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Medicine Prices and Availability

Review Series on

Pharmaceutical Pricing Policies and Interventions

Working Paper 2:

The Role of Health Insurance in the Cost-Effective Use of Medicines
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The Role of Health Insurance in the Cost-Effective Use of Medicines

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<td>ARV</td>
<td>Antiretroviral medicine</td>
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<tr>
<td>CBHI</td>
<td>Community-based health insurance</td>
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<td>DMP</td>
<td>Disease management programme</td>
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<td>DRG</td>
<td>Diagnosis related group</td>
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<td>FFS</td>
<td>Fee-for-service</td>
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<td>GNI</td>
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<td>HAI</td>
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<td>ICIUM</td>
<td>International Conference for Improving Use of Medicines</td>
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<td>IMSS</td>
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<td>LMIC</td>
<td>Low- and middle-income countries</td>
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<td>MHIF</td>
<td>Kyrgyzstan Mandatory Health Insurance Fund</td>
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Foreword

WHO/HAI Project on Medicine Prices and Availability

Since 2001, the World Health Organization (WHO) and Health Action International (HAI) have been working in partnership to collect reliable evidence on medicine prices, availability, affordability and price components in low- and middle-income countries. To date over 80 medicine price and availability surveys have been completed or are underway using the WHO/HAI methodology, with results publicly available on the HAI website (www.haiweb.org/medicineprices). While this work continues to expand, the WHO/HAI project has evolved from supporting research to using the results to effect positive changes in related policies and interventions.

The results of the surveys confirm that substantial opportunities exist to increase availability, lower prices, and improve the affordability of medicines in all regions of the world and at all levels of economic development. However, it can be challenging to identify and prepare suitable lines of response.

At the request of national policy-makers, WHO/HAI and a group of international experts have developed guidance on various policies and interventions to increase medicine availability and make medicines more affordable, with a focus on low- and middle-income countries. This guidance takes the form of a series of in-depth reviews on pharmaceutical pricing policies (generics policies, external reference pricing, mark-up regulation, pharmacoconomics and cost-plus pricing) and other related issues including the role of health insurance in the cost-effective use of medicines, encouraging competition, and sales taxes on medicines. The reviews are not meant to recommend one policy intervention over another, but rather provide guidance to policy-makers on the design and implementation of various policy approaches. For each review, a policy brief will be published that highlights key points from the review.

The results of the policy reviews show that relatively little has been published about the use of pharmaceutical pricing policies and interventions in low- and middle-income countries. Therefore, the review papers are published as working drafts, to be developed as more becomes known on the use of these interventions in low-and middle-income countries. We welcome information and comments that will strengthen these reviews (please forward them to Margaret Ewen, Health Action International email marg@haiweb.org).

WHO and HAI would like to thank the authors of the papers, the reviewers, and all the national contributors who provided information on the use of the interventions in their country. We are also grateful to the members of the Pricing Policy Working Group who have shaped this work.

We hope these papers will be a useful resource, and encourage national policy-makers to tackle the challenge of developing and implementing policies and strategies that ensure universal access to affordable medicines.

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Executive summary

Health insurance systems have great potential to improve the cost-effective use of medicines by leveraging better provider prescribing, more cost-effective use by consumers, and lower prices from pharmaceutical companies. Despite ample evidence from high-income countries, little is known about insurance system strategies targeting medicines in low- and middle-income countries (LMIC). This report provides a description of strategies that can be used by health insurers to improve cost-effective use of medicines, an overview of the use of these strategies in high-income countries and a critical review of the literature on these strategies and their impact in LMIC. The report concludes with policy recommendations for LMIC and case studies on developing and implementing insurance strategies in four LMIC: Ghana, Jordan, Mexico and Thailand.

A systematic review of published peer-reviewed and grey literature was conducted, and insurance system strategies organized into four categories: medicines selection, purchasing, contracting and utilization management. In 63 reviewed publications reasonable evidence was found supporting the use of insurance as an overall strategy to improve access to pharmaceuticals and outcomes in LMIC. Beyond this, most of the literature focused on provider contracting strategies to influence prescribing. There was very little evidence on medicines selection, purchasing, or utilization management strategies.

Although there is ample evidence from high-income countries there is a paucity of published evidence on the impact of insurance system strategies on improving the use of medicines in LMIC. The existing evidence from LMIC is questionable since the majority of the published studies utilize weak study designs. This review highlights the need for well-designed studies to build an evidence base on the impact of medicines management strategies deployed by LMIC insurance programmes.
1. Introduction

This report reviews the use in LMIC of strategies that health insurance systems can employ to influence cost-effective use of medicines. We use the term “cost-effective” to refer to getting the best value for the money spent on medicines, through policies and systems that improve access to affordable medicines by those who need them, encourage appropriate use of these medicines, and result in improved health outcomes. The review pre-supposes the existence of an insurance scheme in a LMIC. We do not discuss the necessary pre-conditions in a LMIC to implement health insurance, a topic well-covered in the literature (see Appendix 1). Similarly, we do not discuss the financial, technical, or human resource requirements for a health insurance scheme to operate efficiently (1).

The report has the following structure. We first describe a framework (see Figure 1) for policy and management strategies through which health insurance systems can influence cost-effective use of medicines and give a brief summary of medicines-focused insurance strategies commonly used in high-income countries. The sections that follow detail the methods of our comprehensive review of published and grey literature from LMIC, the evidence found for each type of strategy presented in the framework, and a summary of four illustrative case studies of insurance strategies in LMIC systems. The report concludes with recommendations for policy considerations and suggestions for future research. Also included is a glossary of terms, and appendices 1 and 2 list the terms used in our literature search and the four case studies respectively.

Essential medicines are critical to reducing morbidity and mortality and improving quality of life. Lack of access to essential medicines is a prominent public health problem that disproportionately affects populations in LMIC (2). The WHO estimates that, overall, 30% of the world’s population does not have regular access to essential medicines, and that in the poorest areas of Asia and Africa over half of the population lacks access (3). Those who do have access to medicines face relatively high cost burden. In LMIC, payments for medicines consume the largest proportion of out-of-pocket health care expenditures (4). Poor households devote 60% to 90% of their health care expenditures to medicines, and medicines consume 25% to 65% of total public and private spending on health (5). In addition, the structure of financial incentives in many health systems tends to promote inappropriate prescribing and use of medicines.

The United Nations has recognized the problem of access to medicines by making it a Millennium Development Goal target to: “In cooperation with pharmaceutical companies, provide access to affordable essential medicines in developing countries” (6) and the WHO created a framework for expanding access to medicines, which consists of four components: rational selection and use of medicines, affordable prices, sustainable financing, and reliable supply system (3). Health insurance schemes can actively contribute to each of these components through the development and implementation of sound medicines coverage and management policies. In 2004, experts at the International Conference for Improving Use of Medicines (ICIUM) concluded that emerging and expanding insurance systems in LMIC have great potential to improve the use of essential medicines and recommended systematic work...
within “insurance systems to leverage better prescribing, more cost-effective use by consumers, and lower prices from industry” (7, 8). We presume that, in addition to their role in financing health care, health insurance systems also have the ability to incentivize patients, providers, and systems to implement affordable, appropriate use of medicines

1.1 Definition of health insurance

In this review, we use the following overall definition of health insurance “The term insurance refers to all types of health insurance programmes, including private, public, for profit and not-for-profit programmes and organizations, particularly those which include the poor. Health insurance programmes pool risks across populations and pay part of or all health-care expenses for their defined population of members (and possibly dependents) from premiums contributed by individuals, employers, nongovernmental organizations and/or government. The services and goods covered by health insurance programmes vary widely. (…) (We) assume that a medicines benefit would be provided in addition to coverage of basic health care services; we are not considering schemes that cover only medicines.”(4)

Our definition goes beyond the financing (i.e. simply paying for medical services and medicine) and economic aspects of insurance (9) and characterizes health insurance systems as organizations with leverage to change behaviour and partake in active purchasing and management. For this review, our definition of health insurance is inclusive of all types of insurance schemes (public, private, community-based, etc.). The medicine policy strategies proposed in this review can be applied in some form in all types of insurance schemes. While we do not consider government-financed national health care delivery systems under our definition of insurance schemes, these systems also need to employ strategies for managing resources to achieve the most health value for their expenditures. The types of policies and management strategies discussed in this review could also be employed in public health care delivery systems. However, the financing structures of such systems (essentially prepayment by governments for the services provided) usually lack the financial incentives that insurance systems can establish for members, providers, and suppliers and would make implementation of some policies discussed in the report more challenging

See the Glossary for definitions of the other terms used in this report.

1.2 Role of health insurance systems in cost-effective medicines use

Comprehensive medicines coverage is often excluded from insurance system benefits. Many insurance systems were developed with the primary focus on reducing catastrophic health expenditures, especially those associated with hospitalization. However, given high out-of-pocket spending on pharmaceuticals, an insurance scheme with no or limited medicines coverage may not prevent cost-induced poverty from medicine expenditures (10). World Health Survey data shows that about half (41% to 56%) of households in LMIC spend all of their health care expenditures on medicines (11). Evidence from high-income countries suggests that higher medicines out-of-pocket co-payments result in lower utilization and poorer health outcomes (12, 13); reducing or eliminating out-of-pocket medicines payments through
insurance coverage in LMIC should translate into greater access to medicines, improved health outcomes and increased satisfaction with the health care system. In fact, studies have shown that consumers place higher value on insurance schemes that include medicines coverage (14).

The primary goal of an insurance scheme should be to maintain and improve the health of its members by financing effective and efficient health care. Insurers need to efficiently and equitably balance the competing objectives of sufficient revenue generation, allocation of appropriate resources to maximize health outcomes given the needs of members, and provision of high quality, timely services at costs that are affordable to the system and to members (15).

Insurance systems have several key features that give them a unique advantage in influencing the use of medicines: a defined population of enrolled members, a defined set of contracted providers and suppliers, data on the types, frequency, and costs of services used by members, rendered by providers, and paid by the system, and financial leverage. For example, insurers can use member volume and financial leverage to negotiate with the pharmaceutical industry for better prices, to structure contracts with providers that promote rational prescribing, and to design benefit policies that encourage proper use among consumers (4). Furthermore, insurance systems can use claims data to monitor use of medicines in order to design and evaluate policies that promote cost-effective use of medicines (4).

There are four broad categories of policies and management strategies that health insurance systems can use to balance the competing goals of improving access to medicines for better health outcomes, encouraging appropriate use, and keeping costs affordable. Two strategies directly focus on medicines provision: 1) defining which medicines will be covered by the system and under what conditions (selection) and 2) negotiating the terms under which medicines are procured or supplied (purchasing). Two other strategies indirectly influence use of medicines: 3) negotiating or dictating the terms under which medical services are provided and medicines dispensed (contracting) and 4) implementing programmes to manage care and educate providers and patients (utilization management) (see Figure 1).

Our framework builds upon the commonly used price-volume framework (16) by adding action-oriented strategies for health insurance systems that can target either price, volume, or both, to reduce cost as well as quality use to improve outcomes. Although this review focuses on evidence from health insurance systems, many of these strategies are applicable to other forms of health care financing and delivery (17).
Examples of strategies in each category include:

*Product Selection* strategies, directed at both consumers and providers: defining a benefit package, formulary and reimbursement restrictions, generic restrictions and substitution requirements, exclusion policies, member cost-sharing or co-payment structures, coverage limits, prior authorization, and internal or generic reference pricing;

*Product Purchasing* strategies, directed at pharmaceutical manufacturers and suppliers: direct (e.g. reimbursement conditions, bidding directly for medicines, negotiating discounts and rebates) and indirect (e.g. creating a formulary, contracting with a preferred pharmacy network) control over the quantity, quality, and price of medicines reimbursed;

*Reimbursement Design and Contracting* strategies, directed towards medical providers (e.g. doctors, pharmacists, hospitals): financial incentives that influence medical utilization or provider prescribing and dispensing. Specific examples include fee-for-service, capitation, case-based, and performance-based payment, setting provider budgets and reimbursement rates.
Utilization Management strategies, directed at providers: policies that separate prescribing and dispensing, utilization review and profiling, or performance incentives. Utilization management strategies can also include educational or care management programmes directed at both providers and members.

1.3 Evidence from high-income countries

There is a large body of literature on the use of medicines benefit management strategies by insurance systems in high-income countries. In almost all high-income countries, insurance systems subsidize the cost of medicines, which is believed to increase consumption because consumers no longer pay the full price of medicines (i.e. moral hazard) (18). To reduce overconsumption and contain costs, insurance systems increase consumer cost-sharing, restrict reimbursement to specific medicines, or limit the number of medicines reimbursed. A large proportion of the literature on insurance medicines selection strategies in high-income countries comes from studies of U.S. Medicaid (the insurance programme for the poor and disabled) policies. However, a recent review concluded that there is a need to develop uniform benchmarks to better evaluate the impact of selection strategies (19).

Evidence shows that introducing or increasing cost-sharing (i.e. co-payments) reduces overall medicines utilization and expenditures and increases consumer out-of-pocket costs, with negative outcomes in vulnerable populations (18, 20, 21, 22, 23, 24). The impact of cost-sharing varies by type of medicine and there is some evidence that cost-sharing may decrease use of essential medicines. However, tiered co-payment structures, with lower co-payments for generics or preferred brands, have been shown to increase use of preferred medications.

Similarly, coverage (i.e. quantity) limits, or caps on the amount of medicines reimbursed, have been shown to decrease medicines expenditures, but may also increase economic burden on consumers and decrease quality of prescribing and overall health care (e.g. higher rates of hospitalization following inadequate outpatient medicines access), especially for vulnerable patients (18, 20, 21, 23). Other administrative tools that limit prescribers through formulary restrictions have had both positive and negative effects, depending on the category of medications affected (20, 21, 25). Prior authorization and step therapy have been shown to lower both the volume and cost of pharmaceutical utilization, but they may also result in unintended disruptions of therapy; little is known about their long-term economic effects (20, 25, 26, 27). Finally, removing medicines from a formulary or preferred drug list generally leads to substitution with alternative therapies, with mixed effects on pharmaceutical expenditures and patient outcomes (21, 25, 27).

