Governance of the private healthcare sector in low- and middle- income countries

A scoping review of approaches, effectiveness, and enablers

World Health Organization

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In accordance with WHO procedures, all external contributors were asked to declare in writing any competing interests prior to their engagement in the development of this document. All external contributors completed and signed a standard WHO declaration of interests (DOI) form and sent it to the responsible technical officers at WHO. No conflict of interest was identified.

Abbreviations

COVID	Coronavirus disease
CSO	civil society organisation
DHIS2	District Health Information System 2
DOTS	directly observed treatment, short-course
FBOs	faith-based organisations
HIV	human immunodeficiency virus
HMIS	health management information system
HMO	health maintenance organisation
HTA	health technology assessment
INGO	international non-governmental organisation
JHIC	Joint Health Inspection Checklist
LMICs	low- and middle-income countries
MeSH	Medical Subject Headings
NGO	non-governmental organisation
OPM	Oxford Policy Management
PFM	public financial management
PPP	public–private partnership
PRISMA	preferred reporting items for systematic reviews and meta-analyses
RCT	randomised controlled trial
SDG	Sustainable Development Goal
TB	tuberculosis
UHC	universal health coverage

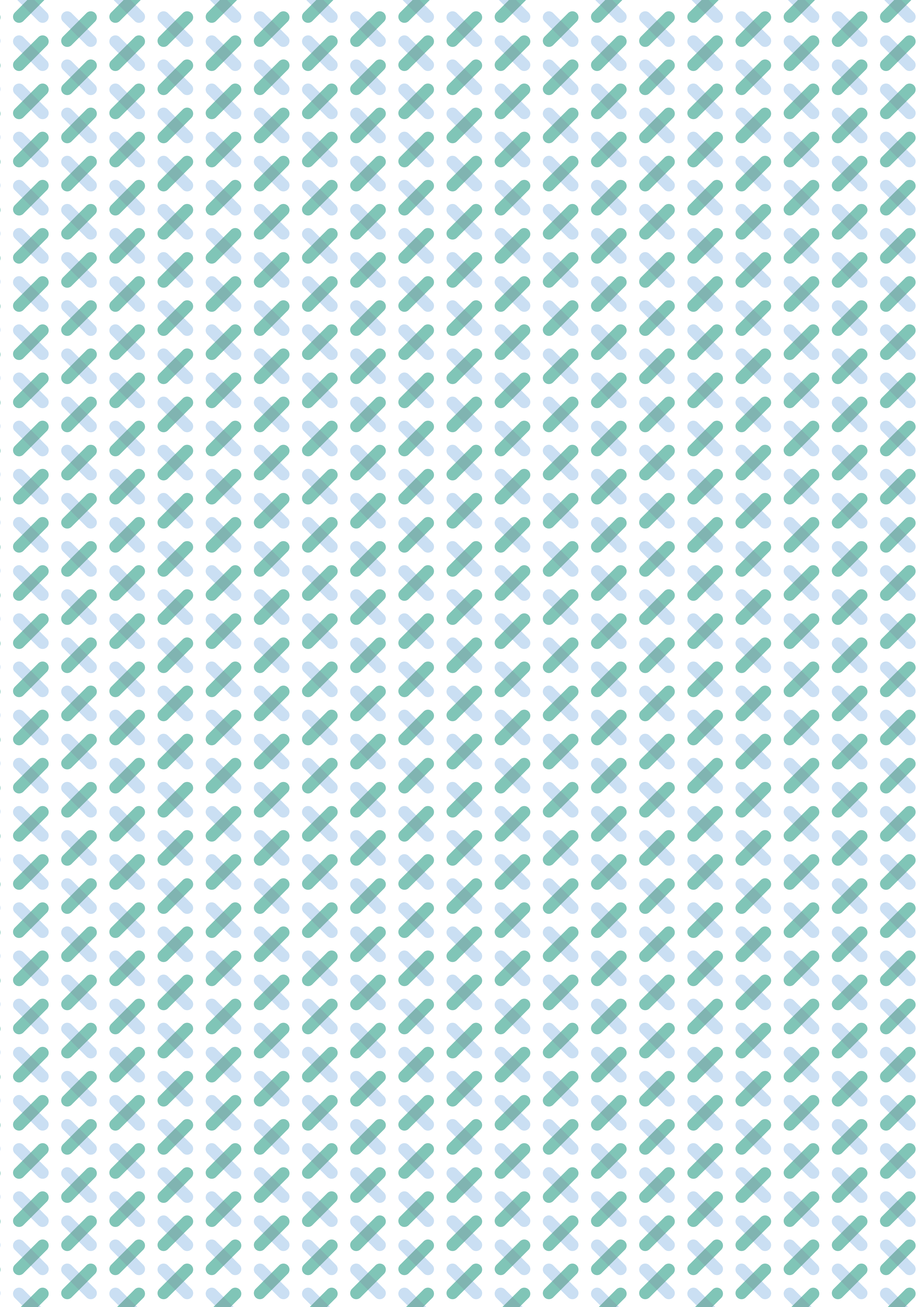
Abstract

The private sector's role in healthcare is growing across many settings. However, the sector remains under-governed in many contexts, particularly in low- and middle-income countries. Further, the understanding of the evidence base relating to private sector governance remains inadequate, with limited information available on the effectiveness of various approaches, and factors which facilitate or hinder their functioning.
This scoping review was commissioned by the World Health Organization (WHO) to address this gap by synthesising the available literature on the governance of private healthcare financing and delivery. The review seeks to answer the following questions:

1. What are the different approaches adopted to govern the private sector?
2. How effective are these approaches?
3. What are the key enablers of, and barriers to, the adoption of these approaches, and what potential avenues have been identified to strengthen Governance Behaviours across different contexts?

Narrative synthesis was conducted on 108 included studies published since 2010, structured around the three research questions for each of the six WHO Governance Behaviours (Deliver Strategy, Enable Stakeholders, Foster Relations, Build Understanding, Align Structures and Nurture Trust), and an additional cross-cutting theme on capacities for governing the private sector.

This report presents the findings around each Governance Behaviour and provides cross-cutting lessons for those involved in governance of the private sector and evidence generation in relation to it. The results of the review have been used to develop a *Progression Pathway for the Governance of Mixed Health Systems*, to assist countries in assessing their governance capacities relating to work effectively with the private sector, prioritising actions to improve governance, and tracking progress over time. The review also highlights important areas for future evidence generation on this important, but neglected, topic.



1 Introduction

Private sector involvement in healthcare delivery and financing is substantial and heterogeneous and spans the healthcare value chain (1)(2). The private sector's role is growing across many settings, reflecting a range of influences on health systems, including urbanisation, income growth, and increased requirements for pandemic preparedness, etc. However, the sector remains under-governed in many contexts, particularly in low- and middle-income countries (LMICs). In many countries, there is very little interaction between the public and private sectors: they use different vocabularies, have different core incentives, and are underpinned by different business/operational processes and funding mechanisms. At the same time, the global burden of disease is increasing, populations are ageing, and governments are under ever-increasing fiscal pressure. In line with the ambitious Sustainable Development Goals (SDGs), the combined resources of the public and private sectors will need to be effectively and efficiently harnessed to meet this demand (3). This will not only require formal governance mechanisms, but also new ways of working, including the two sectors interacting with each other and sharing information. Efforts to govern the sector should be grounded in a rigorous review of theory and practice and should also take account of the contextual nuances of various settings, and the fact that these contexts are in themselves dynamic and adaptive.

Health systems have been conceptualised as comprising a set of six building blocks that together enable the production of health products and services (4). Governance is one of these building blocks. Multiple definitions of the term 'governance' have been proposed by multilateral organisations and authors in the field, with these definitions often overlapping with the related terms 'stewardship' and 'leadership' (5). The World Health Organization (WHO) has defined health systems governance as 'ensuring strategic policy frameworks exist and are combined with effective oversight, coalition-building, regulation, attention to system design and accountability' (4). Other definitions include 'those processes that are formally or informally applied to distribute responsibility or accountability among actors in a given system' (5), 'the rules, processes, and behaviour by which interests are articulated, resources

Table 1. The WHO Governance Behaviours

1	**Deliver Strategy** The government has articulated clear strategic goals for the health system as a whole and the role(s) of the private sector in achieving these.
2	**Enable Stakeholders** Government acts to influence the operation and performance of the private health sector through regulation and financing.
3	**Foster Relations** The government has established inclusive policy processes in which many stakeholders (including the private health sector and other actors) play an active role.
4	**Build Understanding** The government has taken action to ensure access to comprehensive, up-to-date and high-quality data on the operation and performance of the private sector. This information is used for strategic and operational decision-making, and relevant data is shared with the public
5	**Align Structures** The government has established the organisational structures required to achieve its identified strategic goals and objectives for the private health sector.
6	**Nurture Trust** The government protects patients' rights and financial welfare concerning their interaction with the private health sector and provides structures to ensure public accountability / patient redress.

are managed, and power is exercised in society' (European Commission, cited in Barbazza and Tello (5)), and 'making, changing, monitoring and enforcing the rules that govern the demand and supply of health services' (6). While some definitions tend to emphasise a top-down conception of governance, others argue for a more bottom-up conception, with desirable attributes involving processes that are 'inclusive, transparent, accountable to all stakeholders, and responsive to the demands of the governed' (7).

WHO's approach to governance of the private healthcare sector has evolved over the past 25 years. The World Health Report (8) first introduced the concept of stewardship to describe how government actors should take responsibility for the performance of health systems in the public interest. The report provided a practical framework for strengthening health system performance, focused on the improvement of health status, financial protection, and responsiveness, with the intermediate goals of access, quality, efficiency, and equity (8). In 2016, the World Health Assembly (WHA A63.27) resolved to improve countries' effective engagement, oversight, and regulation of private healthcare providers in recognition of the growing and largely unregulated role of the private sector in providing essential health services in many countries.

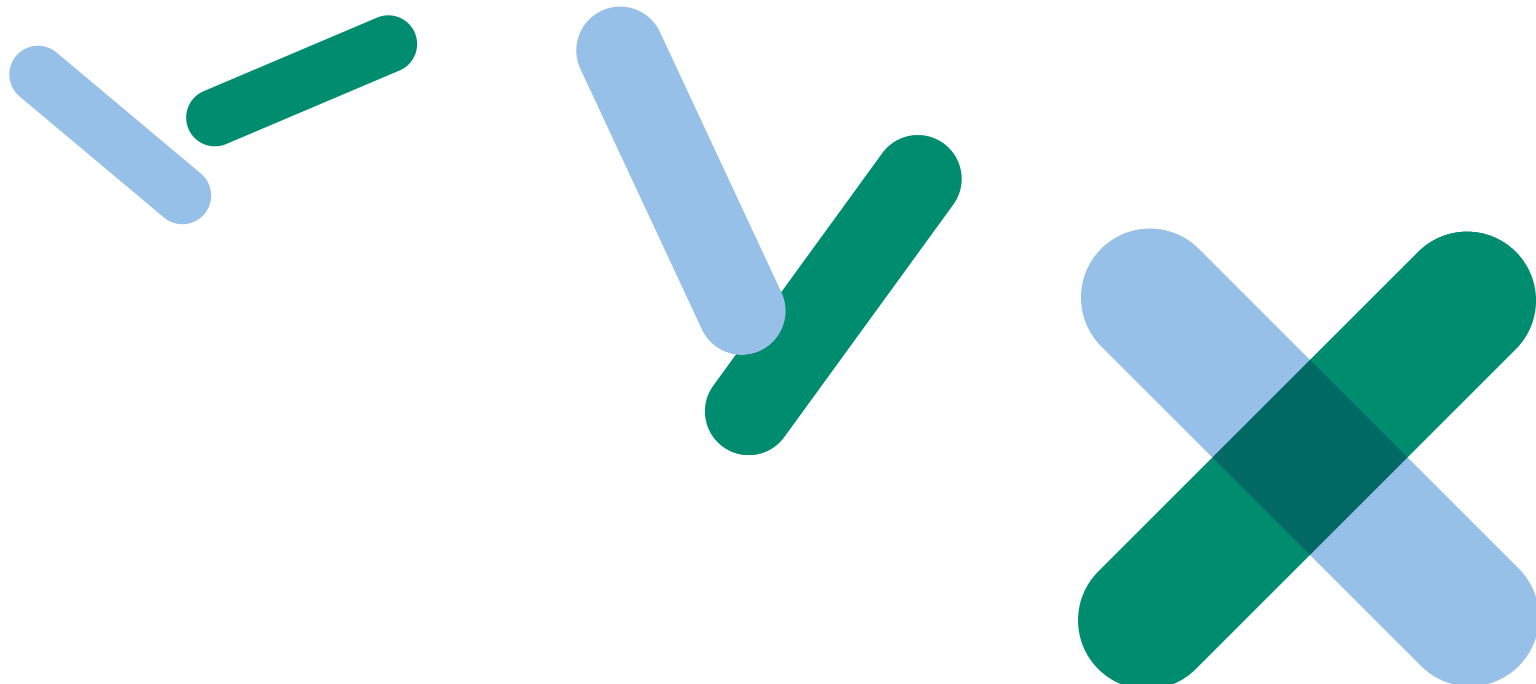
In 2019, WHO issued a call to action on private sector engagement, highlighting the need for a more central role for domestic actors (especially governments but also private and civic actors) in brokering private sector engagement, as part of work on the SDG agenda (9).

