medicine policy and regulatory frameworks.

Although, information on the role of actors were provided in the studies reviewed, the actors' interests, agendas, relative powers, and networking arrangements such as alliance-building were missing. This information can be revealed through stakeholder analyses (74–77) and is often critical to form a comprehensive understanding of policy implementation (78–81). This highlights one outstanding gap in the published knowledge on the implementation of medicine pricing policies, thus representing agenda for further research.

The review showed slightly more reported barriers than facilitators to implementation of medicine pricing policies. This may reflect researchers' bias in revealing more constraints in their investigations (82, 83), though this may also reflect a greater number of contextual inhibitors to the implementation of medicines pricing policies in SSA contexts. The latter can be a particularly important contribution to the field of health policy analysis and transferability of theoretical and practical lessons learned to other health (and non-health) policies.

The ultimate goal of medicine pricing policies is to ensure low and affordable medicine prices as revealed in our review. This finding is in line with another study from Asia which found similar price reductions following implementation of generic medicine pricing policy in Indonesia (84). The authors reported that following the implementation of the policy, the prices of lowest price generic and innovator brands fell from 40–2200% between 2004 and 2010. A review of pharmaceutical pricing policies in developing countries also revealed a similar outcome of reduced medicine pricing policies (68) .

Some policies, however, did not have any effect on the prices of medicine (37, 39, 52). For example, the introduction of a free medicines policy in Cameroon to provide free ART for people living with HIV appeared not to have achieved the goal of improving access to medicines. It was reported that the policy

resulted in shortages in supplies and as result few patients were able to get the second line treatment. This was attributed to the fact that the policy did not ensure that adequate systems and infrastructure were in place to address increased demand and avert resultant challenges impeding access to ARTs (39). This is not new as previous studies revealed that the implementation of generic medicine pricing policy in Europe resulted in higher prices, but higher prices also stimulated competition between generic medicines leading to prices reduction (73).

Implementation of medicine pricing policies can be mediated by different contextual facilitators or barriers. Our review has highlighted that, key contextual barriers comprised weak enforcement or regulatory mechanisms, absence of essential medicines list and the role of foreign exchange currency fluctuations. On the other hand, facilitators included raising awareness about implementation, existence of subsidies, use of essential medicine lists, establishing a fixed profit margin or percentage for manufacturers and the pivotal roles of supportive donor agencies and international policies and interventions. A study in China also revealed contextual barriers such as lack of enforcement of pricing regulations and policies, with authors encouraging strong governance structures and legal frameworks to ensure enforcement (85). The monitoring and enforcement of medicines pricing frameworks need to be supported by well trained and skilled personnel, which is often lacking in different SSA countries (52, 54).

The findings from this review contributes to the field of policy analysis. Specifically, the taxonomies of the categories of policies (i.e., targeted public subsidies, regulatory framework and direct price control, generic medicine policy and purchasing policies), actors groups (e.g., government, community members) involved in implementation and the distinction of micro, meso, and macro levels context, which mirrors other policy studies (8, 9, 68, 86, 87).

Implications for policy and future research

This review suggests three implications for improving implementation of medicine pricing policies in SSA, which can also be applied to other health policies in LMICs more generally. First, four broad groups of policy options are available for reducing medicine pricing: targeted public subsidies, regulatory frameworks and direct price controls, generic medicine policies and purchasing policies. However, it is important to design and apply the country-specific implementation mechanisms to avoid a ‘one-size-fits-all’ approach. Second, different stakeholders from both the public and private sectors can play important roles in the design and implementation of medicine pricing policies. Inclusive policy processes which allow representation of multiple voices of policy actors is, therefore, imperative to ensure sustainability of policy implementation, pooling of resources and collective ownership and acceptance. This is particularly pertinent to medicines pricing, given that the private (for-profit) sector plays a major role in pharmaceutical manufacturing and distribution, but it is also important to encourage participation of under-represented not-for-profit groups such as civil society organisations, in health policy processes. Third, it is important to continuously monitor and evaluate the implementation approaches and emerging effects of these policies, something which our review observed was generally lacking. This can represent

an opportunity for enhancing the culture of evidence-informed decision-making within government agencies, as well as closer partnerships between government agencies and research organisations.

We call for more research on medicine pricing policy implementation, covering three areas. First, more studies need to examine the role of evidence in the design and implementation of medicines pricing policies. The increased interest and attention on evidence-informed policy and planning decisions (86, 88–91) can sustain the momentum, and it is important to strengthen capacity within mainstream information systems to generate robust evidence rather than continuously rely on one-off and 'external' assessments (86, 89, 92). Second, future research on the role of policy actors involved in the policy design process is critical for improving policy implementation, particularly covering actors' interests, agendas, powers, and resultant influences (78–81). Third, it is critical to generate robust evidence on key contextual influences on policy implementation and understand how individual factors can facilitate or constrain implementation in different settings (93–96).

Study limitations

We acknowledge the following limitations. First, the review focused on studies conducted in SSA, but we acknowledge variation in income status, socio-economic contexts, and health care systems across countries. Different contexts inevitably affected how medicine pricing policies were implemented and their outcomes. As a result, we were guided by the generally limited contextual information included in the reviewed studies and resisted making too many assumptions and inferences based on our knowledge of the different countries. We also suggest that experimental studies could report more robust and less biased results, as compared to the reported studies in this review which were largely cross sectional with limited follow-up. Second, although we used comprehensive search terms and the main health science literature databases, we may still have missed some resources. Third, given the different study designs employed, sample sizes and outcome measures, we faced a challenge to analytically compare the outcomes or effects of the policies on the prices and access to essential medicines. This notwithstanding, we feel our analysis provides a useful taxonomy of types of medicines pricing policies and highlights implementation approaches to inform future policy, practice, and research.