In terms of purchasing strategies, there is evidence that direct price regulation, negotiation of prices and rebates with manufacturers, and the creation of purchasing pools (i.e. organizations that band together to obtain increased market power) can decrease costs to insurers (20). However, since manufacturers often give rebates to obtain preferred status on a formulary, there is concern that rebates may encourage use of more high cost medicines and raise prices in the long run, especially in hospital formularies. Limited evidence has shown that preferred pharmacy networks decrease insurer costs and have the potential to increase rates of generic substitution (20).

* Since the focus of this paper is on LMIC, we did not perform a comprehensive literature review on the evidence of medicines benefit management strategies from high-income countries. Please see the cited research articles and reviews for more detailed information.
There is substantial evidence on contracting strategies, particularly payment structures for doctors. In general, fee-for-service payment systems provide implicit financial incentives to increase service quantity whereas fixed reimbursement systems, such as capitation and fixed salaries, give doctors incentive to contain costs (28, 29). Payment systems for doctors that are tied to prescribing and/or dispensing pharmaceuticals will result in increased volume and cost, often at the expense of quality (30). However, a Cochrane review found very limited high-quality evidence of the effect of payment systems on prescribing by primary care providers (31). Only one study looked at the effect on pharmaceuticals and the findings were unexpected – introducing fee-for-service payment (for prescribing among other services) into a capitated system actually reduced prescription renewals.

Provider budgets, which allocate fixed amounts of funds to doctors for the services provided to a group of patients, have had varied outcomes across different countries and health care settings (32). One review concluded that provider budgets decrease pharmaceutical spending and volume and increase generic prescribing (33). However, little is known about the effect of budgets on other types of utilization and health outcomes. Limited evidence exists on the effectiveness of provider performance incentives in improving quality of care (20, 33, 34). In contrast, pharmacy incentives that provide higher reimbursement for generic dispensing have been shown to increase the overall proportion of generic prescribing and dispensing (20).

Finally, substantial evidence exists about the effects of utilization management strategies in high-income countries. A Cochrane review of the effects of printed educational materials alone on physician practice and patient health found a limited effect on process outcomes but not on patient outcomes (35). On the contrary, multiple reviews have found that dissemination of educational materials alone is not effective in changing the behavior of doctors (22, 36, 37). However, these reviews found that several strategies can be effective at improving the prescription and use of medicines, including: implementation of clinical practice guidelines combined with a local consensus process; one-to-one educational outreach visits (i.e. academic detailing); use of local opinion leaders; computerized alerts and reminders; surveillance systems with patient-specific feedback for doctors (i.e. audit and feedback); dissemination of educational materials with free medicines samples; multifaceted disease management programmes that focus on pharmaceutical therapy; and pharmacist-led collaborative care.

Most reviews have concluded that multifaceted interventions have the greatest impact on the behaviour of doctors. A recent review also concluded that audit and feedback and educational outreach visits were effective, but found contradicting and/or insufficient evidence to make claims about the effectiveness of patient-mediated interventions; reminders; local consensus processes; or multidisciplinary teams (38).

There have been several studies on prospective (i.e. at the time of dispensing) and retrospective (using pharmacy claims histories) drug review in the U.S. Medicaid programme. An evaluation of two Medicaid demonstration projects found no effect of pharmacist-initiated prospective drug review on the frequency of medicines problems, utilization of medicines and other health services, or clinical outcomes (39). The evidence of the effectiveness of retrospective drug reviews is mixed. Although one review of Medicaid studies concluded that there were immediate effects of a retrospective drug review on prescribing (in terms of reducing or increasing prescribing of specified medicines), another review found no impact on prescribing errors or patient outcomes (39, 40).
2. Methodology

We performed a comprehensive literature review to find evidence from LMIC on the impact of pharmaceutical policies implemented by health insurance systems on the cost-effective use of medicines. We defined LMIC as countries with a World Bank country classification of low-income economy or lower-middle-income economy according to 2008 GNI per capita (41). When relevant, we also included evidence from countries (e.g. South Korea and Taiwan) that recently went through rapid economic development but which are currently classified as upper-middle-income or high-income economies.

We identified peer-reviewed publications through PubMed (MEDLINE) using search terms in the following four categories: pharmaceutical policy strategies (and effects of), pharmaceuticals, health insurance, and LMIC (see Appendix 1 for full search criteria). The search was conducted in English (although the search results were not limited to English-language articles) and included articles published through July 2009.

We also performed a systematic search for grey literature (e.g. published reports, technical documents, etc.), which included an online search (e.g. Google) with the search terms mentioned above, a search of websites of international organization (e.g. WHO, USAID, World Bank), a review of the reference lists of published papers, and consultations with academic colleagues. In the Results section, we will use the term "published literature" to refer to both peer-reviewed articles and publicly available grey literature.

Pharmaceutical policy strategies used by insurance programmes were classified by country and organized into the four strategies described above (product selection, purchasing, contracting, and utilization management). Articles on the effects of insurance on access to and utilization of pharmaceuticals were also included. In addition to the review of the literature, we developed four country case studies (Mexico, Thailand, Ghana, Jordan) to illustrate the use of medicines policy strategies in insurance systems and the broader political and social contexts in which they were developed and implemented (see Appendix 2). These case studies represent different geographical regions, types of insurance systems, and policy and management strategies. We supplemented limited published evidence on the specific strategies used in the insurance schemes covered in these case studies with information from interviews with one or two in-country stakeholders. Therefore, the case studies are not comprehensive summaries of the implementation or systematic evaluations of the effects of the medicines policies discussed.
3. Results of literature review

We identified 63 publications (56 peer-reviewed articles and 7 grey literature reports, presentations or books) containing information on the effects of pharmaceutical policy strategies used by insurance systems to influence the cost-effective use of medicines in LMIC. Of these, 54 were research articles and 9 were reviews containing evidence from other studies and analyses, mostly by government agencies or non-governmental organizations. Of the 54 research articles, one was a randomized controlled trial, six were time series with at least 4 data points before and after a policy change (although only two of these studies analyzed the data using advanced statistical techniques, such as segmented regression, and only one had a control group), eight were pre-post studies with a comparison group (although only two used difference-in-differences analysis), eight were pre-post studies with no comparison group and 31 were cross-sectional studies.

We found evidence to support the use of insurance as a strategy to improve access to pharmaceuticals and health outcomes in LMIC. We also found a large amount of evidence on the impact of provider contracting strategies, but far less on product selection, purchasing, or utilization management strategies. Many articles described the impact of multiple strategies within or across the four categories.

The following sections outline the available evidence for insurance provision as a general strategy to improve access to medicines, as well as for the four specific categories of strategies used by insurers to improve the cost-effective use of medicines. We conclude with a list of strategies for which we found no evidence in LMIC.

3.1 Insurance provision as a strategy to improve access, utilization, and health outcomes

There is evidence that providing health insurance can improve consumer access to and utilization of pharmaceuticals as well as health outcomes. Studies either compare the insured to the uninsured within a population, or they compare utilization before and after insurance was implemented. Multiple studies have shown that providing insurance was associated with an increased use of medicines (42, 43, 44, 45, 46, 47), with one study finding that insurance is the most important factor for explaining utilization of medicine (44).

There is also evidence to suggest that health insurance reduces financial barriers to access. Insurance is associated with a decreased likelihood of paying for medicines (48, 49), decreased consumer expenditures on medicines (48, 49), decreased out-of-pocket (OOP) spending on medicines as percent of total health expenditure (4), and decreased reported financial barriers to purchasing medicines (42).
Studies have also shown that insurance can improve medicines utilization and health outcomes. Insurance has been associated with an increased percentage of prescriptions that were actually filled (50, 51), decreased probability of a gap in medicines treatment (44), increased utilization of chronic disease medicines (47), increased adherence to a prescribed regimen (52), increased insulin injections per week (but not proportion of people who received any insulin treatment) and probability of having blood glucose controlled (53), and increased probability of receiving antihypertensive treatment and having blood pressure controlled (54). The limited amount of evidence on health outcomes is likely due to lack of data and the complexity of measuring health outcomes. Numerous studies have found that insurance is associated with a decrease in self-medication (55, 56, 57, 58). Self medication has implications for appropriate use – for example, those without prescriptions were three times more likely to purchase inadequate doses of antibiotic (57).

However, a few studies contradict these positive findings about the effect of insurance. The only randomized controlled study to evaluate the impact of the Seguro Popular insurance system in Mexico, a new insurance system for the poor, found no detectable difference in OOP spending on pharmaceuticals (or on general medical utilization and health outcomes), indicating that the insurance did not improve medicine access and affordability for the poor (59). However, the evaluation was conducted only 10 months after implementation of Seguro Popular, which may have been too short a time to notice insurance effects. One study from China did not find any difference in self-medication between the insured and uninsured (60), although this study found that those with private insurance had the highest proportion of members who self-medicated. A study in Brazil found no difference in antimicrobial resistance between insured and uninsured (61).

Evidence from Mexico calls into question the magnitude of the effects of insurance on reducing economic barriers to medicines. One study found that members in Seguro Popular and in the Instituto Mexicano del Seguro Social (IMSS, the social security insurance system for employed individuals and their families) have similar expenditures on medicines and that their expenditures are only slightly lower than those of the uninsured (48). In addition, because Seguro Popular covers low-cost ambulatory care medicines, higher priced medicines, especially those in inpatient settings, remain unaffordable (48, 51). An analysis that controlled for socio-demographic and economic characteristics found that the proportion of people paying for medicines was lower among Seguro Popular members than the uninsured, but higher than among IMSS members (48). Similarly, results from the World Health Survey suggest that insurance does little to improve access to medicines (11). However, this is not surprising given that many insurance schemes in developing countries do not have a comprehensive medicines benefit or require substantial cost-sharing for medicines.

Finally, there is evidence that insurance can impact patient care-seeking. A study from China found no difference between insured and uninsured in average delay in seeking care, but insured patients were more likely to ask their doctors for certain types of medicines (e.g. painkillers and antibiotics) and more likely to be hospitalized (60). Members of insurance programmes that did not cover dependents were also more likely to ask for medicines for family members.
Summary

- Most of the evidence from LMIC suggests that health insurance is associated with increased use of medicines, a reduction in the financial barriers to access, more rational use, and improved health outcomes.
- Some studies comparing insured and uninsured, primarily from Mexico, do not find positive impacts of insurance.
- Very limited evidence suggests that health insurance has both desirable and undesirable effects on patient care-seeking behaviour.

3.2 Product selection strategies

3.2.1 Medicine lists (formularies)

Although many insurers use restricted formularies or medicines reimbursement lists, there is a dearth of information about the effect of limited lists in LMIC. The few studies that exist suggest that implementation of a formulary can decrease medicines expenditures and reduce utilization of medicines that are less cost-effective. In Shanghai, China, the government insurance authorities developed a medicine list for beneficiaries in the government and labour insurance schemes (62). The insurance reimbursed only medicines on this list and patients had to pay OOP for other medicines. In addition, the insurance implemented a policy that capped hospital revenue from medicines sales and raised provider service fees. The combination of these policies successfully decreased the rate of growth for both total medical and medicines expenditures and decreased the use of imported medicines and high cost antibiotics.

Another study modelled the potential impact of formulary design policies in Taiwan on use of medicines for upper respiratory tract infections (URIs) (63). Lang and colleagues found that 43% of expenditures on medicines for URIs were for medicines that are suitable for self-medication; these medicines could be removed from the reimbursement list or subjected to higher consumer cost-sharing. The authors suggested that making consumers responsible for paying for over-the-counter medicines would reduce National Health Insurance (NHI) expenditures and likely decrease the overuse of medicines for URIs.

A social health insurance programme for migrant workers in a sub-provincial city in China used a combination of approaches - a cap on monthly physician reimbursement and a preferred medicines list with consumer coinsurance (20% to 40% of expenditures on medicines) - to decrease the absolute and relative costs of medicines per outpatient visit while decreasing the total cost per outpatient visit and increasing the number of outpatient visits (64).

The South Korea Health Insurance Review Agency recently developed a new positive list, which will take into account cost-effectiveness data and budget impact when making coverage and payment decisions for newly approved medicines (65). The agency is also developing guidelines for the inclusion of economic data in the submission of dossiers for medicines reimbursement. There is no evidence yet about the effectiveness of these strategies.
3.2.2 Consumer cost-sharing

Many insurance programmes have implemented different forms of member cost-sharing (e.g. premiums, co-payments, deductibles, tiered formularies) to contain costs and influence consumer behaviour. Often, cost-sharing is implemented in conjunction with other strategies (e.g. a formulary or medicines list). The few studies in insurance programmes in LMIC have shown that effects largely depend on the details of the cost-sharing scheme. One study in Taiwan found that increased cost-sharing among the elderly reduced medicines utilization and slowed the rate of increase of medicines costs for the system, but reduced utilization of essential medicines more than non-essential ones and increased the number of prescriptions above the upper-limit of cost-sharing (66). However, another study from Taiwan found that introducing co-payments had no impact on pharmaceutical expenditure for the NHI (67).

Cost-sharing also has the potential to impact patient OOP costs. Community-Based Health Insurance (CBHI) schemes in Senegal and Mali that covered outpatient medicines did not decrease member OOP medicines expenditures because large co-payments were required (68). In a different context, the introduction of a formal co-payment system in Kyrgyzstan increased transparency about medicines prices and payment responsibilities, resulting in a 92% decrease in informal payments (69).

3.2.3 Generic substitution policy

Generic substitution policies have been instituted in a few insurance programmes (e.g. Thailand) and national generic substitution policies exist in several countries (e.g. Argentina, Bolivia, Chile, Colombia, Ecuador, Mexico, Peru, Uruguay, Jamaica, South Africa) (70, 71, 72), but there are no studies to show the effectiveness of this policy. A few studies in Thailand have demonstrated that a capitation payment system increased adherence to hospital-level generic substitution policies and increased prescribing of generics rather than originator products, but had mixed results in terms of providing the most cost-effective medicines treatment (84,85,87).