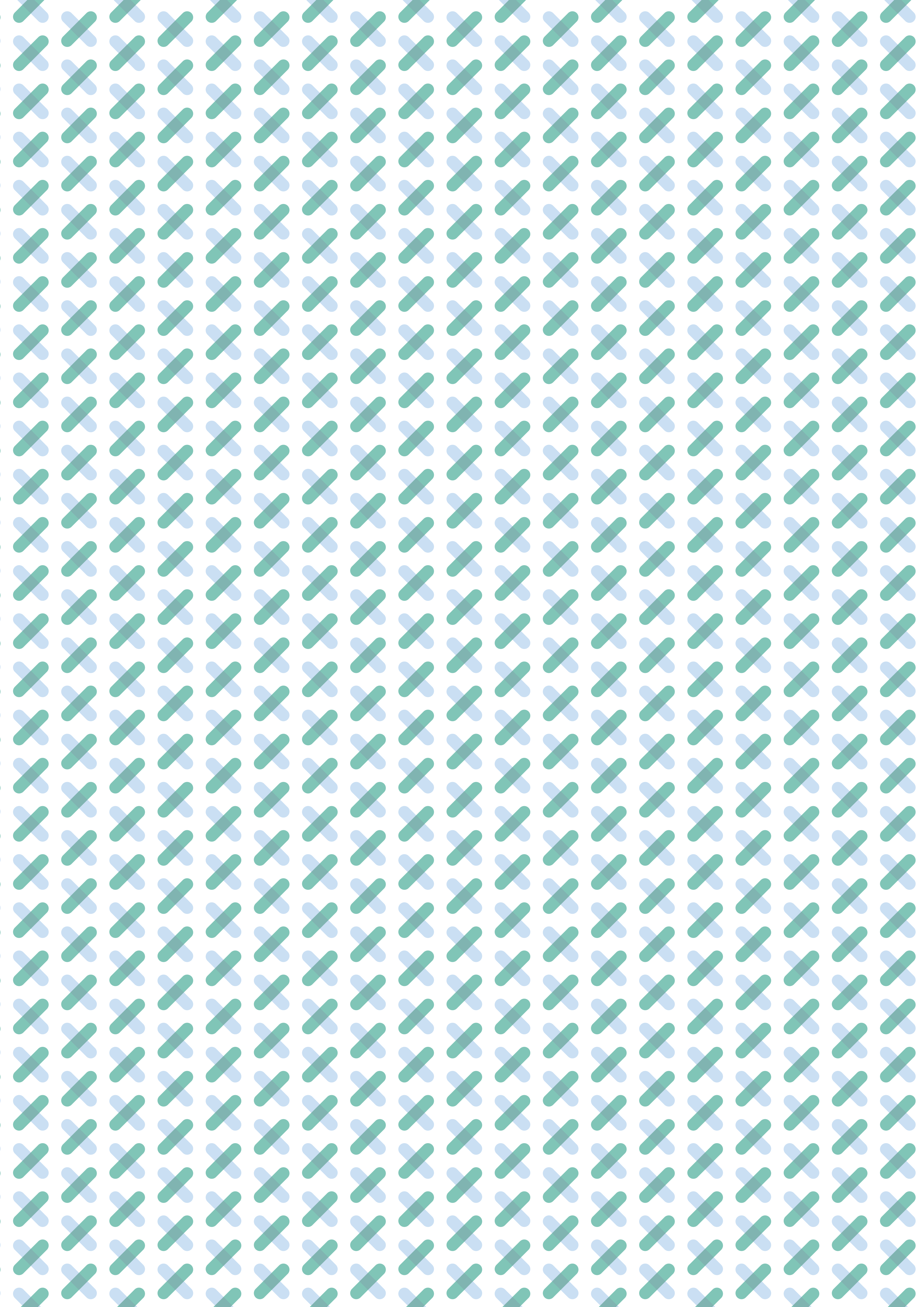
The same year, WHO established a Technical Advisory Group on the Governance of the Private Sector for Universal Health Coverage (UHC), to provide advice on how WHO should approach private sector engagement. The Technical Advisory Group developed and published a strategy called 'Engaging the private health service delivery sector through governance in mixed health systems' (10) (Table 1). The strategy set out six Governance Behaviours, which represent a practice-based approach to governance and draw on earlier work from Travis *et al*. (11) on health system stewardship subfunctions (3).

However, understanding of the evidence base relating to private sector governance remains inadequate, with limited information available on the effectiveness of various approaches, and factors which facilitate or hinder their effectiveness (2). A number of literature reviews have been conducted, covering health system governance more broadly (5), the governance of frontline public health services in Asia (12), health systems governance in conflict-affected states (13), the impact of governance on healthcare quality in LMICs (including engaging the private sector) (14), and governance related to health security in sub-Saharan Africa (15). Other reviews cover all types of private health sector engagement strategies (16)(17), or specific elements of private sector governance, such as regulation of health facilities (18)(19)(20)(21), facility accreditation (22), regulation of pharmacies(23)(24), and contracting of public and private facilities (25)(26)(27)(28). However, we were unable to identify an existing comprehensive review focusing on governance of the private health sector.

This scoping review was commissioned by WHO to address this gap by synthesising the available literature on the governance of private healthcare financing and delivery in LMICs.

The results of the review have been used to develop a ***Progression Pathway for Governance of Mixed Health Systems***, to assist countries in assessing their governance capacities to work effectively with the private sector, prioritising actions to improve governance, and tracking progress over time (29).





2
Methods

We conducted a scoping review based on a systematic search of the literature, in order to address three research questions:

1. What are the different approaches adopted to govern the private sector?
2. How effective are these approaches in governing the private sector?
3. What are the key enablers of, and barriers to, the adoption of the approaches, including governance capacities, and what potential avenues have been identified to strengthen Governance Behaviours across different contexts?

The scoping review methodology was selected to reflect the exploratory nature of the research questions, which covered a considerable breadth of literature. Scoping reviews typically seek to map the scope of a body of literature, and summarise evidence, whilst informing future research (28)(29). This approach was identified as appropriate in order to produce a descriptive synthesis of findings covering both effectiveness and enablers/barriers for governance of the private sector across multiple geographies and governance strategies.

The key steps of the review process are described below. During the development of this output and our ongoing consultations with the core team at WHO, several changes were made to the original protocol for this review, and these amendments are detailed in Annex 2.

2.1 Inclusion criteria

Defining inclusion criteria for a literature review on this topic presented several challenges, reflecting the highly heterogeneous nature of private sector involvement in healthcare, the varied definitions/scope of the term 'governance', and the nature of the literature itself. To address these challenges, we have made a number of key choices regarding our inclusion and exclusion criteria, as summarised in (Table 2).

First, we focus on private actors involved in the financing and delivery of health-related goods and services. Within this definition, we apply a broad perspective, including providers that may be considered formal or informal, with any level of qualification or even none, and which are either for-profit or not-for-profit. Providers may encompass healthcare facilities, retail pharmacies, other service providers (e.g. diagnostic labs, telehealth, information systems), health insurance bodies, as well as health maintenance organisations (HMOs). We exclude other private actors, such as the manufacturing sector, social care, training institutions, and producers of unhealthy commodities (e.g. sugary drinks and tobacco). While these excluded actors all have important impacts on health and require effective governance, they are considered beyond the scope of this review: (i) in order to keep the review tractable, and (ii) because the nature of these actors and their governance mechanisms is quite different from those for healthcare financing and service delivery.

We adopt WHO's broad definition of health systems governance as 'ensuring [that] strategic policy frameworks exist and are combined with effective oversight, coalition-building, regulation, attention to system design and accountability' (4). To ensure we capture all relevant aspects of this broad concept, we refer to the WHO Governance Behaviours conceptualised in the strategy report on 'Engaging the private health service delivery sector through governance in mixed health systems' to understand the scope of activities included. We focus only on national and sub-national governance, excluding issues related to global/multilateral governance: for example, the SDGs, Gavi – the Vaccine Alliance etc. (10). We include papers concerning governance in any LMIC.

We take an extremely broad approach to the inclusion of studies by study design and publication status. We include both published and grey literature, recognising that a significant proportion of recent work on governance is found in reports from multilateral and technical assistance agencies. We include quantitative and qualitative studies, literature reviews, and evidence syntheses. Evaluations of governance strategies using randomised controlled trials (RCTs) or similarly robust quantitative designs are very rare, reflecting the challenges of randomising many legally based interventions, and of quantitatively measuring governance outcomes. However, qualitative studies potentially provide rich information on the complexities of governance dynamics. We also include 'policy' pieces drawing on the reflections of actors engaged in governance, recognising that such internal perspectives can be informative. We additionally include purely descriptive pieces, where these elucidate the types of governance mechanisms used and underlying capacities, tools, and processes. For some individual governance mechanisms, such as regulation, accreditation, or contracting, there is an extensive literature which could merit multiple individual reviews; to maintain tractability, we draw where possible on existing literature reviews or evidence syntheses on these topics, while also including individual empirical papers where suitable reviews are not available or empirical papers help to elaborate key issues.

We include studies in all languages, though we recognise that our use of English search terms may bias towards the identification of pieces in English. Finally, we include studies published since January 2010 to ensure that the health systems context is relevant to the present day (while allowing rare exceptions for seminal pieces).

Table 2. Literature review inclusion and exclusion criteria

	Inclusion criteria	Exclusion criteria
Private healthcare sector	Papers should concern the private healthcare sector, defined as follows: → Engaged in the delivery or finance of health service-related goods and services (e.g. health facilities, pharmacies, drug shops, telehealth providers, health insurance firms etc). → Can be formal or informal, qualified providers, and for-profit or not-for-profit.	→ Manufacturing sector for pharmaceuticals, medical devices, and other commodities. → Provision of unhealthy commodities (e.g. sugary drinks, tobacco). → Health promotion activities that go beyond the health sector (e.g. water and sewerage, clean air, green spaces). → Social care (e.g. long-term residential care for the elderly who need living support rather than healthcare). → Training institutions for healthcare workers.
Governance	→ Relate to one or more of the WHO Governance Behaviours (e.g., Deliver strategy, Build Understanding, Enable Stakeholders, Foster Relations, Align Structures, and Nurture Trust) → Examine governance at national or sub-national (e.g. state or province) level.	→ Papers that describe the private sector in terms of numbers, utilisation, quality, cost, etc. → Governance of multinational private sector engagement/partnerships (e.g. Gavi). → Development impact bonds and other similar financing mechanisms.
Countries	LMICs from all WHO regions.	
Study type	→ Literature reviews (systematic and otherwise). → Papers that draw on/synthesise a body of empirical experience. → Empirical studies of any kind or study design, including both descriptive studies and evaluations of governance mechanisms, using qualitative and/or quantitative data, and any outcome measure.	→ Commentaries and opinion pieces, unless considered critical sources of information on enablers or barriers to effective governance of the private sector.
Publication status	→ Peer-reviewed articles. → Books. → Grey literature (e.g. policy papers, reports).	
Date of publication	→ January 2010 onwards to present date. → Selected earlier studies with substantial significance for the evidence base, as assessed by relevance and frequent citation.	
Language	→ All languages.	

2.2 Selection strategy

The search strategy was developed over multiple iterations and discussions with key experts, librarians at the University of Edinburgh and the London School of Hygiene and Tropical Medicine, and the WHO team.

An initial systematic search for published studies was conducted on 29 January 2023 and this was updated on 14 July 2023, in response to feedback on the search terms. These searches were conducted using three databases (Medline Ovid, Scopus and Web of Science), which were selected to ensure coverage of both the health-related literature and that from social science disciplines, such as sociology, economics, and political science. We searched using free text terms, and, where appropriate, Medical Subject Headings (MeSH) terms, related to the domains of 'private sector' and 'governance'. Additionally, the domain 'health' was in-

cluded when searching in Scopus and Web of Science, which are not health-specific. Papers available till 27 January 2023 were retrieved for further screening. The final search strategy adopted for each of the three databases is summarised in Annex 1.

To supplement these searches, and particularly to identify relevant grey literature, we contacted key stakeholders to obtain their advice on relevant resources, as well as drawing on our knowledge of the literature. The stakeholders were identified in consultation with WHO and included a mix of academics, practitioners, and staff at multilateral or donor organisations. Additionally, we searched the publication repositories of a range of websites of large international non-governmental organisations (INGOs), donor bodies, grant organisations, and universities, etc. (Results for Development, WHO, World Bank e-Library, Institute of Development Studies, University of Sydney, Lee Kuan Yew School of Public Policy, etc.), using a shorter set of search terms.

2.3 Study selection

Following de-duplication, the titles and abstracts from the database searches were screened. Given the large volume of articles, ASReview (**https://asreview.nl/**) was utilised to support the screening process. ASReview is an open-source machine learning tool which learns from the user's article prioritisation approach to suggest the next most appropriate article. Four reviewers piloted the screening of titles and abstracts on a common set of articles to ensure consistency. The articles were then equally divided amongst the four reviewers who screened independently. The reviewers screened at least 10% of their individual tranches and continued to screen until they had identified 50 irrelevant articles in a row (the stopping rule). There is no firm consensus on what a stopping rule should be when using machine learning tools, but these decisions are within the ranges suggested in the literature (32)(33)(34). All articles from the database searches passing screening were then subjected to full-text review, together with those identified through the web searches and through key informants.

We noted that many papers, while strictly relevant to the review, contained very little detail on governance (e.g. a very brief mention in the results, or just a recommendation in the discussion). In selecting the final set of papers for inclusion in the review we therefore only included articles containing a substantial amount of useful information on our research questions and/or information on a topic not widely covered by other papers. The reviewers regularly consulted with other members of the review team, and with WHO staff, to discuss articles for which inclusion was uncertain, with final decisions reached through consensus.

2.4 Data extraction and analysis

The reviewers reviewed the abstracts in ASReview (SS, AB, AS, MB), followed by data extraction (SS, SN, AB, DB). The reviewers extracted the data from the included articles using an agreed extraction matrix in Microsoft Excel, coded according to the three research questions and tagged per the six WHO Governance Behaviours. The articles were divided amongst the reviewers and each article was extracted by one reviewer, with support from other team members. A narrative synthesis was conducted, structured around the three research questions for each of the six WHO Governance Behaviours, and an additional cross-cutting theme on capacities for governing the private sector.