Conclusion

The implementation of medicine pricing policies in SSA focused on four policy options: targeted public subsidies, regulatory framework and direct price control, generic medicine policies and purchasing policies. Implementation of these policies in SSA shows some mixed evidence of improved availability and affordability to essential medicines, and it is important to understand country-specific experiences, diversity of policy actors and contextual barriers and facilitators to policy implementation. Our study suggests three policy implications for improving implementation of medicines pricing policies in SSA: avoiding 'one-size-fits-all' approach, engaging both private and public sector policy actors in policy implementation and continuously monitor implementation and effects of policies. Future studies can usefully examine interests, influences, relative powers, and coalition formation of policy actors during implementation of medicine pricing policies.

List Of Abbreviations

LMICs: Low-middle income countries

SSA: sub-Saharan Africa

Declarations

Ethics approval and consent to participate

No ethics approval was required for this systematic review

Consent for publication

Not applicable as the review does not contain any individual person's data in any form which requires consent for publication

Availability of data and materials

All data generated or analysed during this study are included in this published article

Competing interests

The authors declare that they have no competing interests

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Authors' contributions

AK and TM jointly conceived the study, undertook the systematic review, and drafted the manuscript; LB, AC, ADA, IAA, IAK, TE, and NK undertook the systematic review and revised the manuscript. AK, TM, LB, AC, ADA, IAA, IAK, TE, and NK read and approved the final version of the manuscript.

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Table

Due to technical limitations, table 2 is only available as a download in the Supplemental Files section.

Figures

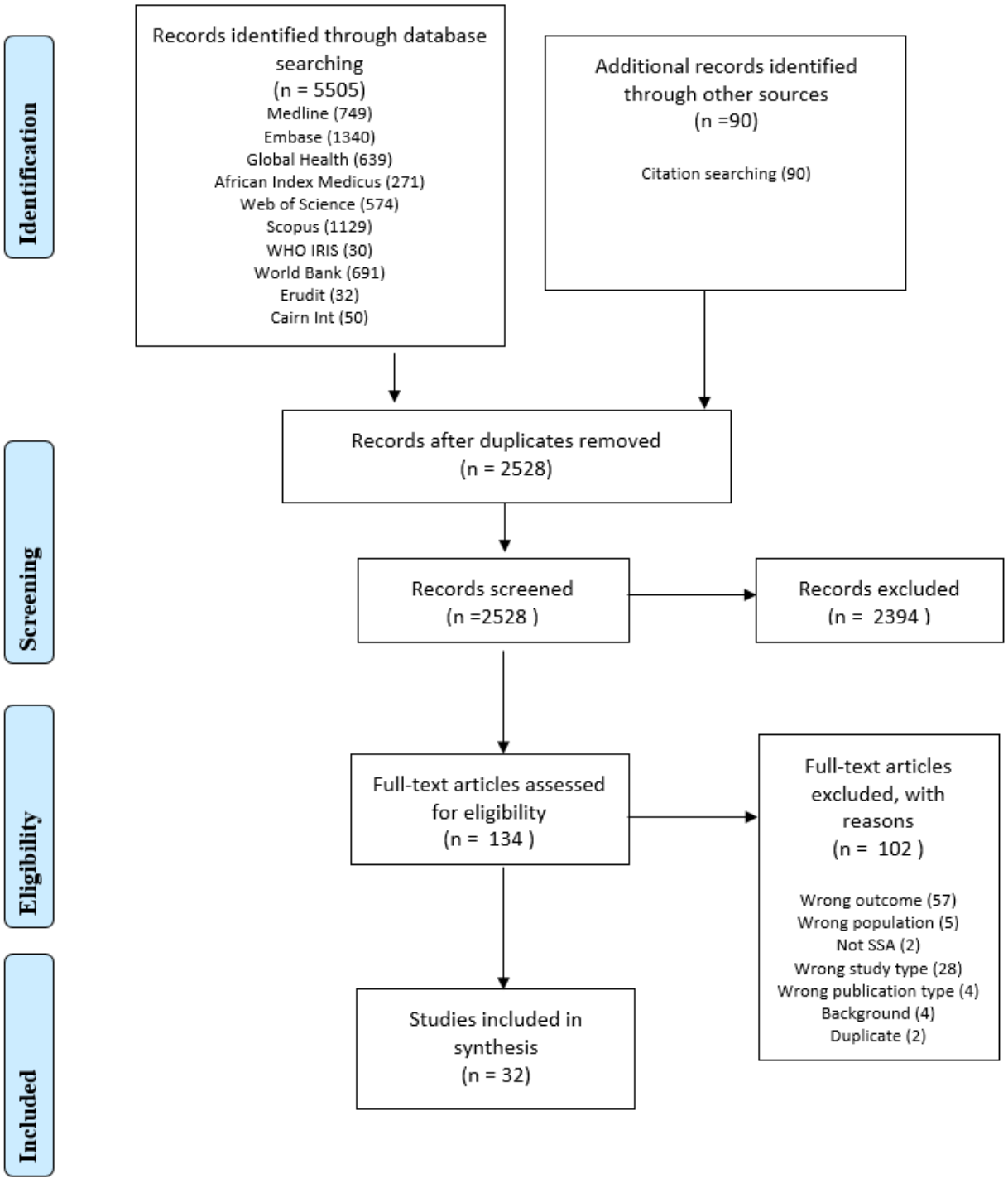

Figure 1

PRISMA flow diagram to illustrate the screening process from the initial search until the final selected studies (Page et al., 2021)

Figure 2

Distribution of selected studies per countries in SSA

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Table2.docx
- AdditionalFile1.SearchStrategy.docx
- Additionalfile2.Screeningflowchart.docx
- Additionalfile3.QualityAssessment.docx