Summary

- Product selection strategies - such as formularies, consumer cost-sharing and generic substitution - are used by a number of insurance schemes in LMIC. However, there is a little evidence regarding the effectiveness of these strategies in LMIC and more research is needed. If these strategies are proven to be effective, they are currently underutilized by insurers in LMIC.

- Evidence from LMIC suggests that insurers can use formularies to decrease medicines expenditures and reduce utilization of medicines that are less cost-effective. Formularies are likely more effective when coupled with other strategies, such as consumer cost-sharing schemes.

- Studies also show that, if designed correctly, consumer cost-sharing schemes in LMIC can provide incentives for appropriate, cost-effective use of medicines and potentially reduce total medicine expenditures. However, poorly designed cost-sharing systems may burden consumers with out-of-pocket costs and create financial barriers to access.

- There is no evidence regarding the impact of generic substitution policies in LMIC.
3.3 Product purchasing strategies

3.3.1 Generic reference pricing

A few insurance programmes in LMIC use generic reference pricing to set reimbursement rates. The literature contains evidence of these policies from Taiwan, Kyrgyzstan, and South Africa. Generic reference pricing is often combined with a utilization management strategy to influence providers (e.g. doctors will only be reimbursed for the price of the generic equivalent) or consumers (e.g. patients will be responsible for the cost of the medicine over the set reimbursement rate). Overall, this strategy has mixed results, similar to those of provider reimbursement reductions and revenue caps.

In Taiwan, NHI patients pay a small co-payment and providers obtain the major part of medicines charges from the NHI at a rate based on chemical generic grouping. This generic reference pricing strategy significantly reduced cost per day for cardiovascular medicines. But the strategy ultimately resulted in a significant increase in days of medicines prescribed (volume) and total expenditures.

The Kyrgyzstan Mandatory Health Insurance Fund (MHIF) has established a reference pricing system that ties reimbursement rate to price of a generic equivalent. Patients can purchase any product from any pharmacy, but they are responsible for the difference in price between the purchased product and the generic equivalent. This form of reference pricing, which increased patient awareness of prices, was found to decrease retail prices, establish stable market prices for medicines, and improve patient access.

3.3.2 Negotiated prices

Very few insurance programmes appear to use their potential leverage as large purchasers (i.e. market power) to negotiate with the pharmaceutical industry to obtain lower medicines prices. However, limited evidence suggests that this strategy can be successful.

As a single-payer, the Kyrgyzstan MHIF has contracted with pharmacies and hospitals to purchase medicines on their behalf. This bulk purchasing arrangement, combined with the introduction of management practices to determine procurement needs, has reduced the prices of medicines (12%-24% decrease in price) and resulted in greater price stability.

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Since its inception, the Taiwan NHI has established a restricted reimbursement list of medicines. Patients cannot request unlisted medicines by paying the difference. Patients pay a small co-payment and providers obtain the rest of the medicine charges from the NHI at a rate based on the following three categories: 1) originator brand medicines, 2) generics with evidence of effectiveness from bioavailability and bioequivalence studies (BA/BE generics), and 3) other generics. Originator brand medicines are priced according to reference prices in ten industrialized countries and the BA/BE generic prices are no higher than 80% of the originator brand price. The common generic price is set at no higher than 80% of the originator brand price or the lowest price of its corresponding BA/BE generic, if available.
An analysis of medicines prices in Mexico found that IMSS has been able to use its market power to procure medicines at prices that are 80% lower than the stamped maximum price for comparable products in the private sector and substantially lower than the 30-40% price discounts typical in that sector (75). Unfortunately, the study also showed that the lowest price products obtained through the IMSS bidding process were often not of good quality. However, recent changes in Mexican pharmaceutical policy are expected to remove all generics without proof of bioequivalency from the Mexican market by 2010* (75).

An example from South Africa demonstrates how an insurance scheme can increase purchasing efficiency by using market power, formularies, and generic reference pricing in tandem. The private insurer Medscheme developed a Medscheme Price List (MPL) in which reimbursements to providers were set by grouping products that are generically similar, with a maximum reimbursement price in each group. Members are allowed to purchase higher priced medicines, but must pay the difference in price. One study that compared medicines prices before and after the MPL went into effect found that this strategy reduced the rate of medicines cost inflation (76). Over half of the medicines on the list either dropped in price or did not increase in price a year after implementation, largely due to increased competition among producers of generic products that lowered prices so that consumers would not be subject to additional co-payments. This supplier-directed strategy also resulted in pharmaceutical companies (of generic, branded generic, and originator brand products) meeting with Medscheme decision-makers, which often led to negotiating price reductions.

Summary

- Very few insurance schemes in LMIC use active purchasing strategies, such as generic reference pricing or negotiations with the pharmaceutical industry, to obtain lower medicines prices. Therefore, there is limited evidence about the effectiveness of these strategies in LMIC.

- Studies suggest that the use of internal generic reference pricing to set reimbursement rates has mixed effects. Although this strategy can successfully reduce medicine prices and encourage patients to choose more cost-effective medicines (i.e. lower priced generics), generic reference pricing may not reduce overall medicine expenditures since it does not guarantee efficient medicines prices or impact the quantity of medicines prescribed.

- Health insurance schemes have considerable market power, which gives them leverage to negotiate with the pharmaceutical industry for lower prices. Although this strategy has proved successful in a few insurance schemes in LMIC, there is a general lack of evidence on the extent of its use and impacts of negotiation on price.

- To improve the cost-effective use of medicines in LMIC, insurers should include provisions regarding product quality and consider appropriate use in their purchasing strategies.

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* The WHO has determined that not all medicines require bioequivalence testing. The 40th report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (whqlibdoc.who.int/trs/who_trs_937_eng.pdf, p.383) has proposed to waive in vivo bioequivalence requirements for immediate-release, solid oral dosage forms on the WHO Model List of Essential Medicines, which constitute a majority of the medicines on the EML.
3.4 Reimbursement design and contracting strategies

The use of economic incentives to influence provider (e.g. doctor, hospital, pharmacist, etc.) behaviour is the most common strategy reported in the literature. There is a large amount of evidence that the type of provider payment system implemented by an insurance programme affects use of medicines. In fee-for-service (FFS) systems, providers are paid for every service, including prescribing and dispensing medicines. In case-based systems (such as U.S. Medicare’s (insurance for those 65 years and older) diagnosis related groups (DRGs)), which are mainly used in hospitals, providers receive a set payment for each case, with varying levels for different conditions/severity. In capitation systems, providers receive a set payment per person.

3.4.1 Fee-for-service reimbursement vs. no insurance

Evidence suggests that FFS insurance payment increases medicines utilization and expenditures in comparison to having no insurance, but most articles do not assess whether these increases were cost-effective. Much of the evidence comes from China, where studies have shown that patients with FFS insurance have higher total medicines costs (77, 78, 79) and higher total medical costs (80) than uninsured patients. Similar results have been obtained in different types of insurance systems (i.e. social vs. community-based) and geographical settings (i.e. urban vs. rural). In China, health institutions and providers are allowed to mark-up medicines prices to obtain a profit, and many rely on selling medicines to maintain financial stability. Providers paid FFS by an insurer (or OOP by patients who have medicines costs partially subsidized by the insurer) are more likely to prescribe medicines, prescribe more medicines per visit, prescribe more newer and higher priced medicines, and prescribe more antibiotics and injectable medicines to insured patients (80, 81). Similarly, a study from South Africa found that doctors prescribed more medicines per visit and that the cost per medicine was higher in a private FFS system than in the public sector (82). However, this study did not control for different characteristics of patients and providers in the private versus public sector that may also impact use of medicines.

Two studies have found contradictory effects of FFS insurance on appropriateness of prescribing. One study on outpatient care in rural China found that the uninsured were significantly more likely to be prescribed antibiotics and receive antibiotic injections than the insured, possibly because the uninsured delayed care and were sicker (83). For cases in which patients received an antibiotic, there was no difference between the insured and uninsured in the number of antibiotics prescribed (average 1.2 antibiotics per visit) or percentage of patients who bought the medicine(s) prescribed (92% vs. 96% for insured and uninsured, respectively). However, insured patients were more likely to be prescribed newer and higher priced antibiotics (although this was only significant at the village level and for certain diseases). In contrast, another study in rural China found that the average number of medicines per outpatient visit was significantly higher for the uninsured than the insured (78), although the insured had significantly higher average medicines expenditure.
3.4.2 Capitation vs. fee-for-service reimbursement

Studies comparing FFS and capitation insurance payment systems suggest that capitation can contain medicines expenditures and promote appropriate use. Most evidence is from Thailand, where services to the majority of the population are now paid on a capitated basis. The social security benefit for private sector employees and the new universal coverage scheme (known previously as the “30 Baht” and now as the “0 Baht” Scheme) pay providers on a capitated basis whereas the civil social insurance (CSMBS) pays FFS and reimburses for all new medicines (84). There is also evidence from a few smaller capitated insurance systems in China. Compared to FFS payments, capitated schemes were associated with prescription of more essential medicines and fewer antibiotics and injections (85, 86) as well as increased generic prescribing and increased adherence to hospital generic substitution policy (78, 79, 87). Members of capitated insurance programmes were also prescribed fewer medicines overall and were less likely to be prescribed newer/originator medicines (78, 79, 87), but were no less likely than FFS patients to receive all the medicines they needed (78). In terms of medicines costs per case for specific conditions, the capitated systems did not always have lower costs nor provide more cost-effective medicine treatment (78). However, a study from China found that capitation was associated with a reduced growth in expenditures for high priced medicines (88).

There is also some evidence about negative impacts of capitated payment systems. One study in Thailand showed that hypertensive patients under capitated payment received fewer medicines and were more likely to be hospitalized than FFS patients at the same hospitals (87). Some hospitals used strategies to abandon capitated patients or deter them from registering. Patients who could afford to pay OOP were more likely to receive new medicines (78) but were no less likely than FFS patients to receive all the medicines they needed (78). In terms of medicines costs per case for specific conditions, the capitated systems did not always have lower costs nor provide more cost-effective medicine treatment (78). However, a study from China found that capitation was associated with a reduced growth in expenditures for high priced medicines (88).

3.4.3 Case-based vs. fee-for-service reimbursement

There is less evidence from insurance programmes that use case-based payment mechanisms, although it would be expected that case-based payments may have similar effects as capitation. The national health insurance systems in South Korea and Taiwan both purchased care on a FFS basis, which may have contributed to rapid increases in health care expenditures in both countries (87). Both countries are now introducing a case-based payment system. A study in Taiwan found that after the implementation of case-base payment for 50 inpatient procedures, the vast majority of hospitals reported that they coped with decreased payments by cutting the costs of medicines (94% of hospitals; although the article does not describe how medicines costs were cut and whether cutting medicines costs negatively impacted patient outcomes) and avoiding prescribing medicines upon discharge (78%) (90). However, under this new system, hospitals also established better communication with the NHI, conducted patient satisfaction surveys, developed practice guidelines, and trained doctors (although guidelines were developed in part to inform providers about how to avoid making a procedure case-based).

In 2008, the Ghana National Health Insurance System (NHIS) replaced its FFS provider reimbursement system with a case-based DRG system, which pays by episode of care (with varying reimbursement for different diseases, levels of care, and sector) (91). Medicines costs are not included in the case-based payment and are billed separately. Data is not yet available to analyze the financial impact of this new
provider payment system. Preliminary analyses suggest that there was a large increase in NHIS claims and a shift to diagnoses that receive a higher payment (91). With medicines exempted from the case-based payment, there was an increase in medicines per prescription and a shift to prescribing more high priced medicines (91).

3.4.4 Financial incentives for quality care

There is very little evidence on pay-for-performance incentives in LMIC. The national health insurance system in the Philippines, PhilHealth, has three mechanisms to promote quality of care: accreditation, review of medical claims (based on clinical guidelines) prior to reimbursement from insurance, and additional insurance payments for meeting quality standards (i.e. becoming accredited and following clinical guidelines) (92). A study found that both accreditation and insurance payments had a positive effect on quality (92). The authors conclude that payment systems that reimburse for claims that comply with clinical guidelines are key to making long-term quality improvements, but there was no direct evidence of effects on cost-effective use of medicines. Similarly, a study of a pay-for-performance programme in the Taiwan NHI found that the programme improved outpatient services and reduced inpatient services and costs, but did not provide evidence specific to medicines (93).

3.4.5 Reducing reimbursement rates for medicines

In attempts to contain pharmaceutical expenditures, insurance systems frequently try to reduce the reimbursement rates to providers. Where it has been evaluated, this strategy has not been successful in LMIC. Most evidence is from reimbursement rate reductions in Taiwan, where pharmaceutical spending increased from 22% of total national health spending in 2000 to 28% in 2003 (67, 94). The NHI’s Pharmaceutical Benefit Scheme (PBS) reimburses both modern medicines and traditional Chinese medicines. The reimbursable list, which includes almost all approved medicines, exceeded 21,000 products in 2001 (95). In 2000, the Taiwan NHI reduced the reimbursement rates for 45% of the medicines listed on the PBS. Overall, this policy resulted in a slight decrease in number of prescriptions, total medicines cost, and average medicines costs per prescription (96). However, doctors in hospitals with fee programmes (i.e. doctor compensation determined by the revenue they generate) responded to the rate decreases by increasing the number and duration of prescriptions. There was also some evidence that doctors substituted medicines that had rate reductions with other medicines that did not. However, providers did not tend to replace essential medicines with non-essential medicines.