GHANA: WHO Malaria Vaccine Implementation Programme visit, August 2023.
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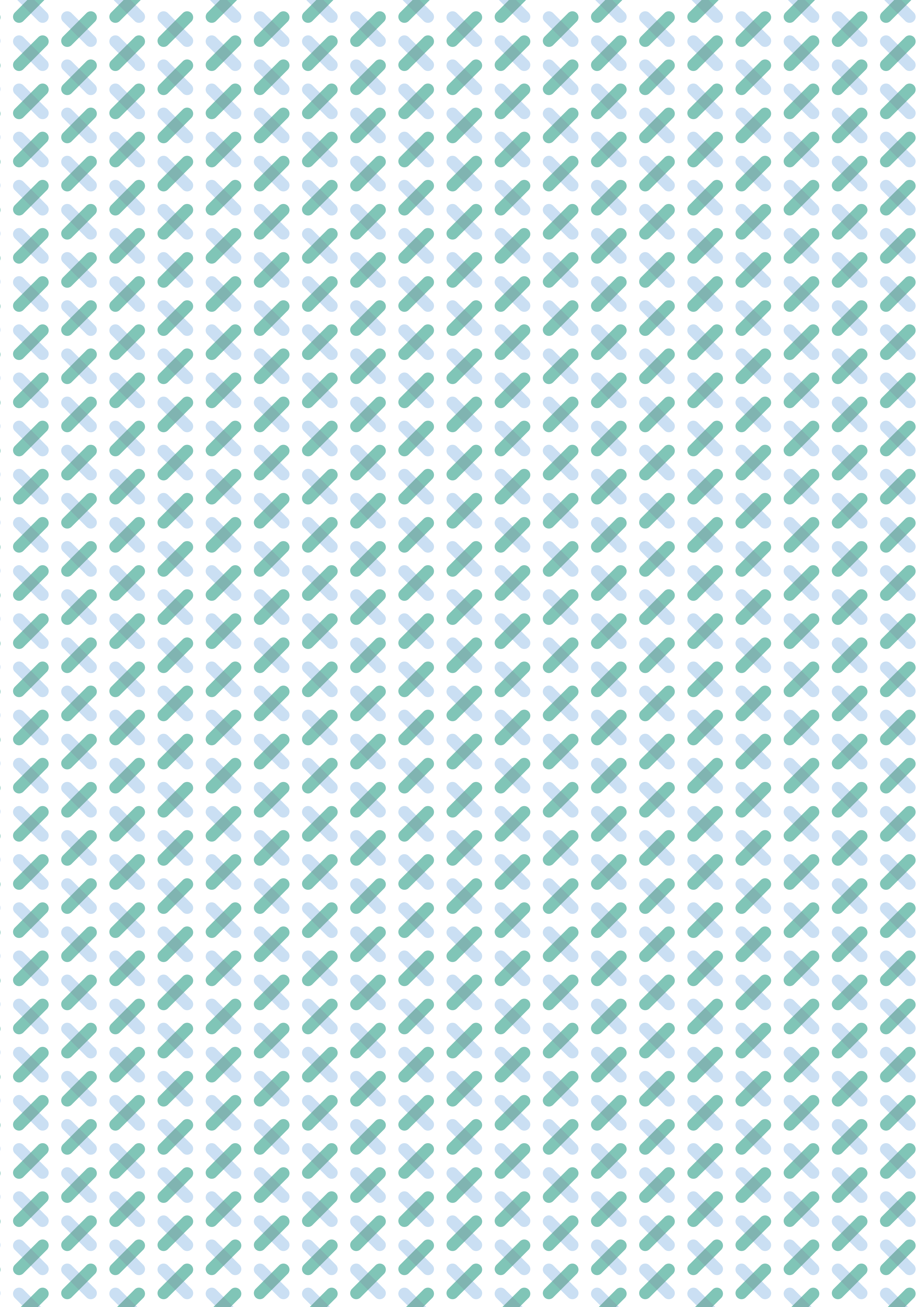

3
Results

3.1 Summary of the literature

3.1.1 Search results

Our initial searches identified 13,899 records from databases, 717 reports identified through the web search, and 85 papers identified by key informants, before de-duplication. Following de-duplication and screening, 338 records were selected for full-text review, of which 230 were excluded after the review, with a total of 108 documents selected for inclusion, or 111 items (as some documents were books with more than one relevant chapter) (Figure 1).

3.1.2 Summary of the literature included

The characteristics of the included papers are shown in Table 3. A table showing the characteristics of each individual study is provided in Web Annex, as a separate document.

The largest category of private actors studied was private facilities (93 papers), followed by private health insurance (30 papers), and NGOs (24 papers). Regulation (63 papers) and contracting (47 papers) were the most common governance tools discussed. In terms of geographical coverage, papers were identified covering 102 individual LMICs, including those from all WHO regions. Concerning the research methods used, qualitative methods were predominant across all topics (46 papers qualitative only; 19 mixed methods).

Below we present the findings of the review, organised by governance behaviour.

Figure 1. PRISMA flow diagram

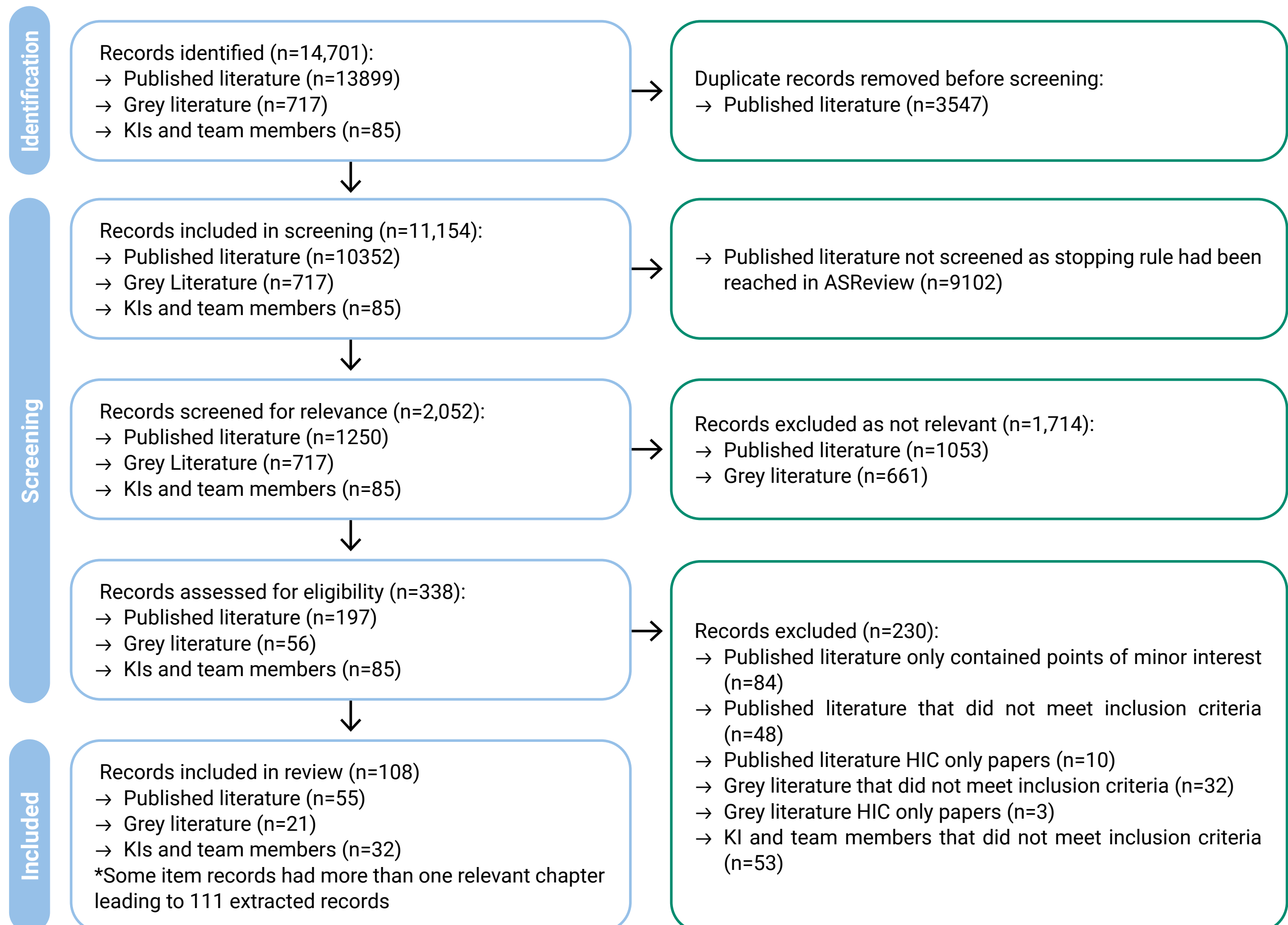

Table 3. Characteristics of included studies

Paper characteristics[1]	Total papers extracted: 111
Number of papers	111
Types of private sector actors covered	
Private healthcare facilities (hospitals, health centres, clinics etc.)	93
Private insurance companies or HMOs	30
Non-governmental organisations (NGOs) (national and international)/civil society organisations (CSOs)	24
Pharmacies and other retailers	21
Laboratories	7
Governance tools discussed	
Regulation/legislation	63
Contracting/purchasing	47
Support/collaboration/guidance	22
Accreditation	8
Taxation	1
Public accountability mechanisms	5
Level of governance covered	
National	89
Sub-national	30
Journal/publication type	
Health and health systems journals	64
Social policy and development journals	11
Reports	27
Other[2]	9
Data collection methods	
Qualitative study	46
Quantitative study	3
Mixed methods	19
Reviews (document/literature)	38
N/A[3]	5

[1] Many publications include more than one category of private sector actor, governance tool, or data collection method.
[2] Other publications include book chapters, policy briefs, and academic theses.
[3] These are papers which do not employ any data collection method and which are conceptual in nature.

3.2 Deliver Strategy

Deliver Strategy is defined as 'government has articulated clear strategic objectives for the health system and a clear definition of roles for the private health sector in achieving these', and is expected to be demonstrated by the existence of up-to-date policies (e.g. legal documents or policy statements) that define clear objectives for the private sector, in line with health system goals, and an articulation of how specific policy mechanisms will be used to influence the operation and performance of the private sector in line with these strategic objectives (3).

3.2.1 What are the different approaches adopted under Deliver Strategy?

The literature indicates that including the private sector within national health sector strategies and plans is widespread. As far back as 2011, the national policies of over 85% of African countries covered the private health sector, though the content varied from just recognising its role to giving it a prominent position in achieving the country's strategic aims (35). A more recent (2020) assessment of 17 LMICs with high levels of private sector utilisation reported that the private sector was mentioned in policies or strategic plans in all countries assessed (i.e. Albania, Bangladesh, Cambodia, Dominican Republic, Egypt, Eswatini, India, Indonesia, Jordan, Kyrgyzstan, Lao People's Democratic Republic, Mexico, Nigeria, Pakistan, Philippines, Suriname, Uganda) (2). Furthermore, all 17 countries included specific objectives on private sector engagement, though the extent of content on the private sector did vary (ibid.). Almost half of the countries outlined the role of the private health sector in achieving their national health goals, though only a few had established a formal partnership framework to facilitate implementation (2). A 2022 review of African countries also concluded that most African countries defined roles for the private sector in their health strategies (specific countries not stated), although this was said to mainly focus on faith-based organisation (FBO) facilities (36). The inclusion of the private sector in national plans and strategies has also been reported in Mongolia, Myanmar, Philippines (37), Ghana (38), Ethiopia (39), South Africa (40), and Afghanistan (41). For example, Ethiopia's Health Sector Transformation Plan 2021–2025 states that 'Strengthening the engagement of the private sector in the health sector priorities is a major strategic area' (39), while Afghanistan's Strategic Plan 2011–2015 identifies 'regulation and standardization of the private sector' as a key 'strategic direction', and commits the Ministry of Health to developing specific policies, regulations, and procedures to support this (41).

Several LMICs also have specific private health sector or public–private partnership (PPP) policies or strategies in place, including Uganda, Nigeria, Philippines (2), Ghana (38), Sudan (42), the United Republic of Tanzania (43), and Afghanistan (41), though WHO's 2020 review found that most countries did not have these in place (2). Uganda's health sector-specific PPP policy acknowledges the role of the private sector in achieving UHC, improving equity, increasing access, and strengthening efficiency, and describes the goals for partnerships, and institutional arrangements for their implementation (2). Afghanistan's National Policy for Private Health Sector provides a vision and principles for government stewardship, a list of policies needed for each type of business, and guidelines for developing policies and regulations (41).

Priority health programmes may also develop their own private sector engagement policies and strategies: for example, related to human immunodeficiency virus/acquired immune deficiency syndrome (HIV/Aids); tuberculosis (TB); immunisation; reproductive, maternal, newborn, and child health; or adolescent health (2)(34)(35)(37)(42).

3.2.2 How effective is the inclusion of the private sector in policy?

There is consensus across the literature on the importance of a strong strategic policy direction for private sector governance and engagement (2)(38)

(40)(42)(43)(44)(45). However, it has been argued that in many settings inclusion in policy documents fails to translate into a clear vision for the private sector's role, and a lack of implementation (34)(40)(45). The 2020 WHO review of countries with high private sector utilisation reports that the formation of effective partnerships required to translate policy frameworks into action was not documented in most countries studied (2). In regard to Mongolia, Tsevelvaanchig et al. report that the health sector Strategic Plan 2005–2016 included provisions to establish an 'optimal public–private mix of services', but detailed policy guidelines had not been developed to implement the required regulation and financing reforms (46). However, this narrative of poor implementation belies the rapid developments in the role of the private sector that have taken place in recent decades in many LMICs: particularly the widespread inclusion of private facilities in purchasing mechanisms for national health insurance described under Enable Stakeholders, as well as progress within other Governance Behaviours. For example, in Ghana it has been argued that the national private sector policy has been implemented on various fronts, most prominently with the inclusion of private providers in the Ghana National Health Insurance Scheme (42).

In sum, there is limited literature covering the specific impact of including the private sector in national policy documents on subsequent governance of the sector, and it would likely be methodologically challenging to separate the impact of inclusion in national policy from other drivers of enhanced governance.

3.2.3 What are the key enablers of, and barriers to, the inclusion of the private sector in policy?

We focus here on the enablers of, and barriers to, the inclusion of the private sector in national policy documents (enablers of, and barriers to, successful implementation of such policies are covered under the other Governance Behaviours).

Particularly in earlier years, a basic barrier to the inclusion of the private sector in health sector strategies was that private sector governance was not seen as a key role or priority of the Ministry of Health in LMICs, which focused primarily on public sector provision (39)(46)(47). This reflected the more limited role of the private sector at the time, together with mutual mistrust between the public and private health sectors, a lack of private provider organisations to interface with, and a lack of relevant skills and funding for private sector governance (39)(46). It has also been argued that a focus on delivering a limited number of priority cost-effective health interventions through priority health programmes, such as HIV/Aids and malaria programmes, may have de-emphasised the government's role in managing broader healthcare provision, and, by contrast, that greater emphasis on more horizontal health system issues could encourage a greater 'whole system' perspective (50).

In some settings, a lack of focus on private sector governance was reinforced by resistance from private actors. For example, in India, the private healthcare sector has frequently opposed state regulation of its activities (49) (see the section on Enable Stakeholders). Hunter et al. quote a former government official explaining the government's reluctance to take responsibility for private healthcare regulation: 'The argument made by the private sector was that government hospitals were experiencing problems, and we should first get our own house in order, before turning attention to others. For this reason, we were not really pushing for standards in the private sector' (49).

As the private sector grew, with greater utilisation of for-profit and non-profit facilities, it was increasingly the case that governance of the sector could no longer be ignored (39). This shift was also influenced by better information on the size and complexity of the private sector (see the section on Build Understanding).