Similarly, in 2001, the Taiwan NHI adjusted reimbursement rates based on a generic reference price policy. This policy resulted in a significant decrease in daily medicines expenditures for the patients who took medicines affected by the policy with no change for patients who took medicines that were not subject to reduced rates (97). However, the number of days per prescription and total medicines expenditures significantly increased for both groups of patients. About half of patients received more than one dose per day of once-a-day medicines after the policy. Therefore, the policy resulted in no savings and inefficient, and possibly dangerous, use of medicines. Another study in China found that a government policy on price controls lowered product prices, but resulted in an increase in utilization and overall expenditure (98). Although this was not an insurance policy, it demonstrates that merely lowering the reimbursement price of medicines is not successful in promoting cost-effective use.
3.4.6 Separating prescribing and dispensing

To reduce potential conflict of interest, many Asian countries have implemented Separation of Prescribing and Dispensing policies (SPD). Although SPD are government policies, the provider payment strategies implemented by insurers are crucial to their success. In 1995, the initiation of the Taiwan NHI replaced FFS payment with daily fixed rates for pharmaceuticals prescribed and dispensed by doctors (doctors received two separate rates for each activity), to control medicines expenditures while still allowing doctors to profit from both prescribing and dispensing (99). However, spending on pharmaceuticals continued to rise at a faster rate than other health spending. In response, in 1997, Taiwan instituted a SDP policy that required all prescriptions to be dispensed by a pharmacy. The NHI encouraged pharmacies to take up this role by increasing the dispensing fee. To compensate for loss of revenue from drug sales and dispensing, NHI provided a bonus to doctors who complied with the law and released their prescriptions to a pharmacy for dispensing (100). In a concession to the Taiwan Medical Association, the NHI made exceptions to the dispensing policy for certain age groups and clinical requirements, and continued to allow payments for medicines dispensed by physician-owned on-site pharmacies. This loophole, which allowed clinics with on-site pharmacies to get the flat fee for prescribing, the fee for releasing their prescription, and the pharmacy fee for dispensing (100), resulted in a significant increase in the number of clinics hiring on-site pharmacists (99). Although the average drug expenditure per visit decreased in clinics without an on-site pharmacy, there was no change in clinics with an on-site pharmacy (99). The policy did not lead to a decrease in total health expenditures since savings were offset by the increase in consultation and dispensing fees.

To encourage more doctors to release their prescriptions to pharmacies, the NHI’s reimbursement rate for doctor dispensing, but not for pharmacy dispensing, was reduced in 2002 and the consultation rate increased (100). This policy resulted in a significant increase in the market share of doctor-owned on-site pharmacies and the percent of total prescriptions dispensed in these pharmacies. Nevertheless, the reduction in the daily reimbursement rate was associated with a significant reduction in medicines costs (67). The authors of these studies conclude that a separation policy could be effective in reducing medicines expenditure, changing provider prescribing behaviour, and promoting appropriate use, but it is not clear that the policy can reduce total health care expenditures.

South Korea has also implemented SPD reforms, which prohibit medical institutions from employing pharmacists or having on-site pharmacies and prohibit pharmacists from providing medicines to patients without a doctors prescription (101). Multiple studies (101,102) have found a decrease in medicines prescribed after the policy went into effect; the policy decreased the percent of patients prescribed antibiotics and injections, decreased the number of antibiotics and other medicines prescribed per episode of illness, and reduced medicines prescribing overall (101, 102, 103). However, government spending on pharmaceuticals actually increased in both outpatient and inpatient settings (101, 102). Although the reform removed profit incentives, providers had no incentive to prescribe cheaper medicines – the percentage of high-price prescriptions increased and the percentage of cheaper generics decreased (102). The separation policy was followed by an overall decline in access, an increase in costs and inconvenience, and an increase in self-medication (101). The policy also resulted in increased pharmaceutical company sales and medicines imports (101, 102). The results may not be due solely to the SDP policy, but due to the dramatic increase in prescription charges (60% increase) and doctors fees (44% increase), which were
implemented to prevent strikes by doctors (100, 102). In January 2008, South Korea implemented a medicines formulary that will financially penalize both providers and consumers who choose high priced brand-name medicines when a cheaper alternative of the same quality is available (102). The effects of this policy have not yet been reported.

### 3.4.7 Preferred provider and dispenser networks

There is very little evidence on the effects of insurers contracting with preferred provider or pharmacy networks. The Kyrgyzstan MHIF has contracted with providers and pharmacies to purchase medicines on their behalf (see above). In South Africa, managed care initiatives that included the establishment of preferred pharmacy networks have contributed to cost-savings (104, 105).

### Summary

- The use of economic incentives to influence provider (e.g. hospital, doctor, pharmacist, etc.) behaviour is the most common strategy reported in the literature.
- Evidence suggests that FFS insurance payment systems increase medicines utilization and expenditures in comparison to having no insurance, but most articles do not assess whether these increases are cost-effective.
- Studies comparing FFS and capitation, and case-based insurance payment systems, suggest that capitation can contain medicines expenditures and promote appropriate use. There is less evidence from insurance programmes that use case-based payment mechanisms, although case-based payments may have similar cost-reducing effects as capitation.
- The evidence on the effects of policies separating prescribing and dispensing and reducing the reimbursement rates for medicines suggests that these strategies have a mixed impact in LMIC, primarily because providers respond by changing their behaviour in undesirable ways.
- There is very little evidence on the effects of pay-for-performance incentives or of insurers contracting with preferred provider or pharmacy networks in LMIC.

### 3.5 Utilization management strategies

#### 3.5.1 Educational strategies

There is a paucity of evidence on the use of educational strategies by insurance programmes in LMIC to influence consumer or provider behaviour. Although some dissemination of information to members accompanies many policy changes, only two articles mentioned educational programmes implemented to educate consumers about generic reference-pricing policies in Kyrgyzstan and South Africa (69, 76). A study from the Philippines found that chronically ill patients insured by micro health insurance units (MIU) were more likely than uninsured patients to adhere to a medicines regimen despite the fact that the MIUs did not provide unlimited medicines coverage (52). The authors postulate that MIU members may have better awareness as a result of “awareness groups” organized by some MIUs, although education level differences between the groups may explain differences in awareness.
There is also little evidence about educational strategies aimed at providers. In Mexico, IMSS implemented a multi-faceted strategy to reform primary care, which included continuing education and implementation of clinical guidelines \((106, 107, 108)\). For the educational component, IMSS used a "professor-visits" model (trained clinical advisors) and distance learning, both of which allowed doctors to learn in their clinics (Family Medicine Units). In addition to improving other clinical benchmarks, the educational intervention was intended to improve the quality of prescribing behaviour, save resources by eliminating excess medicines prescription and use, and decrease resistance to antibiotics. The national rate of provider adherence to clinical practice guidelines for the six target conditions increased from 72% to 84% \((106)\). Treatment according to clinical practice guidelines (which included the prescription of certain medicines) improved significantly after the educational programme, although there were variations in compliance by condition and geographic region. Overall, the education strategy improved prescribing and is cost-effective for IMSS \((107, 108, 109, 110)\).

### 3.5.2 Disease management

Disease management programmes (DMP) combine targeted patient education and management strategies to ensure that patients receive optimal care. Again, there is little information available about the effects of programmes implemented in LMIC. One study from South Africa hints at the possible impact of insurance-supported DMP strategies. The study compared HIV/AIDS medicines uptake between patients who worked for companies with the following three insurance structures: voluntary insurance-run, employer-subsidized DMP (Medscheme); employer-run DMP; and employer-contracted, independent DMP \((111)\). Uptake of medicines was higher in companies that had an employer-run and independent DMP than in the companies relying on Medscheme. Uptake in all three programmes was very low, likely due to stigma surrounding HIV/AIDS and employees' fears that an employer will learn about their status.

### Summary

There is a lack of evidence in LMIC on the impacts of utilization management strategies, such as patient and provider education and disease management programmes. The lack of literature on this topic suggests that utilization management strategies are greatly underused and poorly evaluated in insurance systems in LMIC.

### 3.6 Lack of evidence

We did not find any evidence from LMIC for several strategies included in our search. Among product selection strategies, we did not find any evidence on the impacts of coverage limits or prior authorization, and we found very little direct evidence on formulary restrictiveness. Among product procurement strategies, we found almost no evidence on the effects of insurers directly bidding for medicines or negotiating discounts and rebates with suppliers. Finally, among utilization management strategies, we found no evidence on the impacts of utilization review, physician profiling, or performance incentives, and very little evidence on preferred provider networks or educational programmes. Since our list of target strategies is not comprehensive (and was partly developed based on the available literature), other strategies to increase cost-effective use of medicines in insurance programmes may exist that we did include in this review.
4. **Country case studies**

We explored four examples of how insurance systems in low- and middle-income countries have designed and implemented strategies to improve the use of medicines (see Appendix 2). The four case studies examine:

I **Thailand**:  
*Increasing access to medicines through Thailand’s 30-Baht scheme.* This case study demonstrates the impact of the rapid implementation of a universal health insurance scheme for the poor on access to health care and medicines, and highlights the effect of the structure of provider payment (i.e. capitation vs. fee-for-service) on prescribing behaviour.

II **Ghana**:  
*Change from a fee-for-service to a case-based provider payment system for outpatient care in Ghana.* This case study highlights the tension between providing universal coverage and containing costs and demonstrates the potential unintended consequences of provider payment reform on cost and quality of care, as well as the importance of integrating medicines reimbursement in the case-based payment system.

III **Mexico**:  
*Improving use of medicines in the Mexican Social Health Insurance through physician education.* This case study provides an example of a multi-faceted, long-term policy strategy to improve quality of care in a social security system with an integrated health care delivery system through education of family doctors that led to improved quality of prescribing, more cost-effective use of resources, and improved health outcomes.

IV **Jordan**:  
*Monitoring medicines use in Jordan with smart-card systems.* This case study illustrates how private-sector technical innovation is intended as a mechanism for reducing abuse and improving the cost-effective use of medicines, as well as some of the challenges of implementing a high-tech information system in a middle-income country setting.

The case studies highlight several important lessons:

- Strategies to extend access to medicines through insurance reform and to improve the cost-effective use of medicines through insurance system initiatives can be effective in low- and middle-income countries.
- Strong political will, stakeholder involvement, and transparency of policy processes are crucial aspects of successful policy development and implementation.
• Tension between policy-makers and providers is an inevitable aspect of policy changes that shift provider reimbursement or impact on care processes.

• Many strategies are implemented in windows of political opportunity with little or no evidence about their potential effectiveness or harms.

• There is a need for ongoing evaluation of desired and undesired policy impacts and flexibility to adapt policy contents or change technical aspects of policy implementation on the basis of new evidence.
5. Discussion

We found limited evidence from LMIC that supports the use of insurance as a strategy to improve access to and utilization of pharmaceuticals. However, most studies do not address whether the increased utilization is appropriate (i.e. pent-up demand) or undesirable (i.e. moral hazard). There is limited, but positive, evidence supporting the use of health insurance to improve health outcomes. Overall, we found very little evidence of the effects of specific strategies used by insurance systems in LMIC, and evidence is entirely lacking for strategies used in community-based health insurance systems (113). The majority of the evidence in the literature is on the impact of reimbursement design and contracting strategies. There is hardly any evidence of product selection, product purchasing, or utilization management strategies. We found no evidence from LMIC evaluating some of the mechanisms commonly used by insurance systems in high income countries, such as coverage limits, differential co-payments, prior authorization, pay for performance incentives, utilization review, or physician profiling, and little evidence of insurers negotiating discounts and rebates with suppliers.

Even where the scant evidence exists, one must interpret the results of these studies with caution. Virtually all of the studies from LMIC included in this review have questionable internal validity due to inadequate research designs. To draw causal inference, one must use an experimental (i.e. randomized control trial) or a well-designed quasi-experimental design that has a valid control group and measures the effect of a policy over time. Except for some studies from Mexico, Taiwan and Thailand, the designs in the studies from LMIC are methodologically weak. The majority of the studies are cross-sectional, which makes it impossible to examine trends over time. Although many studies have a control group (e.g. the uninsured), the control group is often biased due to self-selection – the people who choose to enroll in insurance are usually different from the uninsured on important factors such as health status, income, education, etc. For instance, perhaps only wealthier, healthier people are able to afford insurance. Conversely, perhaps only sicker people choose to enroll (i.e. adverse selection). And, in many cases, multiple policies were implemented at the same time (by either the insurance programme or the government), so it is hard to tease apart the effects of separate policies.

Finally, the external validity, or ability to generalize, of these reviewed studies is questionable. Since most have a small, narrowly-defined study population, it is difficult to know whether strategies that prove effective in the study setting will be successful in other settings (i.e. in other countries, different regions within a country, or different time periods). Such research design problems may explain the sometimes contradictory results cited in this paper. The overall impact of a strategy will likely differ depending on the type and design of a health insurance scheme (i.e. public versus private, voluntary versus mandatory) and the health care system context in which it operates. Furthermore, the impact of a strategy will depend of the type of medicine that it targets. Although cost-effective use often implies shifting to equivalent lower-priced products, access to essential high-priced medicines with no available alternatives (e.g. anticancer, biological, second-line ARVs or tuberculosis medicines) is a complex issue that may require different types of strategies.
One key finding from this review is that medicines management strategies are rarely implemented in isolation. While this makes it more difficult to understand the effects of individual strategies, we know from systematic reviews in industrialized countries that a combination of strategies is more likely to be effective. Rather than comparing individual strategies, greater emphasis should be put on determining the best combination of strategies to improve the cost-effective use of medicines in different contexts. For example, in many Asian countries, utilization management strategies that attempt to reduce overall costs (e.g., reducing revenue rates, untying prescribing and dispensing, generic reference pricing, or provider budgets) have been largely unsuccessful under FFS systems since providers respond by increasing prescription volume or shifting to more costly medicines. This suggests that supplier-induced demand, coupled with increased patient financial risk protection from insurance, may negate the effects of utilization management strategies in FFS systems. Insurers may be more successful if they implement a contracting strategy (e.g., capitation or case-based reimbursement) that provides financial incentives for more cost-effective use. In Thailand, evidence suggests that generic substitution policies were better adhered to under capitated payment systems where hospitals shared risk for medicines costs. And in Kyrgyzstan, a combination of generic reference pricing, consumer education about payment responsibilities, and price negotiation with suppliers established stable market pricing for medicines and improved patient access. Finally, by using leverage to improve provider and consumer practices, and potentially to lower industry prices, insurance systems with substantial membership can have overall effects on the health sector itself (i.e. externalities).