External donors and technical advisers have also played an important role in moving towards greater inclusion of the private sector in policy (36)(37)(45)(47). For example, in Pakistan development partners

were said to have influenced the instigation of contracting against a backdrop of lukewarm political support (47). Cross et al. note that in Afghanistan greater private sector engagement was actively supported by the United States Agency for International Development (USAID), the World Bank, and the European Union (41). It is also argued that enthusiasm for including the private sector in policy increased as positive results were observed in early engagements related to immunisation, family planning, emergency services, and TB (37)(39).

3.3 Enable Stakeholders

Enable stakeholders is defined as 'government acts to influence the operation and performance of the private health sector through the use of financing and regulatory policy mechanisms', with the principle focus of financing being on the design and implementation of purchasing and/or contracting arrangements with private actors (3). We present the literature on the two broad areas of regulation and contracting/purchasing in turn.

3.3.1 Regulation

What regulatory approaches have been adopted to govern the private sector?

The legal basis for private healthcare regulation is typically spread across a wide range of laws. First, general health legislation covers both the public and private healthcare sectors, including laws related to public health, professional regulation, telehealth, data, and legal redress (45). Secondly, countries may pass laws specifically related to the private health sector: for example, focused on facility or pharmacy regulation, purchasing, or private health insurance (39)(49)(50). Finally, there are laws that apply across multiple economic sectors, including health: for example, those related to anti-trust/competition, e-commerce, PPPs, and public procurement (41)(50).

A core aspect of health regulation is the registration/licensing of private health facilities, pharmacies, health NGOs, and allied health services, which is in addition to the business licensing requirements required for all commercial enterprises. Both public and private healthcare professionals also have to be certified/licensed as individual practitioners (16)(51), and in some countries health professionals are licensed to work in the private sector only after they have completed a minimum period of public service. Responsibility for licensing premises and individuals may lie with government bodies or it may be delegated to professional associations who are expected to self-regulate (56). Healthcare facilities and retailers are typically supposed to be inspected regularly to ensure that appropriate licences are in place, they comply with regulatory standards, and they do not provide services that are outside of their remit. Failure to comply with mandatory regulation should lead to sanctions in the form of warnings, fines, confiscation of equipment or stock, temporary or permanent facility closure, or even imprisonment (26)(52)(55)(56).

A principal component of health facility regulation is minimum quality and safety requirements for market entry and continued operation, covering staff qualifications and continuing education, infrastructure, and equipment, and in some cases some operating procedures (51)(57). While most regulation focuses on such quality and safety standards, in a minority of cases governments also regulate the geographical location of providers: for example, requiring a certificate of need (CON) to justify the establishment of a new facility in a given location (46), or specifying a minimum distance between pharmacies (57)(58). Other requirements may include mandatory submission of data to the government (61), assuring patient rights to emergency services, and restricting advertising (54)(60).

Facility fees or medicine prices are also regulated in some LMICs (2)(16)(51)(52). For example, in India price caps are placed on essential medicines and, since 2017, on hospital charges for cardiac stents and knee implants (49). During the coronavirus disease (COVID-19) pandemic, concerns about the affordability of treatment and perceived 'price gouging' led to the introduction of additional price caps on COVID-19 testing and treatment in several countries, including the Philippines, Indonesia, and Sri Lanka (61)(62). A more indirect approach to regulating price is through competition (anti-trust) regulations, which exist in most countries but are rarely applied in the health sector. There are important exceptions, such as South Africa and Zimbabwe, where investigations on horizontal and vertical mergers, price collusion, and conflicts of interest have been undertaken (18).

Private health insurers typically also have to be registered, though in many countries their regulation is covered by general rather than health-specific insurance

legislation (18). Registration is generally on the basis of financial soundness, though some countries regulate aspects of enrolment, the benefits package, and the extent of risk rating (18). Some countries also require the registration of brokers who sell insurance to potential customers, and occasionally there are caps on brokers' commissions (18). However, it is argued that in many LMIC settings the industry is under-regulated (18). Consumer protection regulation can also form an important component of the regulatory system. This point is further covered under the section on Nurture Trust.

In addition to statutory rules and self-regulation by professional bodies, described above, some commentators argue for a broader definition of the term 'regulation', encompassing community accountability, contracting arrangements, subsidies, publicly displaying facility data, and quality improvement or assurance activities (53). Within this review these additional activities are covered in the section on 'contracting and purchasing' below, or under other Governance Behaviours (i.e., Nurture Trust, Align Structures). However, we include organisational accreditation under regulation, as it forms a key component of the regulatory system in a number of settings. It is worth noting that the term 'accreditation' is used differently across contexts. It was originally conceived as a voluntary external assessment that health facilities, laboratories, or other providers would undertake to signal their quality standards, with accreditation bodies operating at an international level (e.g. Joint Commission International) or national level (e.g. the National Accreditation Board of Hospitals and Healthcare Providers in India) (14)(47). Over time, social health insurance programmes have also increasingly required accreditation for all empanelled facilities, leading to rapid expansion of accreditation in some middle-income countries (16), and more recently some social health insurance programmes have designed their own specific accreditation schemes (65). Finally, in some countries accreditation by national bodies is compulsory for all facilities, and therefore plays a similar function to registration (66).

How effective are regulatory approaches to governance?

Evidence on regulatory compliance

There is considerable evidence of poor compliance with regulations across multiple LMICs and multiple private provider types, though there are some notable exceptions, such as South Africa (42). Reports published in the earliest part of our review period noted the high number of unlicensed private providers in many countries, meaning that governments were often not even aware of the number and types of providers operating (40)(54). Some countries have made substantial progress in this area since that time. For example, in Kenya in 2022 the majority of private health facilities were said to be registered and included in the Kenya Health Master Facilities List, which provides details on location, ownership, and services offered (61). In Mongolia close to 100% of private facilities were registered in 2015, though the process was noted to focus mainly on accurate completion of application documents, rather than meeting quality requirements (46). However, persistent prevalence of unlicensed providers was reported in the Indian States of Madhya Pradesh and Delhi in 2010 (67), and in Karnataka in 2016 (68). In Bagamoyo District in the United Republic of Tanzania, most private diagnostic laboratories were found to be unregistered (69). Khan et al. note that government data on facility registration may be unreliable: in one (unnamed) country, the government reported zero unlicensed providers in order to signal the success of their regulatory policies, although they were in fact common (70).

There is very limited systematic data on levels of regulatory compliance by health facilities. An exception is a baseline survey of private facilities in three Kenyan counties carried out in 2015, which reported that only 2% scored at least 60% of the maximum inspection score (57). Elsewhere in the literature, poor regulatory compliance at LMIC health facilities has been mentioned in terms of clinicians operating more establishments than legally allowed, health professionals misrepresenting their qualifications, unregistered persons providing healthcare, and the provision of unnecessary services (18). There is also little evidence that regulations limiting geographical location to less well-served areas have

been effective (46).
Many studies highlight regulatory infringements in retail pharmacies or lower-level drug stores, particularly related to a lack of up-to-date licences, underqualified staff, stocking medicines that are not permitted, and, most commonly, the provision of prescription-only medicines without a prescription (21)(57). In a 2016 review of retail pharmacy performance, the sale of prescription-only medicines without a prescription was found to be common in all 14 Asian LMIC countries studied, ranging from around half of transactions in Pakistan and India, to over 80% in Lao People's Democratic Republic and virtually all transactions in Viet Nam and Malaysia (23). In a study in one Ugandan district, 89% of drug shops could not present an up-to-date licence, and 71.9% reported antibiotics in their top five most profitable medicines, although their sale was not permitted (60). In some settings high volumes of medicines were reported to be sold by completely unauthorised outlets, such as market stalls and itinerant vendors in Niger (59). However, in Colombia, Guatemala, and Mexico, it has been argued that the enforcement of prescription laws during the mid- to late-2000s, together with the expansion of pharmaceutical chains, drove a widespread reduction in over-the-counter sales of prescription-only medicines (59).

Countries vary in how permissive their regulations are on dual practice (concurrent employment in public and private health sectors). Where this has been restricted on paper, these rules have been widely flouted in practice (43)(50)(69). However, the merits of restricting dual practice have been debated. It has been argued that it encourages an urban bias in doctor location, reduces public sector quality due to absent staff, and gives incentives for public providers to provide poor quality care in order to shift patients to their private clinics (69)(70). However, in Thailand permitting dual practice was said to have been beneficial in stemming the movement of health workers from the public to the private sector or overseas, though it also exacerbated conflict of interest challenges (73).

Few studies touch on the regulation of healthcare NGOs or CSOs (34)(72)(73). In the Indian State of Uttar Pradesh, NGOs were registered and engaged in information sharing and state planning meetings, but there was limited enforcement of requirements for regular reporting to the state government (74). A 2022 WHO review of African countries found that these types of organisations sometimes fell outside of regulatory oversight altogether, with many local CSOs not registered with Ministries of Health or other regulatory bodies (36). INGOs were described by one respondent as 'more accountable to their donors than their minister of health', which was viewed as particularly problematic in fragile and humanitarian contexts (36). This could lead to a form of power imbalance whereby governments are reliant on the additional resources that INGOs bring, but with INGOs having little accountability to them, as described at the district level in Ghana, for example (75).

Despite the widespread evidence of imperfect compliance with statutory constraints described above, it has been argued that in most settings regulation has an effect on the ordering of private sector provision, and in preventing degeneration into an ungoverned free market (59). For example, in many (though not all) settings, most providers have some form of health qualification, and the sale of medicines is often restricted to specific outlet types (59). Nevertheless, in view of the widespread evidence of poor compliance, the identification of strategies to address this is crucial. We turn next to evidence on the effectiveness of these strategies.

Evidence on the effectiveness of introducing or enhancing regulation

There are only a limited number of robust quantitative studies on the effectiveness of introducing or enhancing regulation (18)(19)(21). In Kenya, a package of reforms was tested through a large-scale RCT in three counties, through a collaboration between the Kenyan Government and the World Bank Group (57). The reforms covered both public and private facilities, involved the harmonisation of facility regulations across all of the different regulatory bodies under a Joint Health Inspection Checklist (JHIC), greatly increased the frequency of facility inspection, and linked the time to re-inspection to facility performance. This led to a substantial increase in inspection scores (57), at an annualised economic cost of US$ 311 per inspec-

tion completed (76). Data were not presented on the impact on clinical quality of care. While the improved inspection scores could be argued to be good value for money, national scale-up would require significant additional investments by the ministry of health. No other robust studies of strategies to enhance facility regulation were identified.

A Cochrane review on public stewardship of private providers identified four studies in the early 2000s on interventions to improve pharmacy regulation in Thailand, Viet Nam, and Lao People's Democratic Republic. The review concluded that a combination of increased visits, information provision, and sanctions, combined in some studies with training and peer influence, improved regulatory performance in three of the four trials (77)(78)(79) ; all cited in (21). For example, the study of a purely regulatory intervention in Lao People's Democratic Republic documented increases in the availability of essential dispensing materials, pharmacy 'orderliness', and information given to customers, and a decrease in the mixing of drugs in the same package (21). No more recent pharmacy-focused evaluations were identified.

Turning to the effects of introducing voluntary accreditation or certification programmes, a 2016 Cochrane review on external inspection of health facilities identified one LMIC study meeting their strict inclusion criteria: a 2003 South African study which showed increased compliance with accreditation standards but no impact on clinical quality of care (20). Similar results were obtained in a more recent RCT of the SafeCare step-wise certification of private facilities in the United Republic of Tanzania, which found a small increase in compliance with certification standards but no improvement in clinical quality of care in terms of correct case management or compliance with infection prevention and control procedures (80). A 2016 review with less restrictive inclusion criteria found multiple studies on accreditation, with most showing a positive effect on quality measures in health facilities and laboratories, though a minority found no effects (16).

There is relatively little evidence in the literature on the effectiveness of private health insurance regulation. However, the few papers that do address this topic emphasise its importance for the development of the whole health system over time (71)(76)(77)(78). In South Africa the deregulation of private health insurance in the early 1990s to allow risk-based premia and open competition for enrolment was said to have led to 'dramatic unintended consequences' in terms of private sector growth, increased costs, and discrimination against people with high risks of poor health (16)(77). Subsequently, South Africa developed extensive legislation around open enrolment, minimum benefit packages, and community rating to address these concerns (82), but a 2015 review found that private health insurance regulation seldom addressed these equity-related issues in other east African and southern African countries (18). Harris and Libardi Maia contrast the private health insurance regulatory choices in Brazil and Thailand, arguing that in Thailand private health insurance development was constrained by strict underwriting of requirements, reducing its affordability and growth (73). Together with the use of participatory governance fora and sustained investment in the public health sector, this led to the development of a heavily controlled private healthcare sector. They contrast this with Brazil, where private sector development was fuelled by a combination of limited regulation and tax breaks for private health insurance, together with contracting practices favouring the private sector. As a result, the Brazilian private sector has been able to exert a much stronger influence on policy, reportedly leading to the 'withering of Brazil's Unified Health System', while Thailand has achieved much greater progress towards achieving UHC (73). Lobato et al. also discuss the challenges with private health insurance regulation in Brazil, including the transfer of private patients to the public sector for complex and expensive procedures, competition for beds between publicly and privately funded services, and particularly poor regulation of less expensive 'C Class' insurance policies for lower income groups (84).

Similar themes are raised in the literature on medical tourism, with concerns that the unregulated development of this sector could have negative consequences for the broader health system, leading to tensions between ministries of commerce and health. Medical

tourism has grown rapidly in many LMICs, including India, Thailand, Brazil, Mexico, Türkiye, Costa Rica, Malaysia, and Ecuador, with estimates that it accounts for up to 30% of private hospital and specialist clinic revenues in South-East Asia (64). Domestic regulation of the medical tourism sector has often been very limited, based on the perception that the care of visiting patients is primarily safeguarded through international accreditation bodies (85). For instance, the situation in Guatemala has been described as a 'regulatory vacuum' (86). However, concerns have been raised about the potentially distortionary impacts of the medical tourism sector on the national health system – for example, if it attracts scarce health workers from the public sector or incentivises the development of tertiary services at the expense of primary healthcare, worsening inequalities (71)(80)(82). This has led to arguments for greater taxation and regulation (86). For example, it was suggested that Guatemala should consider the types of regulations instituted in Israel on earmarking medical tourism tax revenue for the public health system, and limits to international patient numbers based on waiting times and capacities (86). However, no evidence was identified on the implementation or impacts of such strategies in LMICs, while concerns were expressed about their potential effect on the competitiveness of a country's medical tourism sector (71)(81).

What are the key enablers of, and barriers to, effective regulation?

Multiple barriers to effective regulation have been raised in the literature, including gaps or overlaps in the legal framework, limited inspection and enforcement, and under-resourcing, as well as structural challenges related to the nature of the private market, and political challenges reflecting the role of vested interests. These are described below, before turning to potential enablers.

Gaps and overlaps in the legal framework

The multiple laws that apply to the health sector can create a complex legal environment, a situation which is compounded by rapidly changing health technologies, potentially leading to gaps, overlaps, and discrepancies between laws (39)(43)(50)(83). For example, in Mongolia and Yemen the content of legal documents was said to be weak and imprecise (50)(70). In Egypt a 2014 review found that one law allowed a private doctor to own multiple private clinics, but a second law prohibited this (). In Ukraine licensing guidelines contained outdated requirements that were misaligned with current treatment protocols (28). In many countries regulatory mechanisms are said to be duplicative, leading to inefficiencies and increasing compliance costs for providers. For example, in Kenya health facilities were required to register with the Medical Practitioners and Dentists Board, but also with radiology, pharmacy, and laboratory boards, requiring payment of multiple licence fees (65). In Ghana considerable overlap was reported between the regulatory and national insurance bodies, which both required licences and inspections (65), while the United Republic of Tanzania was reported to have more than five regulators involved in regulating health insurers (18).

In some settings 'informal' and 'traditional' health sectors are inadequately covered by legal frameworks, sometimes because they are considered illegal. For example, 2014 reviews in Egypt and Yemen found that regulations mainly 'ignore the informal sector' (defined as traditional providers and non-medically qualified clinicians), despite these services being widely available (50)(84). In contrasts, in the Indian State of Karnataka, laws on facility regulation also covered non-allopathic systems of medicine (Ayurveda, Unani, homeopathy, Yoga, naturopathy, Siddha, acupuncture, acupressure, and integrated medicine) (68).

Limited implementation of regulations

There is considerable evidence, particularly in lower-income settings, that regulation is poorly implemented: there is limited follow-up post-registration, with inspections rare or sporadic, and sanctions are often not applied (2)(16)(40)(50)(51)(57)(65)(68)(70)(83). For example, in Kenya prior to the JHIC intervention only 4% of private facilities were inspected annually (57). In Iraq and Pakistan, despite the existence of regulatory policies, there was said to be 'no evidence of regulation' in practice (45). Hunter et al. describe a regulatory system in India in which the state is 'both conspicuously present and absent', making detailed demands

on private providers but enforcing these sporadically and conducting minimal assessment of the appropriateness of care provided (49). Similarly, Putturaj et al. describe the law regulating private facilities in the Indian State of Karnataka as 'toothless', reflecting a failure to implement sanctions (68). In general, it is argued that enforcement is complicated by the overlapping regulatory mandates of multiple national and local public bodies, and the coordination required with police and judicial offices where enforcement of penalties is required (40)(65). Poor implementation can also indicate a lack of incentives for frontline inspectors, their imperfect access to information (59), and under-resourcing, to which we turn next.

Regulatory bodies are under-resourced

It is very frequently argued that poor implementation reflects the severe under-resourcing of regulatory bodies, both financially and in terms of personnel and logistical support, at both the national and sub-national levels (2)(16)(50)(56)(57)(65)(73). Where responsibility for regulation is delegated to professional associations, they too are often very poorly funded (67). A review of six LMICs found that countries typically had 25–100 staff at a national level focusing on regulation across all regulatory, insurance, accreditation, and professional association bodies (65). For example, in Kenya about 35 staff at the Ministry of Health's Department for Standards, Quality Assurance, and Regulation were responsible for regulation, for a population of 43 million (65). It has been argued that under-resourcing of regulatory agencies reflects a lack of political priority historically given to regulation by governments and their donors, which preferred to focus on funding government-managed service delivery (56). These limited resources have become particularly stretched in light of rapidly growing private healthcare markets, and the fragmented state of this sector, which typically comprises a very high number of small to medium-sized independent organisations, making inspection and enforcement difficult and costly (56).

Compatibility of regulatory compliance with the realities of private provider markets

For regulation to be effective, private actors must be able to achieve compliance within the economic and competitive constraints that they face in the market (51)(57). This starts with the costs of the licensing process itself, which it is argued can be high for certain private actors, reflecting time-consuming and duplicative administrative processes and multiple fees (39)(50)(54)(56)(63), as well as the high cost of accreditation fees, particularly for international accreditation (59). More fundamentally, in some contexts it has been argued that complying with regulatory requirements is incompatible with breaking even as a business. For example, in Ethiopia concern that regulatory standards for private facilities were too strict led to revisions to make them more realistic for the local context (39). The enforcement of regulations limiting the geographical location of new providers to less well-served areas has faced major challenges, with private providers arguing that it would be hard to survive in lower-density, poorer locations (46). Similar issues have been raised in relation to price regulation, with concerns that some price caps are set below a reasonable rate considering the costs involved (90). As a result, price regulation is often not well-implemented, or services end up available only to those able to pay top-up fees above the cap (53)(90). It has also been alleged that price caps lead to the use of lower-quality products and to the slower development of new products (49). However, it is difficult to assess the validity of these concerns given the strong vested interests of some private providers in resisting price regulation (64).

Hutchinson *et al*. describe the situation in Uganda, where drug shop vendors argued that it was impossible to survive financially while complying with rules on the medicines they were allowed to stock (60). A specific example was the stocking of antibiotics and their sale without prescription, which was said to be a key component of drug seller income, and filled a gap created by underfunding and stockouts of antibiotics in the public sector. These issues were acknowledged by district officials, who were seen as a critical source of information about which rules it was possible to break without incurring serious punishment. For example, although drug shops were not allowed to stock antibiotics, regulators were said to be uninterested in adherence to this, while in contrast the practice of providing injections had to be well hidden (60).

Other authors have noted that regulators in some settings accept that enforcing standards could be counterproductive in removing access to services used by poor communities, or by increasing the cost of provision beyond what they can afford (59). This can lead to a gap between the *de jure* regulation in the country's laws and the *de facto* level of regulation that inspectors aim to enforce. The resulting divergence between regulations and common practice provides extensive opportunities for corruption: for example, in the form of 'buying licences', or making bribe payments to avoid inspection visits or adverse reports, which sometimes develop into routine payments (50)(56)(57)(58)(66)(70)(86).

The role of politics and vested interests

Several authors stress that regulation is inherently a political process, with regulatory outcomes determined through the interaction of multiple interests (53) (an issue covered for governance in general under Foster Relations). For example, Machado and Silva characterise the evolution of the Brazilian system described above as a decades-long political battle between a reformist coalition that aimed to introduce and strengthen the universal health system, and a private-sector led, market-oriented coalition supporting further development of private health insurance, private healthcare, and foreign equity investment (92). Powerful vested interests can lead to regulatory capture – when legislation and regulations are drafted to benefit particular interest groups (53). Some private sector stakeholders are particularly powerful and may vehemently, and often effectively, resist legislation that affects their commercial interests. For example, the Indian Medical Association opposed the introduction of the Consumer Protection Act, and successfully campaigned to substantially weaken the terms of the Clinical Establishments Act for facility registration (46)(47)(65). The South African government has fought several lengthy legal battles around health insurance regulation, dispensing fees for pharmacists, and restrictions on geographical location, some of which it has lost (18). Regulatory capture has been a particular concern in situations of self-regulation by professional associations, which tend to focus on providing leadership and protection to the medical community, with minimum discipline of members (46)(47)(65). Regulations may also be undermined by politicians or officials who themselves have investments in the private healthcare sector (49). Khan et al. argue that under-resourcing of regulatory agencies may be deliberate in some contexts, where the regulatory agenda does not suit the interests of influential stakeholders (70).

Private stakeholders do not always oppose regulation: in fact, some groups may actively campaign for regulation to be strengthened. The private sector is highly heterogenous, with conflicting interests sometimes arising between different segments of the private sector (48). The more formal and medically qualified segment may support regulation to ban or constrain the operation of less qualified providers, often arguing that they represent risks to quality and safety (18). For example, the Indian Medical Association supported legislation on private nursing homes to restrict the practices of auxiliary nurse midwives in delivery care (48). However, the less qualified segment of the private sector can also wield political power. In India it was argued by medically qualified providers that the government could not take action to ban unqualified providers because of the political clout of the latter (48). In Uganda a 2016 policy to ban lower-level drug shops from operating within 1.5 km of a retail pharmacy was rescinded in 2018 after the drug shop vendors formed a lobby group called the National Drug Shop Advocacy Initiative to challenge this (60). Members of the public can also wield power against restrictions or penalties imposed on the providers they use: for example, in Uganda inspectors were attacked by community members when they confiscated medicines from an unlicensed shop (60).

Enablers of effective regulation

Before describing potential enablers, it should be noted that, given the substantial variation across LMIC health markets, strategies for effectively strengthening regulatory outcomes are also likely to vary. Bloom et al. comment that 'What works well in health markets with limited types of formal sector actors and a relatively well-resourced regulator may be ineffectual in the context of informal markets with a large variety of actors and an under-resourced regulator' (Bloom *et al*., 2014).

Some general recommendations have been made in this area, by various authors (16)(40)(63). Several speak directly to other Governance Behaviours reviewed in this report, including (i) clarifying regulatory objectives as part of an overarching policy towards the private sector (see section on Deliver Strategy); (ii) developing appropriate databases and monitoring systems (see the section on Build Understanding); (iii) increasing the public's understanding of regulation and their rights (see section on Nurture Trust); or (iv) strengthening regulatory capacity (see section on Governance Capacity). Other specific recommendations include (i) mapping, reviewing, and harmonising the various regulatory laws and rules that apply to the private healthcare sector; (ii) addressing important regulatory gaps (with suggested areas including private health insurance and quality of care); and (iii) reviewing sanctions to ensure they are set at appropriate levels. While these recommendations arise from the well-documented barriers described above, they are not generally based on robust studies of their implementation and their impact on regulatory outcomes.

One exception is a qualitative study by Tama et al. which assessed the factors enabling the successful implementation of the JHIC intervention to strengthen health facility regulation in Kenya (91). The authors note that an inclusive reform development process had led to high buy-in across regulatory agencies. Inspections were generally viewed as fair, objective, and transparent, enhancing their perceived legitimacy. For example, facilities received a copy of the JHIC in advance, as well as a summary report explaining the inspection outcome. In addition, the same regulatory system was applied to public and private facilities, addressing a common perception that there are 'double standards' in regulation, with private facilities held to higher standards than public facilities (42), and subject to more frequent inspection (65) or more severe sanctions (39). Under the JHIC, interactions with inspectors were described as friendly and supportive, in contrast to the punitive culture of previous inspections, in which bribery had been common. High-quality inspector training and the use of an electronic checklist were also seen as key strengths. Tama et al. also highlight the importance of logistical resources and management. They conclude that effective facility inspection involves more than just good 'hardware', such as checklists, protocols, and training: cultural, relational, and institutional 'software' are also crucial for legitimacy, and for ensuring the feasibility of implementation and enforceability, and need to be carefully integrated into regulatory reform (91).

Other authors provide broader guidance on approaches to regulation. Hutchinson et al. argue that poor compliance with regulations is driven by the inadequacies of health systems, rather than the private interests of 'immoral individuals' (60). They suggest that improvements in governance should begin by identifying and working with actors who are currently rule-breaking but who have the capacity to become rule-abiding, and should then proceed to identifying policy changes that would support them to change and improve their practice (60).

Authors stress the importance of positive incentives for regulatory compliance, promoted through links with purchasing mechanisms, and greater transparency around private sector performance (16)(63). Bloom et al. argue that states alone are unable to regulate today's complex health systems effectively, emphasising the role of partnerships between the state, market actors, and civil society in the formulation and implementation of market governance arrangements (53). Hunter et al. highlight the de facto 'decentred regulation' of health facilities that already exists in India through the roles of private accreditation bodies, private and public health insurance organisations, consumer courts, and, more recently, online marketplace platforms (49). They note that health insurance organisations have a major influence on the control of prices and audits of testing and treatment provided, and that online marketplaces can potentially restrict which healthcare providers are listed on their platforms and set rules for providers on data usage (49). However, they argue that regulation through these multiple loci can be partial and disjointed, reflecting a range of vested interests.

Some authors have argued that regulation cannot effectively control low-quality, underqualified providers if

they are the only credible source of care for large populations, even where regulatory capacity is strengthened (57)(88). McPake and Hanson argue that in such settings the only viable solution is to provide a subsidised alternative of reasonable quality that can drive out the low-quality element in a process termed 'regulation by competition' or 'beneficial competition' (93). Such an approach relies on consumer behaviour to drive change, rather than on command-and-control structures which may not be incentive-compatible for providers or patients. They support this argument with cross-country data showing that in countries where governments commit a higher share of gross domestic product to health, the reliance on unqualified providers decreases, and they give Sri Lanka and Thailand as positive examples of this approach to crowding out low-quality providers (93).

Finally, there is general agreement that regulatory strategies must not underestimate the power of lobby groups to influence the design and implementation of regulation, and that this must be addressed through detailed stakeholder analysis, careful alliance-building, and the establishment of political mechanisms to prevent undue influence by these powerful interest groups (see section on Foster Relations) (16)(51).

3.3.2 Contracting and purchasing

What contracting/purchasing approaches have been adopted to govern the private sector?

Contracting or purchasing in healthcare refers to a formal agreement where a government purchases healthcare services from one or more providers using public funds, typically (though not always) through a legal contract (94). In LMICs the practice of contracting from private healthcare providers has grown over the past three to four decades, involving an expansion in the government's role from service provision to also include stewardship over contracted providers. Contracting has been used to allow more rapid expansion of services and to address concerns about the quality, efficiency, and responsiveness of public provision (59). In sub-Saharan Africa, historically, one of the most common forms of contracting has been with faith-based facilities, as mission facilities form a key part of service delivery infrastructure, especially to poorer and rural populations (95). Contracting primary care provision in a defined geographical area has also been implemented, most commonly through contracting NGOs to provide services in fragile and post-conflict states, such as Cambodia and Afghanistan, typically with donor support (54)(57)(89). Contracting arrangements can reflect a recognition that private expertise and equipment can fill a specialised need, such as the provision of dialysis services or surgical care (44)(57). While contracting has typically involved service delivery contracts with privately owned facilities, in some countries management contracts have been used to address poor quality in public provision, where a private organisation is contracted in to provide services within existing government facilities, such as has happened at a large scale in Pakistan, India, Bangladesh, Cambodia, Brazil, and Afghanistan (60)(89).