5.1 Policy recommendations

In light of the scarcity of high quality evidence from LMIC, we suggest for consideration in LMIC some policy recommendations based primarily on evidence from high-income countries. However, since results from high-income countries may not generalize to LMIC, it will be important to evaluate the suggested policies in such settings before widespread adoption. The following policy recommendations for LMIC were developed with input from the WHO/HAI Project on Medicine Prices and Availability Pricing Policy Working Group.

1. Extend medicines coverage to both inpatient and outpatient settings. Outpatient coverage of medicines is likely to increase member satisfaction and retention, improve adherence to treatment for chronic illness, prevent disease progression, and reduce unnecessary hospitalizations. Isolating and managing medicines utilization as a separate component of inpatient care allows greater financial control and improved ability to monitor the implementation of evidence-based pharmaceutical care practice.

2. Focus on public sector medicines supply system efficiency. Public sector systems generally purchase more efficiently, have higher rates of generic prescribing and dispensing, and have lower end-user prices than private retail outlets. However, inefficient systems and constraints on cash flow can cause frequent stock-outs. Insurance reimbursements can help to improve the efficiency of public sector supply systems, and reduce disruptions to prescribing caused by stock-outs, reduce rates of unfilled prescriptions, and reduce cost per filled prescription. To realize this potential, medicines dispensing outlets need to be connected to and have efficient, reliable mechanisms to receive funds from insurance systems. The details of establishing relationships (i.e. procurement system) to ensure efficient medicines purchasing and prevent fraud are important to the success of all purchasing strategies.
3. **Negotiate medicines prices frequently with pharmaceutical manufacturers and suppliers.** Insurance programmes can take advantage of the negotiating leverage offered by their large populations and their ability to include or exclude specific medicines from their reimbursement lists to negotiate favorable prices for members. A less fragmented system of purchasing medicines will also have lower transaction costs. In insurance systems that reimburse for medicines dispensed in the private sector, contracting with preferred pharmacy networks can ensure product quality and reduce cost.

4. **Consider trade-offs and incentives when designing a medicines reimbursement list.** Many high-income countries have developed various types of restrictive or tiered formularies, using evidence-based and cost-effectiveness criteria, to increase quality and decrease costs (112). A short reimbursement list that includes only essential medicines may provide a basic benefit that is easy to manage. However, if a list is too constrained, patients may end up purchasing medicines that are excluded from the list at high out-of-pocket costs, especially if provider payment incentives encourage prescribing non-formulary medicines. Political acceptance and support for the insurance scheme also hinges on the generosity of the reimbursement list.

5. **Implement multi-faceted strategies to increase generic utilization.** A high rate of generic prescribing and dispensing is one essential strategy to achieve cost-effective medicines utilization. Specific components of a broad programme to increase generics use include: consumer and provider education and information, financial incentives for achieving target rates of generics prescribing, mandatory generic substitution by dispensers, incentives for dispensers, tiered patient co-payments (with generics in the lower-cost tier) and generic reference pricing.

6. **Use differential co-payment levels as price signals to consumers.** Differential co-payments can be used to create financial incentives for consumers to request generics, preferred brands, or more cost-effective medicines in a therapeutic category. However, for these strategies to work, both prescribers and consumers must have adequate information about available alternatives, product quality, and therapeutic equivalence.

7. **Align provider and patient incentives with desired practices.** Provider payment mechanisms (e.g. shift to capitation or case-based payment) and financial incentives (e.g. higher reimbursement for preferred services, global prescribing budgets or pay for performance) can be used to encourage more cost-effective prescribing (e.g. higher rates of generic prescribing, greater reliance on low-cost therapeutic alternatives, and closer adherence to clinical guidelines). In a similar way, insurance programmes can provide financial incentives to members to encourage more cost-effective use of medicines (e.g. low or no co-payment for generics, rebates for achieving care targets, free participation in disease management programmes).

8. **Be cautious when setting arbitrary utilization limits.** Arbitrary limits intended to reduce medicine expenditures (e.g. caps on the number or cost of medicines prescribed or dispensed during a hospitalization or a defined period of time) may be harmful to sicker members and may actually increase overall health care expenditures. When arbitrary limits in medicines utilization are implemented, it is important for insurance programmes to assess their impacts on subgroups of patients at or near the limit to ensure adequate continuity and quality of care, and to prevent unintended increases in use of other costly services.
9. **Implement specific strategies to manage high-cost medicines.** Although cost-effective for some serious illnesses, uncontrolled use of very high priced medicines (e.g. newer biologicals) can break a pharmaceutical budget. Requiring substantial patient cost-sharing for these medicines may limit costs, but result in poor adherence to medically necessary medicines. Insurance programmes can use other targeted strategies to manage utilization and costs (e.g. prior authorization, disease management programmes, preferred providers).

10. **Build a robust system for monitoring and evaluation.** One strength of insurance systems is the availability of routine data on utilization of medicines and other health services (e.g. claims, medical records). Without effective and timely use of such data, it is impossible to administer an economically viable insurance programme. Besides financial management, routine utilization data should also be the basis for monitoring other key programme objectives, such as equitable access to services, efficiency and quality of care, and health outcomes. This requires adequate investment in information technology infrastructure, coding systems, data quality, and analytic capacity.

### 5.2 Recommendations for research

This report highlights the need for stronger research designs in evaluating the impacts of medicines strategies on cost-effective use of medicines in insurance programmes in LMIC. Previous reviews have also shown the lack of high quality literature to evaluate the effects of pharmaceutical policy strategies in LMIC (113, 114, 115).

Future research is needed to create a portfolio of evidence on the desired and undesired effects of pharmaceutical policy strategies used by insurers in LMIC. Given the importance of context in understanding and interpreting results of policy interventions, it is crucial that these studies also include adequate descriptions of the health care system and institutional context, as well the array of complementary national and local policies that might impact use of medicines or other health services. Since implementing multifaceted strategies will likely be the most cost-effective way to manage medicines (22), it is important for researchers to evaluate the joint impact of all strategies implemented by an insurer. It is also important to evaluate the impact of insurers’ pharmaceutical strategies on the health of the entire population. By using leverage to improve provider and consumer practices, and potentially to lower industry prices, insurance systems with substantial membership may have overall effects on the health sector itself (i.e. externalities).

Many of the studies in the review relied on data from insurance claims to evaluate utilization and costs. One challenge in future research on the impacts of insurance on access to and use of medicines will be to obtain data from uninsured members of the population, or pre-insurance utilization for those who obtain insurance. This will require well-planned prospective studies to collect the data necessary to evaluate the impacts of insurance coverage. The development of an evidence base on medicines policy effects in insurance programmes in LMIC will also benefit from the development of a set of standard indicators to assess utilization, cost, clinical outcomes, and cost-effective use of medicines in these settings.
## Glossary

(Borrowed from the Medicines and Insurance Coverage (MedIC) Initiative Survey for Health Insurance Programmes)

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>Adverse Selection</td>
<td>An economic term which, in the context of health insurance, refers to the scenario in which people with higher risk (in terms of current or predicted need for health services) buy insurance. Asymmetric information between the insurer and consumer is necessary for adverse selection to occur i.e. the consumer knows his health status and the insurer does not.</td>
</tr>
<tr>
<td>Benefit package</td>
<td>Range of (health) services offered to an insured or a monetary sum payable to a recipient for whom the insurance company has received the premiums.</td>
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<tr>
<td>Brand name products</td>
<td>Products manufactured by the company who first marketed a product. (Note: referred to as originator brands in WHO/HAI price measurement manual) Brand name products are usually higher priced than generic products.</td>
</tr>
<tr>
<td>Charge</td>
<td>In regard to fees for medical services, the charge is the nominal amount appearing on the billing to the customer or the insurer.</td>
</tr>
<tr>
<td>Claim</td>
<td>Request by an insured for indemnification by an insurance company for loss incurred from an insured peril; the monetary amount called to settle the liability arising out of the occurrence of the insured risk.</td>
</tr>
<tr>
<td>Coinsurance</td>
<td>The portion of the balance of covered medical expenses which a beneficiary/patient must pay after payment of the deductible.</td>
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<tr>
<td>Compulsory insurance</td>
<td>Coverage required by the laws of a particular country/state; Many countries/states stipulate minimum amounts of automobile liability insurance which must be carried.</td>
</tr>
<tr>
<td>Cost-sharing</td>
<td>Required partial payment for health expenses by the beneficiary/patient, including the deductibles, co-payments, coinsurance, and balance.</td>
</tr>
<tr>
<td>Co-payment</td>
<td>A payment required from the covered person to become entitled to a medical service. Partial payment of medical service expenses required in group health insurance, in addition to a membership fee, for example, for each visit to a physician, a member may be required to pay $5, regardless of the expense of the services rendered. Or, for each prescription for drugs and medicines, the member may have to pay a flat $2 regardless</td>
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<tr>
<td>Term</td>
<td>of the actual cost.</td>
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<tr>
<td>Coverage</td>
<td>The extent of benefits provided.</td>
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<tr>
<td>Covered expenses</td>
<td>In health insurances, medically related expenses for which the insurance will reimburse the insured and/or pay the provider; expenses may include charges for room and board, surgery, medicines, ambulance service to and from a hospital, operating room services, laboratory tests, etc.</td>
</tr>
<tr>
<td>Current Procedural Terminology (CPT®) Codes</td>
<td>Current Procedural Terminology (CPT®) is a listing of descriptive terms and identifying codes for reporting medical services and procedures. The American Medical Association (AMA) first developed and published CPT in 1966. The purpose of CPT is to provide a uniform language that accurately describes medical, surgical, and diagnostic services, and thereby serves as an effective means for reliable communication among doctors, and other healthcare providers, patients, and third parties.</td>
</tr>
<tr>
<td>Deductible</td>
<td>The amount an individual must pay for health care expenses before insurance (or a self-insured company) covers the costs; Often, insurance plans are based on yearly deductible amounts.</td>
</tr>
<tr>
<td>Disease</td>
<td>Illness or sickness, interruption or disorder of body functions, systems or organs such as cancer, leukemia, diphtheria, scarlet fever, tetanus and meningitis; Expenses for these may be covered by health insurance policies as specified.</td>
</tr>
<tr>
<td>Essential Medicines List (EML)</td>
<td>A list of essential medicines which are those that satisfy the health care needs of the majority of the population and should therefore be available at all times in adequate amounts, in the appropriate dosage forms, and at a price that individuals and the community can afford. Countries may develop essential medicines lists and insurances may reimburse only for medicines on an EML.</td>
</tr>
<tr>
<td>Exemption</td>
<td>The freedom from payment of a tax or other duties, either in whole or in part, usually given for a specific reason of an economic and social nature, such as low income of a person.</td>
</tr>
<tr>
<td>Formulary</td>
<td>A list of medicines. Health insurances may establish or refer to lists of medicines which qualify for reimbursement by the insurance.</td>
</tr>
<tr>
<td>For-profit organization</td>
<td>An institution, corporation, or other legal entity, which is organized for the profit or benefit of its shareholders or other owners.</td>
</tr>
<tr>
<td>Fraud</td>
<td>The common-law offence of making or altering any document (e.g. medical bills) with the intention of causing harm to another person’s rights (e.g. the insurance company’s rights).</td>
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<tr>
<td>Generic products</td>
<td>A pharmaceutical product that is intended to be interchangeable with the originator brand product. (Note: definition under review.) Generic products are usually less costly than originator brand.</td>
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<td>Term</td>
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<tr>
<td>Health insurance</td>
<td>A generic term applying to all types of insurances indemnifying or reimbursing for losses caused by bodily accidents or sickness or for expenses of medical treatment necessitated by sickness or bodily injury. A system for the advance financing of medical expenses by means of contributions or taxes paid into a common fund to pay for all or part of health services specified in an insurance policy or law. The key elements in health insurance are advance payment or premiums or taxes, pooling of funds and eligibility for benefits on the basis of contributions or employment without an income or assets test. Health insurance may apply to a limited or comprehensive range of medical services and may provide for full or partial payment of the costs of specific service. Benefits may consist of the right to certain medical services or reimbursement of the insured for specified medical costs and may sometimes include income benefits for working time lost owing to sickness or maternity leave. A health insurance company or other private agency, with the provisions specified in a contract is a private or voluntary, health insurance. Private health insurance is usually financed on a group basis, but most plans also provide for individual policies. Private group plans are usually financed by groups of employees whose payments may be subsidized by their employer, with the money going into a special fund. Insurance of hospital costs is the most prevalent form of private health insurance coverage; another type is major medical expense protection, which provides protection against large medical costs but avoids the financial and administrative burdens involved in insuring small costs. If a system is financed by compulsory contributions mandated by law or by taxes and the system’s provisions are specified by legal statute, it is a government, or social health insurance plan (see social insurance). This type of medical insurance plan dates from 1883, when the government of Germany initiated a plan based on contributions by employers and employees in particular industries. In the United States, Medicare (medical insurance for the elderly) and Medicaid (medical insurance for the poor) are government health insurance programmes. The distinction between public and private programmes is not clear because some governments subsidize private insurance programmes. Quite different, however, are socialized medicine and government medical-care programmes. In these systems which are usually financed from general tax revenues, doctors are employed, directly or indirectly, by a government agency and</td>
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<tr>
<td>Health insurance programme</td>
<td>An insurance programme which provides (financial) benefits in the event of personal accident, illness or maternity.</td>
</tr>
<tr>
<td>Illness</td>
<td>Illness, (sickness, malady, disease, ailment) is any kind of (usually organic) interruption, cessation, or disorder of body functions or organs.</td>
</tr>
<tr>
<td>In-patient</td>
<td>A resident patient of a medical institution who has gone through the full hospital admission procedure and is occupying a bed in an in-patient department (previously health insurance benefits were limited to in-patient care) =&gt; out-patient care</td>
</tr>
<tr>
<td>Insurance</td>
<td>Mechanism for contractually shifting burdens (and consequences, e.g. financial losses) of a number of pure risks by pooling them.</td>
</tr>
<tr>
<td>Insurance benefit</td>
<td>A benefit provided under an insurance system.</td>
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<tr>
<td>Insurance policy</td>
<td>Written contract between an insured and an insurance company stating the obligations and responsibilities of each party</td>
</tr>
<tr>
<td>Insured</td>
<td>The person or organization covered by an insurance policy, including the 'named insured' and any other party for whom protection is provided under the policy terms, e.g. dependants of the policyholder</td>
</tr>
<tr>
<td>International Classification of Diseases (ICD and ICD-CM)</td>
<td>A system of codes originally developed to classify and code mortality data, such as from death certificates; In its expanded &quot;clinical modification&quot; (ICD-CM), it has come to be used for morbidity (illness and disease) data in a broad range of settings, such as inpatient and outpatient clinic records, physician offices, and other surveys. The current version, ICD-10, is copyrighted by the World Health Organization (WHO), which owns and publishes the classification.</td>
</tr>
<tr>
<td>Membership</td>
<td>Participation in an insurance or social security system or scheme</td>
</tr>
<tr>
<td>Moral hazard</td>
<td>The tendency of insurance to change behaviour to increase the risk of misfortune if that risk is covered by the insurance; A dishonest predisposition (or careless attitude) on the part of an insured that increases the chance of loss or causes losses to be greater than would otherwise be the case</td>
</tr>
<tr>
<td>Morbidity</td>
<td>The incidence and severity of sickness and diseases in a well-defined class or classes of persons</td>
</tr>
<tr>
<td>Negative list</td>
<td>A list of medicines which are excluded from reimbursement</td>
</tr>
<tr>
<td>Not-for-profit organization</td>
<td>An incorporated organization which exists for educational or charitable reasons, and from which its shareholders or trustees do not benefit financially; Also called a non-profit organization</td>
</tr>
</tbody>
</table>
| Outpatient                                | A patient attending hospital or clinic for minor treatment, consultation, advice, etc., who is not
<table>
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<tr>
<th>Term</th>
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<tbody>
<tr>
<td>admitted to the hospital</td>
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</tr>
<tr>
<td>Parastatal health insurance</td>
<td>A semi-autonomous, quasi-governmental, state-owned enterprise</td>
</tr>
<tr>
<td>Pharmaceutical expenses</td>
<td>The costs incurred for purchasing medicines</td>
</tr>
<tr>
<td>Prior authorization (PA)</td>
<td>A medicines utilization management strategy; a health plan or pharmacy benefits manager must authorize a particular prescription before it can be filled and reimbursed by the health plan. Authorization depends on criteria for use of the drug that may need to be met (for example, previous failure of another, less costly therapy). PA may be required for medicines in certain classes and/or medicines that are not on the insurance formulary.</td>
</tr>
<tr>
<td>Premium</td>
<td>In private insurance, the sum paid by a policyholder to keep the insurance policy in force and thus receive continued insurance protection</td>
</tr>
<tr>
<td>Primary care</td>
<td>Community health care provided through doctors, dentists, district nurses, health workers and health visitors</td>
</tr>
<tr>
<td>Private health insurance</td>
<td>A health care financing organization which pools risks and which receives contributions directly (not through a tax collector); It can be not-for-profit or for-profit. It can provide principal or supplemental coverage.</td>
</tr>
<tr>
<td>Provider</td>
<td>An individual or organization which provides health care, such as a primary care doctor or a hospital and sells its services to purchasers</td>
</tr>
<tr>
<td>Public health insurance</td>
<td>A health care financing organization which pools risks and which receives contributions through a tax collector</td>
</tr>
<tr>
<td>Reference price (i.e. internal reference price)</td>
<td>A price as a basis for reimbursement of medicines; A reference price may be the price of the least costly product in a particular therapeutic class or the price of a selected product in the class. The insurance covers the cost of products in the class at or lower than the reference price. Patients pay amounts above the reference price.</td>
</tr>
<tr>
<td>Reimbursement</td>
<td>A payment made to an insured by a social security scheme or by an insurer compensating expenses incurred for treatment</td>
</tr>
<tr>
<td>Subsidy</td>
<td>The opposite of a tax: the government funds a portion of the costs of a good; Producers and consumers may benefit depending on how competitive a market is.</td>
</tr>
<tr>
<td>Tertiary care</td>
<td>The health care provided in highly developed hospitals, special clinics or at the university level for such specialized treatments as radiotherapy, neurology and cardiac surgery</td>
</tr>
</tbody>
</table>
Appendix 1: PubMed search terms