Contracts can be used to leverage private funds for health facility construction or refurbishment, with examples of this in Brazil, Mexico, Lesotho, and Thailand (59). Termed 'private financing initiatives' or PPPs (though the latter term is sometimes used to describe all forms of public–private engagement), these arrangements involve long-term contracts (e.g. 10–20 years), in which the private party is expected to bear significant risk and management responsibility for construction, and may have a concession to provide services for a defined period, after which the government takes over control (38)(91)(92)(93).

The past 20 years have seen a substantial increase in the contracting of private facilities, particularly reflecting the expansion of social health insurance programmes (we use the terms contracting and purchasing interchangeably in this review, though in the literature the term purchasing is more commonly used in the context of social health insurance). This involves a central purchasing agency contracting both public and private facilities to provide care, either for specific population groups (e.g. civil servants) or the entire population (99). Under an alternative 'managed competition' model common in Latin America, private insurers

and HMOs compete to serve the clients of both contributory and subsidised social health insurance programmes through public and private facilities (83). The COVID-19 pandemic also led to a specific flurry of new contracting activity, as governments struggled to provide and finance adequate levels of testing and treatment, often having to use ad hoc approaches where established purchasing systems did not already exist (63) (described in the section on Align Structures).

Engaging in these contracting strategies provides potentially powerful governance opportunities to influence private provider behaviour. Historically, these opportunities have often not been realised as purchasing has been passive, with payments based on past expenditure or norms, with little consideration of performance or compliance with regulatory requirements (70)(95)(96). However, in recent decades there has emerged in global policy discourse a strong emphasis on 'strategic purchasing', defined as involving a proactive 'continuous search for the best ways to maximize health system performance by deciding which interventions should be purchased, how, and from whom' (McIntyre et al., 2016, cited in (53), with the goal of encouraging efficiency, equity, and quality improvement (101). This includes (i) the selection of facilities that meet pre-defined quality standards, sometimes demonstrated through accreditation with an independent body; (ii) the development of incentive-compatible payment mechanisms, which may include a mix of fixed budgets, capitation, fee-for-service, case-based payments, and pay-for-performance incentives; and (iii) performance monitoring (43)(64)(70)(88)(94)(95)(97).

How effective are contracting/ purchasing approaches to governance?

We drew on existing literature reviews of contracting and purchasing to provide evidence on the effectiveness of these strategies, which are generally evaluated in comparison to government provision. A 2018 Cochrane review on contracting out clinical health services in LMICs identified only two studies meeting their study design inclusion criteria (26). The first, a 2006 cluster-randomised trial conducted in Cambodia, compared contracting out district health services to INGOs with government provision, and a 2015 controlled before-after study in Guatemala evaluated contracting of mobile clinic services to local NGOs. The Cambodia study found probable effects on reducing out-of-pocket spending on curative care, but neither study found an impact on utilisation or service delivery outcomes (26). An earlier 2009 Cochrane review with slightly broader inclusion criteria included three studies and came to similar conclusions (Lagarde and Palmer, 2009, cited in (26)).

Other reviews with less restrictive inclusion criteria have been generally more positive in their findings, though some are quite outdated. In their review of reviews, Nachtnebel et al. note that non-Cochrane reviews have found evidence that contracting out improved availability and utilisation of care, especially by under-served populations, and could be an effective way to quickly expand coverage (25). However, they report insufficient evidence to assess the impact on quality of care or efficiency of provision (25). Zaidi et al. report consistent evidence that contracting out has increased utilisation of services such as antenatal care, institutional delivery, and urban primary care, though they find no improvement in immunisation (62). They find some evidence of improvements in the availability of infrastructure, staff, and supplies, and in patient satisfaction, but a lack of evidence on the impact on clinical quality of care (62). A review by Thomas et al. cites two more recent contracting evaluations, reporting that (i) contracting out primary care services in Brazil to NGOs increased utilisation and reduced hospitalisation for preventable disease (Greve and Coelho, 2017, cited in (103)), and (ii) management contracts in Pakistan improved utilisation of maternal and child health services (Imtiaz et al., 2017, cited in (103)). They also report several studies on the Chiranjeevi Yojana scheme to contract private providers to provide delivery services in Gujarat, India, which report conflicting evidence on the impact on institutional deliveries and health outcomes (103). Finally, Rao et al. report mixed evidence on utilisation across a set of country case studies in Africa and Asia, finding that, in practice, private providers faced many of the same service delivery challenges as their public sector coun-

terparts, including difficulty in recruiting and retaining health workers, and ensuring service quality (94).

It can be argued that the key question for many governments is how best to contract, rather than whether to contract, given that private sector contracting may be unavoidable due to gaps in public provision, ambitions for scaling up health coverage, or political realities (23)(89). The literature provides little quantitative evidence on the relative effectiveness of alternative contracting mechanisms. (An exception is the sizeable literature on the effects of pay-for-performance payment methods, which we consider beyond the scope of this review as these approaches are mainly implemented in public facilities, and only occasionally in FBO facilities, and this literature has been recently reviewed elsewhere (104)(105)). More broadly, it is possible to draw on a large, mainly qualitative, body of literature to understand factors that may support effective contracting of private providers. We turn to this in the next section.

What are the key enablers of, and barriers to, effective contracting/purchasing?

Four recent publications synthesise experiences with purchasing across multiple LMICs, all based primarily on qualitative interviews and document/literature review (53)(89)(95)(96). A 2023 review by WHO analysed governance for strategic purchasing in 10 countries in eastern Europe and central Asia that have all implemented a single purchaser model (Armenia, Azerbaijan, Estonia, Georgia, Kyrgyzstan, Latvia, Lithuania, Republic of Moldova, Ukraine, Uzbekistan). All were middle-income countries when their purchasing reforms commenced, though some are now high-income countries (55). Gatome-Munyua et al. synthesise experiences with purchasing experiences in nine African countries (Benin, Burkina Faso, Cameroon, Ghana, Kenya, Nigeria, Rwanda, the United Republic of Tanzania, Uganda) based on the Strategic Purchasing Africa Resource Center (SPARC) framework (100). Hanson et al. draw on coordinated research studies from seven LMICs (India, Indonesia, Kenya, Nigeria, South Africa, Thailand, Viet Nam) (101), and Rao et al. synthesise findings from case studies in five LMICs in Africa and Asia (Afghanistan, Bangladesh, Ghana, South Africa, the United Republic of Tanzania, Uganda) (94). We supplement these syntheses with a number of individual studies of contracting mechanisms in order to identify key enablers and barriers. It should be noted that much of the literature covers mechanisms to purchase from both public and private sector providers and does not always separate the governance issues affecting the two sectors.

Contract design and monitoring

To be an effective governance mechanism, contracting must be based on a carefully considered contract design that provides appropriate and balanced incentives to ensure quality, efficiency, and equity. Key elements of the contract design include clear specification of the service delivery requirements, payment terms, referral and gatekeeping guidelines, and mechanisms for redress (100), which should be transparently published online (55). Honda and Obse discuss the complexity of setting the payment type and level, which involves balancing the risks of generating incentives for over- or under-provision, inefficiency, additional patient charges, or a failure of private providers to enrol (99). Fee-for-service payments can provide incentives for over-provision, or if fees do not adequately cover costs of service provision it can lead to little care being supplied. Capitation and case-based payments risk leading to incentives for under-provision and the selection of less severe cases (83). If payment rates are set too high, this leads to inefficiencies in terms of unnecessary costs to the public purchaser, but if rates are set too low compared to provider costs, private providers may decide not to enrol, treat patients covered by the publicly funded system differently, or charge patient additional 'balance-billing' fees (99). Other unintended incentives resulting from payment terms may include encouraging unnecessary admissions (where inpatient and outpatient care are reimbursed differently), and unnecessary referral of costly patients to alternative providers (44)(78). Honda and Obse stress the importance of transparent processes for determining payment type and rates that involve all stakeholders, including provider representatives (99).

As noted above, many contracting arrangements have been 'passive', with little adoption of more high-powered payment mechanisms and little use of the purchaser's power to set quality standards and enforce

them. Gatome-Munyya et al. argue that governance may be strengthened by including quality or service delivery targets in contracts (100).

Rao et al. stress the importance of 'relational contracts' in some contexts, where the specific stipulations of a contract are subordinated to building a trusting partnership between the parties (94). They give the example of contracts with FBO facilities in sub-Saharan Africa, which have historically been semi-formalised through collaborative memoranda of understanding (95), though in more recent years legally based service-level agreements have become more common (94). They note that in some cases the relational nature of contracts is more a reflection of limited monitoring capacity than intentional design, and may lead to weak accountability (94). However, Whyle and Oliver emphasise that relational agreements with African FBOs build on their stated motivation to serve poorer groups, with trust developed through longstanding commitments (95).

Challenges in monitoring performance and applying sanctions have been described in multiple settings (23)(89)(92). For example, in the Indian states of Punjab and Haryana, the monitoring strategy for purchasing under the national health insurance scheme for poor households was described as a 'major gap in contract design', being loosely stated in the contract, without well-defined parameters or monitoring mechanisms, or a specific monitoring budget (88). In Lesotho a lack of effective monitoring meant that the government was unable to impose deductions and penalties when the performance of the private provider responsible for hospital construction fell short of contracted standards (97). However, the contract included a 'back-stop' arrangement whereby, to maintain the contract, the provider had to obtain accreditation with the Council for Health Service Accreditation of Southern Africa (COHSASA), providing a powerful motivation to sustain quality standards (97).

In a number of settings, other types of third-party monitoring have been used to strengthen compliance. For example, in Afghanistan a third party monitored NGO performance to inform the government on quality of care and other service delivery issues, and in South Africa an independent 'district support partner' was hired to manage contract performance (94). In Burkina Faso, INGOs helped monitor providers contracted through the publicly funded Gratuité programme by reviewing claims for discrepancies between services delivered and amounts paid, with the Ministry of Health adjusting disbursements accordingly (though this scheme covered only a few private facilities) (100). Investment in digitised and automated processes was also recommended to enhance monitoring, as well as being a strategy to improve efficiency and transparency (53)(101)(102).

Gatome-Munyya et al. recognise that many African countries have made 'pockets of progress' on contract design and monitoring, but that in most cases this has not yet led to large-scale health system improvements, because of inadequate funding and high fragmentation across health financing schemes (100). We turn to these two issues next.

Funding inadequacies and fluctuations

While it is recognised that many countries have taken important steps to strengthen contract design and monitoring, it is argued that the overall progress in regard to purchasing mechanisms achieving large-scale benefits has been heavily constrained by chronic underfunding for health services (53)(89)(95). Rao et al. describe inadequate financing and inconsistent fund disbursements as an important constraint, which, for example, had a substantial negative effect on private provider performance in Bangladesh and in the United Republic of Tanzania (94). Late payments were very common (62)(95)(103)(104)(105), and in the United Republic of Tanzania and Malawi this adversely affected relationships between private providers and government (104)(106). Inadequate funding was widely reported to have led to payment rates or tariffs that did not cover the costs of care and were rarely updated in line with inflation (55)(111). Inadequate and late payments were both said to have resulted in additional costs for patients, either under permitted balance-billing or through informal charges (53)(95)(106), which were argued to have a powerful impact on provider incentives (55). It has therefore been argued that, where possible, governments should mobilise a step increase in public financing for health at the outset of

major purchasing reforms to avoid this situation, with examples of countries where this has been done being Azerbaijan, Georgia, Kyrgyzstan, and the Republic of Moldova (55).

In many countries, donors have played an important role in financing contracting mechanisms and so addressing funding gaps to some degree (94). The value of technical advice from WHO and other development agencies, such as the World Bank, over the past 20–30 years is also recognised to have been relevant and helpful in mechanism design and in building capacity, and to have facilitated intercountry learning (23)(53). However, the role of development partners also brought sustainability challenges when funding was withdrawn (25). Where contracting schemes were donor-led, there could also be a low sense of ownership by government, and purchasing mechanisms were implemented in parallel, rather than integrated with existing schemes (55)(100). In some countries, the review cycle for purchasing agencies was said to be largely driven by development partners and not connected to country accountability mechanisms (55). By contrast, in Afghanistan it was noted that, despite markedly diverging views on procurement and contracting practices, international donors agreed to the Ministry of Health being the unique, centralised contractor, which was argued to be an important enabler of the success of this model (94).

Fragmentation across purchasers

It is argued that fragmentation among purchasers is a key barrier to effective contracting. Due to the presence of multiple contracting mechanisms, a given facility is often contracted by multiple purchasers, including various national health insurance schemes, voluntary private and community-based health insurance, occupational health insurance, and donor-funded schemes (95)(96). For example, 30 schemes were identified in Cameroon, and over 70 in Kenya, with private facilities typically participating in several of these. This creates a series of parallel agency relationships that must be navigated by the provider, and which lead to uncoordinated provider incentives, as each purchaser has a different service package and provider payment mechanism, and different reporting requirements (95)(96). The fragmented purchasing environment can also unnecessarily increase administrative costs (99). Gatome-Munyua et al. suggest that greater consolidation of purchasers would increase the power of the main purchasing agency in regard to strengthening incentives and accountability, citing Ghana and Rwanda as countries where this has worked well (100). Where consolidation is not possible, they advocate for greater alignment and coordination between purchasers (100).

Fragmentation in the provider market

Others have argued that a high degree of fragmentation on the provider side (i.e. a very large number of small facilities) creates an extremely challenging environment in terms of the costs and logistics of establishing and monitoring so many contracts (2)(102). In addition, smaller facilities which may serve poorer users may struggle to enrol due to financial or bureaucratic hurdles (102)(103). It is argued that to address this the sector needs to become more formally organised or consolidated in some way (2). Aiyenigba et al. suggest that intermediaries, such as HMOs or faith-based facility associations, may play an important role in facilitating contracting with government in such fragmented markets (112). For example, in Ghana the National Health Insurance Authority contracts FBO facilities through their umbrella body, the Christian Health Association of Ghana, thus reducing the transaction costs of contracting with each individual facility (90)(95). It is also suggested that these kinds of intermediaries can play a role in controlling the behaviour of their networked facilities – for example, through internal quality assurance mechanisms – though evidence in this area remains limited (112). In Kenya and Ghana, under the African Health Markets for Equity (AHME) initiative, small for-profit facilities were supported by INGOs to prepare for empanelment in national health insurance schemes, including help with preparing paperwork, obtaining necessary licences, conducting mock inspections, and facilitating communication with officials, giving them a ‘hand to hold’ as they pursued their path to insurance accreditation (102)(103).