Policy strategy search terms: "Fees and Charges" OR "Costs and Cost Analysis" "Group Purchasing"(Mesh) OR "Self Medication"(Mesh) OR "Formularies as Topic"(Mesh) OR "Utilization Review"(Mesh) OR "Education, Continuing"(Mesh) OR "Clinical Protocols"(Mesh) OR "Disease Management"(Mesh) OR "Drug Utilization"(Mesh) OR cost OR expense OR fees OR charges OR price OR pricing OR purchasing OR discounts OR rebates OR mark-ups OR mark up OR reimbursement OR out of pocket cost OR out-of-pocket cost OR cost sharing OR coinsurance OR self-medication OR self medication OR formulary OR co-payment OR co-payment OR coverage limit OR cap OR prior authorization OR step therapy OR reference pricing OR utilization management OR provider contracting OR providers budgets OR preferred provider network OR utilization review OR utilization profiling OR performance incentives OR pay for performance OR pay-for-performance OR education OR academic detailing OR outreach OR prescribing behaviour OR disease management OR generic substitution OR treatment guideline OR utilization OR consumption

Pharmaceutical search terms: "Drugs, Generic"(Mesh) OR "Nonprescription Drugs"(Mesh) OR "Pharmaceutical Preparations"(Mesh) OR "Drugs, Essential"(Mesh) OR "Prescription Drugs"(Mesh) OR "Drug Utilization"(Mesh) OR "Self Medication"(Mesh) OR "drugs, generic" OR "prescriptions, drug" OR (pharmaceutical preparations) OR drug utilization OR pharmacoepidemiology OR pharmacoeconomic* OR prescribing(ti) OR medicines(ti) OR self-medication(ti) OR "drug safety"(ti) OR drug therapy(ti) OR prescription fees OR drugs, non-prescription OR drug costs OR drug information service(ti) OR antibiotic OR antimicrobial OR antimalarial OR "rational drug use" OR (rational use(tw) AND and AND (medicine(tw) OR medicines(tw) OR drug(tw)) OR pharmaceutical(tw) OR medication(tw)) NOT (ab(sh) OR ae(sh) OR ag(sh) OR aa(sh) OR an(sh) OR ah(sh) OR ai(sh) OR bi(sh) OR bl(sh) OR bs(sh) OR cf(sh) OR cs(sh) OR ch(sh) OR ci(sh) OR cl(sh) OR co(sh) OR ct(sh) OR cn(sh) OR cy(sh) OR df(sh) OR ge(sh) OR gd(sh) AND em(sh) OR en(sh) OR im(sh) OR in(sh) OR is(sh) OR ir(sh) OR ip(sh) OR mi(sh) OR mi(sh) OR m(sh) OR mo(sh) OR ps(sh) OR py(sh) OR pa(sh) OR pk(sh) OR pd(sh) OR ph(sh) OR pp(sh) OR ra(sh) OR ri(sh) OR rt(sh) OR rh(sh) OR re(sh) OR sc(sh) AND se(sh) OR su(sh) OR to(sh) OR tr(sh) OR ul(sh) OR ur(sh) OR us(sh) OR vi(sh) OR ve(sh))

Health Insurance search terms: ((Insurance AND "(Mesh) OR " AND Insurance, Health(Mesh) OR health insurance))

Developing country search terms: ((Developing countries OR ((Asia OR West Indies OR Polynesia OR Micronesia OR middle east OR Afghanistan OR Armenia OR Azerbaijan OR Bahrain OR Bangladesh OR Bhutan OR Brunei OR Burma OR Cambodia OR China OR Cyprus OR Gaza OR "georgia (republic)"(MeSH Terms) OR India OR Indonesia OR Iran OR Iraq OR Jordan OR Kazakhstan OR Korea OR Kuwait OR Kyrgyzstan OR Laos OR Lebanon OR Malaysia OR Mongolia OR Nepal OR Nepal OR Oman OR Pakistan OR Papua New Guinea OR Philippines OR Qatar OR Saudi Arabia OR Singapore OR Sri Lanka OR Syria OR Tajikistan OR Thailand OR Turkmenistan OR United Arab Emirates OR Uzbekistan OR Vietnam OR Yemen OR Israel OR Japan OR Korea OR Taiwan OR Turkey) NOT (Israel OR Japan OR
Korea OR Taiwan OR Turkey)) OR (Africa OR Algeria OR Angola OR Benin OR Botswana OR Burkina Faso OR Burundi OR Cameroon OR Central African Republic OR Chad OR Congo OR Cote d'Ivoire OR Ivory Coast OR Djibouti OR Egypt OR Equatorial Guinea OR Eritrea OR Ethiopia OR Gabon OR Gambia OR Ghana OR Guinea OR Guinea-Bissau OR Kenya OR Lesotho OR Liberia OR Libya OR Madagascar OR Malawi OR Mali OR Mauritania OR Morocco OR Mozambique OR Namibia OR Niger OR Nigeria OR Rwanda OR Sao Tome OR Principe OR Senegal OR Sierra Leone OR Somalia OR South Africa OR North Africa OR Sub Saharan Africa OR Sudan OR Swaziland OR Tanzania OR Togo OR Tunisia OR Uganda OR Western Sahara OR Zambia OR Zimbabwe) OR Latin America OR Central America OR South America OR Argentina OR Belize OR Bolivia OR Brazil OR Chile OR Colombia OR Costa Rica OR Ecuador OR El Salvador OR French Guiana OR Guatemala OR Guyana OR Honduras OR Nicaragua OR Panama OR Paraguay OR Peru OR Surinam OR Uruguay OR Venezuela OR Mexico))
Appendix 2: Policy case studies

Case Study I:
Increasing access to medicines through Thailand’s 30-Baht Scheme

Interview with:
Sauwakon Ratanawijitrasin, Ph.D., Associate Professor, Faculty of Social Sciences and Humanities, Mahidol University
Viroj Na Ranong, Ph.D., Research Director, Health Economics and Agriculture, Thailand Development Research Institute

Overview of the 30-Baht Scheme

In 2001, Thailand introduced a compulsory national universal health insurance scheme – the 30-Baht Scheme - that consolidated multiple insurance schemes for the poor and extended coverage to all of the uninsured (116). Two other public insurance schemes also cover substantial portions of the Thai population: the Civil Service Medical Benefits Scheme (CSMBS), which covers government employees their spouses and dependents; and the Social Security Scheme (SSS), which covers private business employees (117). After implementation of the 30-Baht Scheme, the percentage of the Thai population covered by public insurance schemes jumped from 40% in 2001 to 95.5% in 2004 (116), with the 30-Baht scheme covering 76.6% of the population in 2007 (117).

Under the 30-Baht Scheme, hospitals receive an annual capitated payment—which varies from hospital to hospital—to provide outpatient care and medicines to registered patients in their catchment area; inpatient services and medicines are paid by a case-based DRG system. To receive services, 30-Baht members must register on an individual basis with an area hospital and receive a registration card that entitles them to health services at that hospital and other catchment area health facilities (116). The scheme covers services at both public and private facilities, although the great majority of the beneficiaries (about 90%), are registered with government-owned hospitals (118). Approximately 80% of 30-Baht beneficiaries live in rural areas outside of Bangkok.

Patients were initially charged a flat co-payment of 30 Baht (about US$0.90) per health encounter that covered all costs of the encounter, including prescription medicines. Recent reforms have eliminated even this small co-payment (119). The 30-Baht Scheme is funded primarily by tax revenue; co-payments accounted for less than 2% of the revenue (116).

Note: spouses and dependents of SSS beneficiaries are not covered by SSS and are therefore covered by the 30-Baht Scheme.
**Medicines benefits within the 30-Baht Scheme**

The 30-Baht Scheme covers both outpatient and inpatient medicines. Only medicines on the National Essential Drugs List are covered (116). Patients receive their medicines from hospital pharmacies without additional charges. Each hospital purchases medicines individually, which results in variation of procurement costs and generic suppliers across hospitals (117).

**Development of the 30-Baht Scheme and its medicines policy**

The goals of the 30-Baht Scheme were: universal coverage, cost containment, and increased efficiency of hospitals, which can provide medicines at lower costs. At its inception, the 30 Baht Scheme had no explicit “medicine policy.” The general policy was that all services, including medicines, would be covered under a fixed per person payment.

The 30-Baht Scheme was formulated and implemented very quickly. After Prime Minister Thaksin Shinawatra’s landslide victory in 2001, policy-makers believed that the incoming government had a short window of opportunity to achieve promised universal health insurance coverage. The concern over possible unequal treatment among beneficiaries of different schemes led to an initial plan to merge all existing insurance schemes into a single universal scheme. However, this approach encountered strong opposition from administrators and beneficiaries of existing schemes, especially SSS. (120). Rather than waiting for legislation to pass (the National Health Security Act was eventually passed in 2002), the government promulgated the 30-Baht Scheme by decree and funded it by pooling Ministry of Public Health budgets from public hospitals and health facilities and existing insurance schemes for the poor. The 30-Baht Scheme was created to be similar to the SSS scheme, but with more emphasis on primary care and prevention and lower capitation payments.

Within three months of his election, the Prime Minister convened a meeting of officials from the Ministry of Public Health, hospitals, and academia, which resulted in immediate implementation of a 30-Baht pilot project in six provinces. Two months later, the pilot programme was rolled out to 40 provinces and was implemented throughout the entire country within a year of the election.

**Effects of the 30-Baht Scheme**

The 30-Baht Scheme resulted in a shift in the primary form of payment to hospitals, as well as a reduction in out of pocket payments for health care and medicines for a large percentage of the Thai population. Previously, most services were paid for by patients on a fee-for-service basis, whereas now, the majority of the population is covered by a capitated payment scheme (117).

A recent study found that members of the 30-Baht Scheme used a lower overall volume of medicines than members of the other health insurance schemes (117). Given the financial incentives of capitated payment, providers were more likely to prescribe less costly older medicines and generics to 30-Baht patients (117). There is strong evidence that Thailand’s national generic substitution policy is better adhered to for members of capitated systems i.e. SSS and 30-Baht) than for fee-for-service members i.e. CSMBS) (117). However, there is little evidence about the quality of prescribing to members of different insurance schemes or the overall effect of universal health insurance coverage on access to and use of medicines in Thailand. And, there is a lack of evidence on the quality of generic medicines - although studies have shown generics meet quality standards in Bangkok, little is known of the quality of generics in the rural areas.
Anecdotal evidence suggests that universal coverage with capitated payment left many hospitals with sizable budget deficits (120). Hospitals reportedly responded by charging more for medicines to other schemes, establishing a cross-subsidy between insurance programmes. Although local manufacturers compete to supply generics to members of all schemes, multinational companies have focused on supplying medicines to the higher-priced CSMBS system.

The number of impoverished households fell following the 30-Baht Scheme’s implementation, although it increased slightly in 2006-2007 (121). However, household surveys from 2002-2007 revealed that households in lower income deciles, most of which are 30 Baht beneficiaries, still spent a substantially higher share of their income on health care than those in upper income deciles (120, 121).

The 30-Baht Scheme ranks as one of the most popular government policies among the poor. However, concerns over the type and quality of medicines provided under this scheme led many eligible individuals to opt out and either buy private health insurance or pay out-of-pocket.

Spending in the 30-Baht Scheme has been increasing at a lower rate than spending in the CSMBS. Through increased financial risk sharing, the system of capitated payments has successfully encouraged hospitals to implement a variety of cost-containment strategies (119).

**Take-away lessons**

Policy-makers capitalized on a unique window of opportunity to establish universal insurance coverage in Thailand. Despite good intentions, the development and implementation of the scheme lacked solid preparation and planning. Policy-makers largely ignored concerns raised by many researchers and stakeholders and the speed of implementation left many practical question unanswered. Nevertheless, the rapid registration of beneficiaries suggests that the administration system was highly effective (120). The 30-Baht policy has evolved over time in response to increasing evidence; for example, hospital capitation rates have been increased in response to deficits and insufficient funding for teaching and research (120) and patient co-payments have been eliminated.

However, there are still many gaps in the evidence. Evaluations to date have largely been based on hospital data; few have addressed the impact of the 30-Baht Scheme on member behaviour (e.g. propensity to seek care or purchase medicines outside of the system), affordability of care, or quality of care, including appropriate use of medicines.
This case study yields several key lessons for other countries:

1. While policy decisions are often made during a window of political feasibility, it is important to allow adequate time for pilot testing of programme models before full-scale implementation.

2. Findings from evaluation research can be used to inform evidence-based policy changes.

3. Implementing universal health insurance coverage, including access to essential medicines, is feasible in middle income countries.

4. There is a need to monitor the effects of expanded coverage on patterns and appropriateness of medicines use, cost and affordability of care, and health outcomes.

5. Capitated payment arrangements that share risk with health providers can encourage greater reliance on generic medicines, although results on affordability and quality of care are uncertain.

Case Study II:

Change from a fee-for-service to a case-based provider payment system for outpatient care in Ghana

Interview with:
Kwesi Eghan, MBA Senior Technical Advisor, Management Sciences for Health

Overview of Ghana’s National Health Insurance System

Following the passage of the National Health Insurance Act of 2003, Ghana’s government created the National Health Insurance Scheme (NHIS) (122). The NHIS is a universal national social health insurance system that was built upon existing district-based mutual health insurance schemes (DMHIS) (91). Enrollment has increased steadily over the years and the majority (61%) of the population was covered by NHIS in 2008 (123). Membership in the NHIS is mandatory unless individuals obtain private health insurance (less than 1% of the population) (124). About two-thirds of current members are exempt from paying contributions: pensioners, those over age 70, those under age 18 with both parents as members, and the indigent (91). There is a six-month gap between enrolling in the NHIS and becoming eligible for services.

The NHIS relies on tax revenue for 75% of its expenditures, in particular a National Health Insurance Levy in the form of a 2.5% value-added-tax on consumer goods and services (91, 124). A newly created National Health Insurance Fund (NHIF) also provides funding for the NHIS. Formal sector workers must contribute 2.5% of their income through payroll deductions into a trust fund. In addition, informal sector workers pay income-rated contributions directly to the DMHIS, ranging from $8 USD to $53 USD. The NHIF was established to pay for subsidies
and reinsurance for district schemes, to cover the cost of enrolling the indigent and other exempt
groups, and to increase access to health care (91).

**Medicine benefits within the NHIS**

The National Health Insurance Authority (NHIA) has established a minimum benefit package
that all DMHIS must offer. This minimum benefit package is quite comprehensive covering
95% of all health care services including preventive care and treatment of communicable
diseases (91). Services covered include most outpatient and inpatient services at accredited
facilities, community-based public health services, and all drugs on the National Health
Insurance Drug List. There are no co-payments or coverage limits and little effort at gate-
keeping. Services not covered include: cosmetic services, antiretroviral drugs (covered under
other national programmes), assisted reproduction, dialysis, and cancer treatment other than for
cervical and breast cancer. The uninsured also have access to a comprehensive range of
services through public and private providers, but access is limited by their ability to pay (124).

**Development of the NHIS and its medicines policy**

Before implementation of the NHIS, the Ghanaian health care system was fragmented. The
country is split into 138 decentralized districts and ten administrative regions. In the 1990s,
many districts developed mutual health organizations - DMHIS District Mutual Health
Insurance Scheme. However, the DMHISs typically covered only catastrophic costs (91) and
the system of multiple small risk pools was not financially sustainable (124). Out-of-pocket
expenditures accounted for almost half (45%) of the total expenditure on health (124) and
22.4% of households reported catastrophic health spending (11). Public health system resources
were distributed inequitably – in the 1990s the poorest quintile of the population received 12%
of public health funding whereas the upper quintile received 33% (124).

In the 2000 election' the New Patriotic Party (NPP) promised to abolish user fees for health care
services (outpatient services and drugs) at public facilities (122). The NPP won the election and
fulfilled its campaign promise by passing the National Health Insurance Act in 2003 and
creating the NHIS the following year.

Public and some not-for-profit private facilities are allocated a budget and the staff is paid
salaries to cover services not paid by insurance (124). In order to receive DMHIS payment,
providers must be accredited by the NHIA. All providers – public or private – are eligible for
accreditation, which is reviewed every five years (91). Public and private sector providers are
paid the same rates. DMHIS payments to all health facilities, laboratories, and pharmacies were
initially fee-for-service (FFS, i.e., discrete itemized billing) and were supposed to be reimbursed
by the NHIA within four weeks of receiving a claim.

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*Ghana is a presidential democracy. The country has an elected parliament and independent judiciary system.*
Starting in 2008, the NHIS experienced severe cash-flow problems and owed US$ 34 million in unpaid claims to health facilities (91). Multiple factors led to these financial problems:

- The reinsurance payments to “distressed” DMHIS was larger than expected (91) because of a significant gap between the government budget i.e. subsidy per member) allocated to schemes and the costs they incur.

- The DMHIS rely on the NHIA for 80-90% of their revenue (91). However, the per person NHIA subsidy amounts were based on the much more limited benefit packages provided by DMHIS in the past. Furthermore, the subsidy for exempt members is quite low and the percent of members that are exempt is very high.

- In 2008, pharmaceutical costs accounted for 46% of the NHIS annual expenditure (122).

- Initial evaluations show increased utilization of health services among the insured population after the implementation of the NHIS (91). However, it is not clear if all services are necessary, of high quality, or cost-effective. Although they had no direct evidence, NHIA officials believed that the FFS system resulted in an increased volume of services that did not improve quality of care or health outcomes.

In light of the financial problems, the government debated moving to capitation-based payment. However, the NHIA lacked the necessary resources and data to implement such a system and assumed that a capitated payment system would be too costly and administratively burdensome. Instead, the NHIA switched to case-based payment with the goal of eventually moving to capitation. In 2008, the NHIA implemented a new Diagnostic Related Group (DRG) payment scheme for providers and hospitals, which pays per episode according to disease group and level/sector of care (91). However, medicine costs are still billed separately on top of the DRG payment.

**Challenges in the implementation of the case-based payment system**

Prior to implementing case-based payment, the NHIA needed to establish diagnostic-related groups (DRG). The NHIA conducted a wide consultation that included doctors, hospitals, and pharmacies from the public and private sector, borrowing from the US Medicare DRG system and tailoring it to Ghana’s health needs. Initial proposals included medicines in the DRG payments. After stakeholders agreed on diagnostic groupings, they had to decide on reimbursement amounts, a process which created considerable tension. There was general opposition from all providers, but private providers were more strongly opposed to the set amounts and more resistant to a new payment mechanism. Aided by the media, providers attempted to turn patients – who had no role in the decision making process - against the NHIA by telling them they could get better services outside of the NHIS. Despite opposition, the NHIA implemented the case-based system, but in a concession, NHIA decided to allow medicines to be billed separately. Medicines reimbursement amounts are set at a median price for each reimbursable drug determined by a national survey of medicines costs in public and private facilities. Private and public sector providers receive the same reimbursement for all services and medicines, despite higher prices in the private sector.

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\(a\) The Ministry of Health conducts a nationwide price survey on a basket of 50 medicines in both public and private facilities every six months.
The implementation of the case-based system required considerable upfront effort to educate providers about the rationale for the system and its technical aspects (i.e. the diagnostic groups and coding system). The NHIA held training sessions for every DMHIS and provided funding for similar training within private sector facilities. The system was implemented relatively quickly in 2008.

**Effects of the switch to a case-based payment system**

The case-based payment policy was intended to provide financial incentives to reduce the volume of unnecessary health services, improve quality of care (implicit in the DRG groupings), and reduce costs. Some initial effects have been observed.

In terms of the effects on providers, service volume has not changed and because of the generous DRG payments, the NHIA is actually paying more now than under FFS. Public sector facilities have benefited since they now receive an average of the previous private and public sector prices. Furthermore, there is anecdotal evidence that quality of care has been compromised – since providers are paid by diagnosis rather than service, there is an incentive to provide fewer services. Although a cap on medicine reimbursements encourages the use of lower priced generics, it also provides incentives for the use of medicines of inferior quality. Given that medicines are exempt from the DRG payments, it is likely that medicine expenditures will continue to rise due to misaligned incentives. Preliminary analyses show an increase in the number of medicines per prescription and a tendency to prescribe more high priced medicines (91).

There have also been media reports that some providers may be gaming the system by up-coding DRGs or billing for medicines not actually dispensed. Although there is no systematic evaluation of the accuracy of claims submitted, the NHIA audits facilities where the number of claims submitted rises suddenly. The NHIA recently revoked accreditation of two facilities in one district after such an audit. In addition, with funding from the World Bank, the NHIA is developing a centralized, electronic medical information system to facilitate the monitoring of claims. In 2010, the information system has been rolled out to 25-30% of the districts.

In terms of the impact of the case-based payment policy on other stakeholders, pharmaceutical manufacturers and suppliers have complained about the medicines reimbursement cap, but there has been little documented impact on drug supply or price. Consumer behaviour has also not been impacted since they pay the same premiums and cost-sharing amounts as under the previous FFS payment system.

**Take-away lessons**

Government support in the face of a looming financial crisis provided a window of opportunity to switch from FFS to case-based payment in the Ghana NHIS, despite provider resistance. A comprehensive training process led to a smooth transition and alleviated some initial fears about the novel system. However, the switch was implemented hastily with little evidence about the proper diagnostic groups or efficient reimbursement amounts. Furthermore, there was no plan to systematically monitor the impact of the change in reimbursement on cost, quality of care, and health outcomes. Although the NHIA successfully implemented payment reform, greater involvement by the Ministry of Health – a larger and more politically powerful stakeholder - may have led to a more efficient policy (e.g. lower DRG payments or inclusion of medicines in the DRG payments).
The case study provides several key lessons for other countries and insurance systems establishing similar types of payment reform:

1. Political will is key to implementing payment reform, especially in the face of opposition by providers.

2. The insurance scheme must have legal authority to penalize provider fraud and abuse (e.g., ability to revoke accreditation).

3. Changes in provider payments need to be evaluated regarding their impact on quantity and quality of care, cost to insurance scheme, affordability, and health outcomes.

4. Transparent consultation with providers in establishing the technical details of a policy facilitates implementation, but patients and suppliers should also be included in these discussions.

5. Insurance schemes should use available evidence from other countries to aid system design, consider phased-in implementation, and use monitoring results to modify details of the policy.

Case Study III:

Improving use of medicines in the Mexican Social Health Insurance.

Interview with:
Ricardo Pérez-Cuevas, MD, MSc, MHS, DrPH Epidemiology and Health Services Research Unit, Mexican Institute of Social Security (IMSS)

Overview of the Mexican Institute of Social Security
The Mexican Institute of Social Security (IMSS), established in 1943, is the largest public health insurance programme and the largest health care system in Mexico (125). The system includes 1450 primary care clinics (staffed by approximately 14 000 family doctors) as well as 240 secondary and tertiary care hospitals.