The importance of a clear and well-sequenced policy direction

Clear policy objectives and direction are considered to

be important enablers of effective purchasing, which should shape the mindset of all stakeholders involved (53)(96), but many countries are reported to lack a consistent vision for system design over time, often reflecting political instability (World Health Organization, Regional Office for Europe, 2023).

Some countries experience long periods of stasis, or even erosion of progress (55). By contrast, 'golden periods' have also been identified, where there was rapid progress on multiple reform pillars, reflecting the presence of strong leadership with a strategic vision, good Ministry of Health–purchaser cooperation, a shared vision with the broader government, and support from external development partners (55).

However, in some contexts there has been concern that progress was too rapid, with a rush to implementation, sometimes in response to political imperatives (72)(88)(111). In India, the Rashtriya Swasthya Bima Yojana (RSBY) national health insurance scheme was announced just before a general election, to signal a pro-poor policy agenda, and, as a result, organisational structures and implementation procedures were not well developed when implementation began (88). Challenges from rapid implementation were also seen in Malawi, where a lack of clear systems, guidelines, policies, procedures, and roles among stakeholders was reported to have negatively affected contracting performance, with the lack of adequate preparation overwhelming providers, institutions, and stakeholders (111). The use of pilots was recommended before nationwide roll-out, accompanied by evaluation to resolve practical issues and ensure effective sequencing of reforms (55).

'Task networks' with clear roles and responsibilities

Hanson et al. argue for clearly delineated responsibilities across a 'task network' of organisations, to support strategic purchasing (101). They give the example of the task network in Thailand, where the purchaser, the National Health Security Office, is supported by the following organisations: the Health Intervention and Technology Assessment Programme, which sets the benefits package; the Healthcare Accreditation Institute, which accredits public and private healthcare providers; departments of the Ministry of Public Health, which are responsible for service quality; the National Health Commission Office, which supports civil society involvement; and the Thai Health Promotion Foundation, which supports all sectors in health promotion (101).

However, in many contexts roles across agencies have been described as unclear (55). For example, when the social health insurance scheme was introduced in Indonesia in 2014, implementation was negatively affected by confusion among the central-level public purchaser, the Ministry of Health, the District Health Offices, and local government about who would supervise the central purchaser, who would pay primary healthcare providers, who would monitor healthcare providers, and to whom public providers were accountable (101).

In a context of weak-quality regulation of health facilities in many countries, roles related to the assessment and assurance of quality standards has become a particular concern for purchasing agencies (55). A delay in developing quality standards and regulation by the Ministry of Health or accreditation bodies can result in pressure to contract unassessed or even sub-standard providers, or to force the purchasing agency to develop their own criteria and standards, which may lead to role overlap and conflict with the Ministry of Health (55). Delays in the implementation of healthcare provider information systems can also limit the scope for the purchaser to monitor quality, or to introduce performance-related payments into contracts.

Political interference and vested interests

Concern has been expressed about undue political interference and the influence of vested interests in purchasing and contracting mechanisms (55)(94). Studies in Afghanistan, in the United Republic of Tanzania, and in Bangladesh identified political interference in the selection of areas to be serviced and facilities to be contracted, and in human resource decisions (94). Among some of the eastern European and central Asian countries, powerful, politically connected private interest groups were reported to have a disproportionate influence on appointments to the purchasing agency, increasing the role of private health insurance companies, biasing the selection of private providers,

over-pricing tariffs, and pushing for greater deregulation (55). In Nigeria HMO representatives were said to have had a substantial influence on the development of a proposed national health insurance scheme (as described in the section on Foster Relations) (81).

Governance arrangements for purchasing agencies

It is argued that the way in which purchasing agencies are established and monitored has an important impact on their performance and alignment with health sector goals (55)(100). Among the eastern European and central Asian countries in the WHO review there was consensus on the need for the Ministry of Health to have stewardship over the purchaser, but for the purchaser to be an independent legal entity, with some autonomy over technical and operational matters and its own budget (55). The appropriate degree of autonomy was debated. Excessive external control over the purchasing agency, particularly where the Ministry of Health is the owner of public facilities in the purchasing network, was argued to inhibit the development of strategic purchasing, such as the introduction of output-based payment strategies, and enforcement of quality standards (55). On the other hand, subordination to the Ministry of Health may make it easier to coordinate purchasing with other health sector strategies. Some interviewees who contributed to the review also recommended caution about giving the purchaser a high level of autonomy in countries with low capacity and weak public financial management (PFM) (55).

The governance structure for independent purchasing agencies varied among this group of eastern European and central Asian countries (55). In some cases, the chief executive officer (CEO) and management team were accountable to a supervisory board, while in others they were accountable to the Ministry of Health, with advisory boards or councils established for consulting stakeholders and advising the Ministry of Health and the purchaser. The review's authors concluded that either model could work (55). However, despite being more independent in theory, in practice supervisory boards sometimes lacked effectiveness, partly due to a cultural context of personalised accountability of the CEO to the president, bypassing the board (55). Whatever the governance structure selected, it was argued that it is important for purchasing agencies to be subject to a clear accountability framework, specifying the strategic goals, the governing laws and regulations, financial controls, transparency requirements, and a monitoring framework (55). It was argued that senior purchasing staff should also be protected from undue political pressure through having civil service status or through specified appointment procedures and terms of office (55).

Little information is provided on governance arrangements for purchasing agencies in the rest of the literature reviewed, an exception being the description of the establishment of a governing board for the Abia State Health Insurance Agency in Nigeria (102). It was noted that appropriate PFM rules were central to accountability but should allow sufficient autonomy and flexibility to facilitate strategic purchasing (55)(100). It was stressed that Ministries of Health and purchasing agencies should work closely with ministries of finance in the design and implementation of purchasing, to ensure alignment between PFM and public administration systems and health purchasing mechanisms (55).

There is unanimous consensus that capacity within purchasing agencies was frequently inadequate, in terms of both technical and managerial capacity and staff numbers, at central and lower administrative levels (25)(55)(94)(97)(98)(101)(107). This topic is covered in more detail in the section on Capacity for Governance.

Finally, a lack of effective engagement with citizens and patients is highlighted as an important challenge (101), as covered in the section on Nurture Trust.

3.4 Foster Relations

Foster relations is defined as the 'government has established inclusive policy processes, in which a broad range of stakeholders (including the private health sector, but also other actors) play an active role' (3).

3.4.1 What approaches have been adopted to foster relations between the public and private sectors?

The literature covers a variety of approaches to public–private dialogue, interaction, and collaboration. Some studies focus on donor-driven platforms established to support the delivery of specific programmatic objectives (44)(45)(113), such as enhanced services for maternal and newborn health. For example, in Kakamega County in Kenya, a donor-funded one-year project supported the development of a multi-stakeholder forum to enable dialogue between public, private, and non-state actors. This was observed to increase private sector representation in the county's strategic planning processes (113). In cases where policy processes have been led by domestic stakeholders, this has often occurred in connection with the implementation of reforms in which the private sector is implicated: for example, the introduction of contracting arrangements (47)(88)(100)(106)(109), PPPs (38)(43)(69), and regulatory changes (49)(66)(70).

Most of the engagement structures covered in the literature focus on health facilities, and in some cases private health insurance entities/HMOs (and there is coverage of pharmaceutical manufacturers, though governance mechanisms for this sector are outside the scope of this review). In addition, one example of public–private dialogue focused on telehealth in the Philippines is covered (114). No examples are mentioned in the literature about fora for other categories of private sector stakeholders, such as pharmacies. In general, there is a lack of detail across the coverage. For example, there is very little evidence on the composition of such platforms, the frequency of meetings, specific remits, or rules/procedures for management of conflicts of interest.

3.4.2 How effective are these approaches to fostering relations?

As noted, many dialogue structures are established by donors, in support of their programmes. Studies suggest that donor involvement can generate benefits – especially the financial resources and technical expertise that donors can provide (109). However, this can also generate challenges in the long term: for example, dialogue structures may not be sustainable beyond the life of an individual programme (36). In the Kakamega County case, the role of the donor's implementing partner in supporting the stakeholder forum was found to be critical to its activities, raising questions about its sustainability in the absence of such support (113). The evidence indicates the importance of ensuring that public–private dialogue is embedded within the domestic policy context.

More generally, public–private dialogue is considered to be a positive component of governance, being key for information exchange, building trust, and balancing interests (36). However, many authors note the potential for such structures to enable private entities with interests in a given policy area to influence the content of reforms in their favour – including in ways that compromise the government's strategic objectives (3)(34)(53)(66)(76). For example, in Ukraine, private providers have aimed to modify rules that preclude them charging co-payments on top of payments made by the public payer ('balance-billing'), which, if successful, would be likely to increase financial barriers to needed health services, and expose patients to financial exploitation (28).

3.4.3 What are the key enablers of, and barriers to, fostering relations in an effective way?

The dialogue structures covered in the literature include both for-profit and non-profit actors. It has been observed that dialogue with for-profit entities can be complicated: in some cases, it is character-

ised by low levels of trust, and competitive or adversarial relationships at the national (52) and local levels (37)(41)(108). It is suggested that dialogue with non-profit entities, such as FBOs, can be easier for governments, as the public sector and FBOs are perceived as sharing similar social goals, including a commitment to serve poor people (90)(104). It has also been observed that FBOs' representative associations tend to be better organised and have a clearer leadership structure than others – providing policymakers with a defined point of contact. Historically, such representative associations have been less common for for-profits (42). However, in recent years the number of private sector associations has grown: for example, over 25 such 'healthcare federations' had been established in Africa by 2022, often with donor support (36).

It is generally considered desirable for governments to engage with such organisations, rather than individual private actors (42). Alternatively, professional associations that represent private entrepreneurs/employees have played this role (49). However, where professional bodies exist, they are often under-resourced, and may operate only at a national level (36).The literature indicates that it can be challenging to ensure that such organisations are representative of the full range of private sector stakeholders, with small-scale primary care providers, including those in rural areas, likely to be excluded (36). More generally, it can be challenging to ensure that the information, perspectives, and interests of diverse stakeholders are considered in policy formulation, rather than only those of the most powerful stakeholders (47)(66). A message that emerges from the literature is the importance of ensuring that policy processes are open, inclusive, and transparent. For instance, where policy dialogue takes place 'behind closed doors', this can create risks of state capture, bias, and corruption (41)(76)(92)(104). This is a particular challenge in countries where there is a disproportionate influence of private economic interest groups spanning multiple sectors that are well-connected to the political system and/or political party financing (the problem of state capture). Non-transparent influence of such interests (e.g. in the areas of service provision or insurance) can result in undue influence on policymaking, to the potential detriment of UHC (55). For example, in the domain of state purchasing/contracting, such influence may distort policy decisions in relation to, for example, benefit package design, eligibility criteria, contractual specifications, pricing, and the regulations, if any, on co-payments (balance/extra billing) (55). In Nigeria, HMO representatives, politicians, and senior bureaucrats with interests in the HMO industry became dominant in policy processes relating to a proposed national health insurance scheme (81). This allowed HMOs to influence the reform process, such that HMOs were ultimately given the status of intermediary operators of the scheme, replacing State Health Insurance Boards, which had initially been intended to play this role. This ultimately led to a loss of support for the national health insurance scheme among the states, which, given the decentralised nature of service delivery in Nigeria, undermined its realisation. Overall, the authors concluded that a lack of deliberate management of stakeholders by policymakers enabled elites to distort the policy process to serve their own narrow interests.

To mitigate such risks, it has been observed that governments need to develop mechanisms for engaging with the private sector that are broadly representative, directed at the public interest, and avoid conflicts of interest (55). In addition, without the inclusion of other interests, including inter alia patients, social insurance recipients, CSOs, etc., it is difficult for state authorities to balance legitimate stakeholder interests. Hunter et al. describe private sector interest group opposition to regulation of private hospitals in Maharashtra in India (49), as described above under the heading 'Regulation'. This resulted in the Maharashtra government's failure to adopt a Clinical Establishments Act, despite this being a federal act that required adoption by individual state-level governments. Opposition exerted through lobbying and other actions (including national protests conducted by parts of the medical profession) was cited as the main reason for non-implementation of the Clinical Establishments Act.

However, it has also been noted that power imbalances can, in some cases, favour the public sector vis-à-vis the private sector (38). In Uttar Pradesh in India, non-state partners, such as NGOs, were included in fora, but were not given reciprocal information or real roles in planning (74). In addition, in the United Republic of Tanzania a lack of effective private sector representation was reported in district health governing bodies and strategic planning, to the detriment of such actors (69). A separate study on the United Republic of Tanzania found that private providers had been included in planning fora, but were said to feel 'overpowered by government bodies', and to lack trust that decisions would take their interests into account (43).

3.5 Build Understanding

Build understanding is defined as 'government has taken action to ensure that it has access to comprehensive, up-to-date and high-quality data on the operation and performance of the private sector, that this information is used for strategic and operational decision-making, and that relevant data is shared with the public' (3).

3.5.1 What approaches have been adopted to build understanding for governance of mixed health systems?

Most LMIC governments have limited data on what the private sector does, for whom, on what terms, and at what level of quality (115). However, the literature documents multiple efforts by governments and other stakeholders (notably donors and their implementation partners) to encourage private sector entities to provide information. Studies from countries including India, Burkina Faso, Kenya, Egypt, the United Republic of Tanzania, and Lebanon document a range of mandates obliging private facilities and providers to collect and share data with state authorities at the national and sub-national levels (40)(42)(50)(66)(101).

In many LMICs, licensure and registration processes generate information on health facilities – including private facilities. For example, in many countries in sub-Saharan Africa, master facility lists contain information on the location, ownership, facility type, and services offered: for example, inpatient, outpatient, pharmacy, laboratory, etc. (116). However, this information is not always complete or up to date. Where this is the case, the scope for more advanced data collection processes – e.g. inclusion of the private sector in national health information systems (HMIS) – may in some cases be curtailed. For example, in Senegal, it was necessary to update and consolidate a directory of private facilities by conducting a private sector census before inclusion of the private sector in the national HMIS (District Health Information System 2 (DHIS2)) could proceed (116).