IMSS provides health care to 45% of the Mexican population (approximately 48 million people), including: private sector employees; the self-employed, small businesses and farmers; informal workers; and pensioners (108, 126). Membership is compulsory by law for these groups, except for informal workers who can voluntarily enroll. Although IMSS initially only covered workers, benefits were extended to workers’ families in 1949: spouses/partners, children (up to 18 years) and parents of the primary beneficiary are now covered (108, 126). Approximately 80% of the beneficiaries live in urban settings (126).
The system is financed through contributions from employers, states and individually paying members. IMSS has a comprehensive benefit package, which includes: economic support for the primary beneficiary in case of an accident, diseases or occupational hazard; social benefits (e.g., day care centers for children under 6 years old, social services for the elderly); and both inpatient and outpatient health care and medicines.

**Medicines benefits within IMSS**

Since its establishment, IMSS has included both an inpatient and outpatient medicine benefit that is available to all members. A written list of the medicines covered, which included 5541 products in 2004, is updated yearly and is publicly available to all members and doctors (127). The list includes inpatient and outpatient medicines (both prescription and OTC) as well as medical devices (e.g., needles/syringes needed to administer medicines). In order to be covered by IMSS, medicines must be on the formulary, the generic versions dispensed (if a generic is available), and must be dispensed by an IMSS pharmacy. There is no patient cost-sharing.

**Evolution of the IMSS Quality Improvement Programme**

Since 2001, IMSS has implemented a multifaceted strategy for educating doctors in primary care clinics, under a broader Family Medicine Improvement Process (FMIP), with the goal of improving family doctors’ clinical treatment and prescribing practices. The components of the IMSS utilization management strategy include: (1) the creation of evidence-based clinical guidelines (for 12 medical conditions), (2) a programme for training clinical tutors, and (3) an educational intervention, consisting of three phases (interactive clinical workshops, in-service training, and round-table peer review sessions) (107).

The educational strategy started as a local intervention to improve upon low-quality health care in family clinics and to counter the alarmingly high rates of infant mortality from pneumonia and diarrhoea – both preventable causes of mortality. Components of the strategy began in 1995 and were scaled up over time (110). Throughout the development of the educational strategy, researchers and policy-makers identified and learned about the strengths and weaknesses of the primary health care system in Mexico, which led to the development of the FMIP. Over two decades, the strategy has evolved through an iterative process from a specific, local strategy into a multi-faceted intervention at the national level, which now resembles a utilization management programme. Although there was some initial opposition from doctors unions and IMSS officials, the strategy as a whole has been implemented relatively smoothly.

**Effects of the IMSS Quality Improvement Programme**

The utilization management intervention was aimed only at family doctors and was intended to improve the quality of their prescribing behaviour, save resources by eliminating excess medicines prescription and use, and decrease resistance to antibiotics. Studies have found that the IMSS utilization management strategy has improved both the quality and volume of prescribing and is cost-effective for IMSS (109).

During the course of implementation, a few unintended consequences became apparent, all of which eventually advanced the multi-faceted strategy. First, problems with the availability of medicines became apparent. IMSS authorities decreased medicines shortages by allocating more resources to medicines and strengthening procurement and purchasing of medicines at IMSS state delegations. Second, IMSS leadership realized that to measure the impact of their utilization management strategy, IMSS needed to develop a health information system and
appropriate performance indicators, both of which were eventually accomplished. An electronic medical record system, which includes basic indicators of productivity, coverage (preventive care) and quality, was designed and implemented in a four-year period. Third, it became clear that training nurses to prescribe maintenance medicines and to educate patients on diet and exercise would increase the efficiency and effectiveness of utilization management, especially among diabetic and hypertensive patient populations. The Senate passed a bill that allowed nurses to prescribe and nurses are now more actively involved in a chronic illness management in IMSS. In the future, IMSS leadership intends to utilize the newly developed IMSS integrated health information system to assist in the educational strategy with point-of-care feedback to providers to improve quality of care and prescribing.

**Take-away lessons**

The key to the successful policy implementation in IMSS was a commitment to continuous operations improvement – researchers and policy-makers collected data, produced evidence, and continuously acted on it to make changes. This incremental back and forth between researchers and government authorities, which started in 1987, was crucial to the success of such a widespread, multi-faceted policy strategy. From a political perspective, an incremental utilization management strategy was preferable and less likely to encounter opposition from stakeholders and government authorities. From a policy perspective, the incremental evolution of the strategy informed future policy decisions and contributed to successful implementation.

This case study yields several key lessons for other countries:

1. Think locally about identifying health needs of the population.

2. Align the stakeholders (i.e. doctors, government authorities, patients) that will be affected in the early stages of policy development and create a sense of shared ‘ownership’ of the strategy.

3. Identify achievable short-term outcomes to gain commitment from those with the resources and authority to carry out the strategy.

4. Establish a process of continued formal evaluation of the policy strategy implemented, learn from its results, and adjust the strategy accordingly.

5. Be transparent and accountable, providing evidence of successes and challenges along the way to all stakeholders.
Case Study IV:

Monitoring medicines use in Jordan with smart-card systems

Interview with:
Nazeer Bate General Manager, Medexa
Rafif Hamad, Research and Development Manager, Medexa
Ahmad Tijani, CEO, NatHealth

Overview of the Jordan Health Insurance System

The majority of Jordanians have health insurance: 68% of the population is covered by public sector health insurance and another 8% to 12% is covered by private health insurance schemes (128). Although the delivery of care in Jordan is predominately in the public sector, over half (53%) of health services are privately financed i.e. by private insurance, self-insured employers or out-of-pocket payments by patients (128). Pharmaceutical expenditures account for 27% of the total health care expenditures and 2% of the GDP (128). Spending on medicines is increasing rapidly (by 17% per year compared to the 3.3% annual growth in GDP) (128). Three-quarters of medicines expenditures is spent in the private sector (129). High pharmaceutical expenditures are thought to be in part due to overuse of high priced medicines.

The domestic pharmaceutical industry is a significant contributor to the national economy and policy-makers must balance ensuring the prosperity of the industry and creating incentives for appropriate use of medicines (17). There have been several recent health reforms in Jordan, namely the implementation and expansion of the national health insurance system (a primary aim of the National Health Strategy of 1998), the development of a national medicines policy in 2002 (which included a national medicines formulary and essential medicines list), and the establishment of the Jordan Food and Drug Administration (JFDA) in 2003 (130).

Many common tools for improving use of medicines, such as generic substitution policies and clinical guidelines for doctors, do not exist. Furthermore, there is evidence of substantial fraud and abuse in the pharmaceutical sector.

Description of Medexa

Medexa International is a private, third-party administrator (TPA) for health insurance schemes in Jordan. It was founded in 1999 in Amman, Jordan and is expanding into private health insurance markets in other Middle Eastern and African countries, such as Syria, Oman, Egypt and Libya (131). In Jordan, Medexa currently contracts with private health insurance schemes (including companies who self-insure and provide services to their employees) to manage the health insurance accounts of more than 150 000 beneficiaries, making it the largest TPA in the Middle East (131). As a TPA, Medexa is responsible for claims processing and does not share the financial risk borne by the insurer. Medexa identified pharmaceuticals as one of the most important targets to reduce health care costs for its clients.
Description of the Medexa Smart Card

Responding to the need for decreasing fraud and containing costs, Medexa developed a smart card to improve the management of health insurance claims, and ultimately of health care, for its contracted insurers. Smart cards look like credit cards, but contain a microprocessor chip that allows data to be securely entered, stored and exchanged (132). Smart cards have great potential to improve the efficiency of health care systems (133). Multiple high-income countries and a handful of LMICs have smart health card systems. The Medexa smart cards contain a patient’s medical record, including information about current prescribed medications and allergies, and key demographic information (e.g. gender, age).

Use of the smart card is mandatory for beneficiaries in the insurance schemes that contract with Medexa. To be reimbursed for their services by the insurer, doctors and pharmacists who treat members and dependents in these schemes must use the smart card system.

In terms of medicines, the smart card provides a point of service system that is intended to increase the efficiency of prescribing and dispensing. Doctors enter diagnoses (ICD-10 codes), laboratory requests, radiology requests and prescriptions into the smart card system via an online system. The smart card can also be used if Internet access is not available. To obtain medicines, the beneficiaries must bring their smart card to a contracted pharmacy, where pharmacists who have been provided with smart card readers will swipe the card and fill the prescription when authorized by the system.

Medexa has marketed the smart card technology as a strategy to improve the use of medicines by emphasizing the following expected advantages:

- Improving medicines use and quality through reducing prescribing and dispensing errors. The smart card system will not allow pharmacists to dispense a prescription that is contraindicated given a patient’s demographics (e.g. age or gender), medical history, or concomitant medicines.
- Controlling medicine consumption. The smart card system rejects attempts to dispense a prescription if it has been filled and should not yet be re-filled, and if members do not meet insurance eligibility requirements.
- Reducing costs through improved quality and reduction of unnecessary use of medicines.
- Guaranteed payment for pharmacy claims. Pharmacists can guarantee that a patient is eligible for insurance and that a particular medicine is covered by insurance before dispensing the medicine. Pharmacists can also determine at the point of dispensing if the patient is required to pay a co-payment or has reached a coverage limit set by the insurance.
- Increasing ease of both prescribing and patient acquisition of medicines, for chronic disease patients on routine medicines.
- Improving health care delivery. The smart card system is expected to facilitate continuity of care between multiple doctors and pharmacists.
- Reducing fraud and abuse by patients and providers through rejection of likely fraudulent claims.
Appendix 2: Policy case studies

- Collecting data on medical services and medicines utilization. The data collected for claims payment can be used to identify problems with use of medicines and medical services.
- Creating an efficient, paperless system to monitor medicines and health care use.

**Effects of the Medexa Smart Card**

Providers were initially averse to the new technology. However, after training sessions by Medexa the smart card system was implemented with little resistance from doctors and pharmacists, probably because their reimbursement was dependent on their use of the system. Medexa has also received generally positive feedback from patients.

To evaluate the effects of the smart card, Medexa has compared the cost and utilization of medicines in contracted insurance schemes that have implemented the smart card scheme to those that have not. Internal evaluations show that the smart card system decreases overall medicines consumption, reduces insurance costs by 15% to 25% and improves quality of prescribing and care.

There are no peer-reviewed studies that have evaluated the smart card system. Although Medexa states that the system is flexible (e.g. a pharmacist can over-ride the system to dispense unauthorized medicines in an emergency situation), little is known about potential negative effects of the smart card introduction. For example, the percent and type of claims that are rejected is unknown, as are patients’ and providers’ reactions to rejected claims, the impacts of rejections of quality and affordability of medicines and care, and the type of changes in therapy that contributed to decreased expenditures. No information is available on potential concerns of patients about confidentiality of their health information or of doctors about external monitoring of their treatment decisions. More research is needed to evaluate the desired and potential undesired effects of the smart cards.

Expected cost-saving effects of the smart card have created demand for Medexa’s smart card technology in other Middle Eastern and African countries and Medexa has shown that the technology can be applied to different settings with different levels of technological capacity (e.g. Internet availability). In Jordan, the use of smart cards to improve the use of medicines has gained national attention. As part of an initiative to modernize Jordan’s information and technology sector, the Jordanian government, with the aid of the U.S. Trade and Development Agency, is developing a strategy for a national smart card system. The goal of the smart card is to increase the efficiency of government and private institutions. Among other things, the national smart cards will include health insurance and drug dispensing information.

**NatHealth**

Established in 1997, NatHealth was the first TPA in Jordan (134). The private company serves health insurance funds, insurance companies and self-insured funds and has a network of 2400 providers, including 1300 doctors and 400 pharmacies. Like Medexa, NatHealth has also developed a smart card system. Although the technical aspects of the NatHealth and Medexa smart card systems differ, the two TPAs have had similar experiences with the development and implementation of their systems and there is limited evidence of the effects of both systems.
NatHealth claims that the smart card will improve the efficiency of the company, reduce company costs by 30% and minimize fraud and abuse in the health care system. In addition to making claims and provider payment process faster and more efficient, the smart card system allows the company to monitor for fraud and inappropriate prescribing. The system’s electronic database facilitates audits of prescribing and dispensing. Doctors and pharmacies that have questionable prescribing or dispensing behaviour can be eliminated from the NatHealth network.

However, the deployment of the smart card system has been very slow – only 5% of NatHealth’s contracted providers use the electronic system. The company has encountered many obstacles to scaling up the smart card system, including: resistance from providers, insufficient training for providers and support staff, providers’ lack of knowledge of the diagnosis code system (ICD-9), and inadequate funds for providers to implement the electronic systems and hire the appropriate information technology staff. In addition to financial barriers, the resistance from providers stems from their lack of familiarity with computers and online systems and limited understanding of English, the language used in the coding system. The company expects that uptake will increase as more computer-savvy graduates enter the health workforce and as providers recognize the advantages of expedited payment and the potential cost-savings from using the smart card system.

**Take-away lessons**

This case provides a few key lessons for insurance schemes that are thinking about implementing an electronic health system to improve the use of medicines:

1. Private sector innovation has the potential to provide important contributions to improving the use of medicines.

2. Systems that operate at the point of service (i.e., prescribing and dispensing) may provide a way to ensure that patients receive appropriate medicines and that pharmacies will be reimbursed for their claims.

3. Upfront infrastructure and training costs constitute considerable barriers to the implementation of an electronic medical system, such as the smart card system.

4. Providers (doctors and pharmacists) may more readily adopt new technology if reimbursement of their services is contingent upon its use.

5. Providers may be more likely to adhere to appropriate prescribing guidelines if they are being monitored and if there are repercussions for inappropriate or fraudulent prescribing and dispensing (e.g., removal from the preferred network of providers).

6. It is crucial to evaluate whether new technology results in the desired and/or potential undesired effects on patients and providers.
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12. The following presentation by Andreas Seiter at OBIG (particularly the diagram on page 18 – and “Typical patterns of dysfunction” on slide 15): http://ppri.oebig.at/Downloads/Presentations/04_Worldbank_Mr_Seiter.pdf