Even where government datasets are reasonably complete, the format of the information (or updates to the information) may be non-standardised (as in Ukraine (28)), in which case it is difficult to aggregate the information to establish, for instance, the extent of private sector capacity in a given service area.

In addition to information provided through the licensing process, it is common – but not universal – for the licensing criteria to include a requirement for the private sector to provide data of various kinds (115). In particular, in some countries (e.g. Ethiopia), private facilities are required, as a condition of their licence, to provide information on matters of public health importance, including reportable epidemic diseases, vertical programmes related to (for example), HIV, malaria, and TB, and family planning utilisation (117).

The literature indicates that reporting on service delivery in general can be limited, even in settings in which the private sector accounts for a significant proportion of service provision. For example, Gautham et al. (2016) report that in Uttar Pradesh in India the private sector provides 18% of institutional deliveries in the state. However, a health facility survey carried out during 2013 in 25 districts of the state reported that half of the 731 mapped private facilities providing institutional deliveries did not maintain any relevant records – and thus had no reliable data to share with state authorities (118).

3.5.2 How effective are these approaches to building understanding?

Many LMIC governments do not have the data they need to inform their approach to governance (115). Even where government datasets are reasonably complete, they are often not organised in a way that facilitates evidence-based policy analysis and decision-making (117). In addition, government agencies often lack sufficient capacity to use the information in such ways (61).

One study suggests that, where information sharing is voluntary, compliance can be variable. For example, in India private facilities have been reluctant to bear the costs of voluntary data sharing requirements, resulting in inadequate reporting (68). In addition, Ministries of Health can support electronic reporting to a national DHIS2 platform in the private sector (116).
There is some evidence that the situation is improving, in part due to technological developments (36). In many settings, data can be reported electronically, through DHIS2 modules or other HMIS. However, given the challenges and costs associated with collecting and submitting data, levels of compliance are usually limited, unless encouraged by financial incentives: for example, if such information is necessary for reimbursement under state purchasing arrangements, compliance with reporting rules can increase substantially (97). Additional pressure to provide data – or to put in place the digital systems required to do so – may also come from accreditation processes, which may be linked to eligibility criteria for state purchasing. However, such measures may generate a material improvement only if a significant proportion of private clinics and hospitals decide to accept state-funded patients (115).

Most countries have limited data on private entities other than health facilities. However, countries such as Uganda, Eswatini, and Nigeria have, under donor influence and for specific programmes, attempted to extend their information systems to include private pharmacies, reflecting the significant role played by such providers in related patient pathways (66). Yet gaps in data remain, impeding understanding of care-seeking levels, inequities in care-seeking, and access to specific sources of care (66).

3.5.3 What are the key enablers of, and barriers to, building understanding?

Data collection challenges are driven by a lack of trained personnel, high staff turnover rates, the burden of paper-based reporting (which remains common in LMICs), and uncertainty and/or misunderstanding about the purpose or value of reporting (37)(59)(111). In many countries, the flow of data is 'one way': the private sector shares data with the public sector but does not receive informative data about their clinic or catchment area in return, particularly when reporting is paper-based. Standardised reporting forms are often designed for larger public facilities that offer a suite of generalised services. This makes reporting complicated and cumbersome for smaller facilities (116).

Studies also point to a lack of interoperability between data systems as a key challenge across LMICs. One study in China found that the different information systems in different hospitals, with non-standard clinical case records, resulted in diverse data standards, making data difficult to analyse (119). The integrity, accuracy, and timeliness of healthcare data were also difficult to manage. Other data usage challenges included a lack of standardised quality indicators (113). In some cases, reports from private facilities were merged with those from the public sector at the sub-national level, making it impossible to analyse the private sector's contribution separately in HMIS dashboards or reports (39).

Other challenges documented in the literature include providers' perceptions that there are risks associated with information disclosure (118), including the risk of weaknesses in data systems being exposed, and commercial interests being compromised if, for example, data on service coverage, volumes, and prices are shared. In many such cases, a lack of trust remains a key barrier to the exchange of data between the public and private sectors (66).

However, Gautham et al. suggest that, while private facilities fear information disclosure and the additional burden of reporting, they are willing to share data if asked officially, provided the process is simple and they are assured of confidentiality (118). It is notable, also, that during the COVID-19 pandemic, platforms for encouraging increased frequency and quality of information were achieved in several cases (e.g. in Kenya, according to Tolmie et al. (2021)) (108)(113). This may indicate that the levels of trust

required to facilitate improved information-sharing can be built under pressures created by health emergencies.

A more comprehensive approach to addressing current barriers is proposed by Mangone and Romorini, who suggest, on the basis of experience in several countries in sub-Saharan Africa, that a significant increase in reporting performance among private sector entities in LMICs can result from a combination of the following: (i) equitable distribution of reporting tools for all registered facilities; (ii) flexible arrangements for submission of paper reporting forms; (iii) the development of digital reporting tools to facilitate reporting; and (iv) the simplification of forms so that they are shorter, less complex, and more directly reflective of how service provision is organised in a given service domain (116).

3.6 Align Structures

Align structures is defined as 'government has established the organisational structures required to achieve its identified strategic goals and objectives in relation to the private health sector' (3). This includes the government taking action to ensure alignment and coordination between the private sector and the public sector in service delivery, which covers three areas – how the government acts to:

- include the private health sector in all relevant quality of care initiatives;
- include the private health sector in all relevant public health programmes; and
- ensure that the private health sector is included in all relevant referral networks (3).

3.6.1 What governance approaches have been adopted to align structures between the public and private sector?

These three areas are described individually in this section, although they share some overlapping features and lessons.

Quality of care initiatives

Support for the use, and enforcement, of clinical guidelines, standards, and protocols is one approach that has been taken to support quality of care in the private sector. This is often linked to other areas of intervention, such as contracting and inclusion in health insurance programmes and essential healthcare packages. In the National Health Insurance Fund of the United Republic of Tanzania and Kenya's National Hospital Insurance Fund, for example, contracts include requirements to adhere to service guidelines and protocols, which are then used for assessing claims prior to payment, and for performance monitoring of providers through medical audit of claims (100). Regulatory approaches can include creating and supporting the work of independent quality regulators (see the section on Enable Stakeholders).

The literature also highlights network-based approaches, often led by private for-profit or not-for-profit organisations, that provide incentives for quality: for example, through social franchising and social marketing that include training on and monitoring of quality standards (54)(57)(107). However, as these are typically not government-led, we do not focus on them here.

To encourage the use of standard treatment guidelines and improve access, the inclusion of private providers in free or subsidised publicly funded training programmes is common. This arrangement is premised on the assumption that the main reasons for inadequate care relate to the inadequate knowledge of private providers, which can be addressed through short, focused training sessions (59). PPP focused on tackling specific issues, such as reducing antimicrobial resistance, can also be a vehicle for developing and applying clinical guidelines to the private sector. In India, for example, professional societies from both the public and the private sector were engaged in the Kerala PPP, which developed state-wide antibiotic clinical guidelines, revised the post-graduate and undergraduate medical curriculum to include them, and implemented a training programme covering all general practitioners within the state (120).

Inclusion in priority health programmes

In this section we examine approaches to ensuring that the private sector contributes to public health goals, through implementing reciprocal arrangements within specific health programmes such that private providers engage in specific services or activities without receiving direct payment but benefit from elements such as training or the provision of supplies and equipment. These arrangements can be enacted through memoranda of understanding that are non-binding but which clearly state the intentions and contributions of the parties (36).

Many LMICs have established public health programmes of national importance, and a number of these programmes engage with private health providers, as they are often the first point of contact for diseases or prevention services. Many have set up referral and notification systems from private health providers to the public sector, especially for infectious diseases (66). Another common point of engagement is with national immunisation and family planning programmes,

which provide commodities and equipment to facilitate provision of services, with clear reporting requirements (66). These approaches share some features with the details discussed in the section above, in that engagement in priority programmes can include capacity building, monitoring, and also the requirement to comply with government guidelines (121). Employment-based occupational health and private health insurance can also implement health programmes, linking to national guidelines, as exemplified in Ghana and South Africa.

Much of the experience of engaging the private sector in public health programmes relates to TB. In 18 LMICs reviewed by one study (66), national TB control programmes were noted to most commonly establish formal partnerships with the private sector. In India, NGOs can collaborate with the TB programme and undertake activities as large as running testing labs or running a sputum collection centre. Private practitioners can refer suspected TB cases for sputum samples to designated microscopy centres and, if willing, can act as Directly Observed Treatment, Short Course (DOTS) providers for patients diagnosed with TB (56). These partnerships often aim to strengthen the referral systems between the public, private, and NGO sectors (linking to the third component of Align Structures, see below) in order to reach out to more patients and provide standardised diagnosis and treatment (122). In India, private providers can get involved in a single activity or in multiple activities, depending on their capacity and interest, and the requirements of the programme. DOTS providers are expected to ensure follow-up sputum collection and late patient retrieval, as well as to maintain records for patients, and to permit on-site monitoring by TB programme supervisory staff, as per their guidelines. Referring providers refer TB suspects for diagnosis and treatment, irrespective of whether the client is diagnosed as having TB in a private lab or not. DOTS providers refer suspected cases and treat them, receiving an honorarium for each successfully completed case (with the payment depending on whether the TB is multidrug resistant or not) (122).

Some studies highlight the role of the private sector in contributing to immunisation programme goals in disrupted settings, such as Darfur in Sudan (123). For more than two decades, the private sector in Sudan, including NGOs and for-profit providers, have worked with the states' immunisation programmes, receiving training in vaccination and disease surveillance and being incorporated in annual district immunisation plans. The agreements that the providers enter into with state governments necessitate that they are licensed (meeting quality standards to obtain and maintain their licence), follow the national immunisation policy and reporting and supervision requirements, use the vaccines supplied by government, and offer vaccinations free-of-charge. The private sector is fully integrated in monthly district review meetings, and receives regular supervisory visits to ensure that quality standards are met (e.g. in vaccine and cold chain management, and vaccine administration), along with cold chain equipment in some cases. The providers must submit their monthly reports to the district immunisation officer before they can receive the next month's vaccine supply, and licences are withdrawn if quality standards are not met, or if providers are found to have been charging patients for immunisation (123). Private health facilities are included in the mapping of services that the immunisation programme undertakes each year as part of the states' annual needs assessment (123). If gaps in the coverage of vaccination services are found in a geographical area, the programme may ask a private provider to establish immunisation services within its existing facilities or to set up a new outreach site. The facilities are then responsible for providing immunisation services in their designated catchment area – under the supervision of the district immunisation officer – as well as other routine immunisation programme activities, such as default tracking and social mobilisation. While this process most often involves NGOs, a few for-profit facilities, such as private maternity hospitals in under-served areas, have also become part of this collaborative arrangement. In addition to routine immunisation service delivery, national and international NGOs have conducted immunisation campaigns (e.g. for polio and measles) in conflict-affected areas, in coordination with the district immunisation officer. Moreover, several private hospitals and paediatric clinics serve as sites for the country's vaccine-preventable diseases surveillance system.

Similar examples have been identified in Benin, Malawi, and Georgia, where the Ministries of Health provide vaccines, injections, and other supplies to private providers (faith-based, NGO, and for-profit), along with training and supervision and the requirement for reporting on national immunisation programme-supported vaccinations (124). Facilities need to be qualified and willing to offer the services, and the public sector must have a defined need for additional access to vaccination services. In Georgia, if a health facility wants to provide vaccination services, it must notify the State Regulation Agency for Medical Activities and it must have a vaccination room that meets all of the governmental requirements, such as storing vaccines at recommended temperatures (124).

There is a smaller literature on engagement in other health programme areas with target populations, such as adolescent health. Azzopardi et al. highlight examples from three countries, including a partnership between mining companies and the United Nations to support adolescent reproductive health in Mongolia, and a partnership between government, an NGO, and a private mall to provide an adolescent health clinic in the Philippines (37).

There is now a growing literature on the COVID-19 experience, which looks at the contribution of private sector engagement, which is seen as one factor supporting effective responses to the pandemic (63). The Indian federal government constituted a task force on private sector engagement, which was replicated in many cases at state level (90). The federal government developed clinical guidelines and protocols, accredited private laboratories for testing, prescribed tariffs, and facilitated access to private healthcare facilities for patients covered under government-supported insurance schemes. The federal government also focused on mobilising the private sector to improve the supply of COVID-19 tools, as well as co-investment in research and development for vaccine development (90).

Referral systems

Much of the discussion of referrals in relation to governance of the private sector relates to managing referrals from the public sector to the private sector – and the potential for this to be distorting, corrupting, and profit-maximising (68). Studies also focus on the management of referrals within private networks: for example, in India and Mexico (112).

As described above, encouraging referrals from private providers is a key component of some of the strategies for engaging private providers in vertical programmes. Of 18 LMICs studied, seven included private sector referral policies for TB, compared to six for immunisation and four for malaria (2). One study reported on a training programme with private pharmacies in Viet Nam to deliver reproductive health services for youth and to identify possible TB cases. PATH and the Ministry of Health established a referral system between the private pharmacies and local health facilities through referral slips or coupons, and regular workshops were organised to promote healthcare networks (10). However, studies examining approaches to improving private sector integration into public referral systems (beyond the vertical programmes described above) are limited.

3.6.2 How effective are these approaches to governance?

Evidence on the effectiveness of approaches is limited, and most of the studies focus more on technical lessons relating to the mechanisms, rather than on the governance of these mechanisms.

Quality of care initiatives

In many contexts, clinical guidelines, standards, and protocols are part of a wider legal and regulatory system for licensing and accreditation, which also includes continuing professional development. Evidence on the effectiveness of these wider interventions is considered under the Governance Behaviour, Enable Stakeholders. Quality criteria relating to healthcare processes are noted to be generally absent, though some countries, such as South Africa, have introduced comprehensive quality criteria that are applicable to both public and private facilities (18). However, if there is no routine process of inspection or monitoring, the incentive to comply with evidence-based guidelines is

limited or negligible (28).

Inclusion in vertical programmes

The case studies of private sector contributions to immunisation in Malawi, Benin, and Georgia (124) revealed that service quality at private facilities was mixed, a finding that is similar to the findings of other studies on private sector vaccination. The three countries varied in how well the Ministries of Health managed and supervised private sector services. The majority of private facilities reported that they stored vaccines, ranging from 60% in Benin to 98% in Georgia. Among the private facilities that stored vaccines, most had cold chain equipment that met the national standards. The percentage of facilities that did not meet standards was lowest in Benin (17%) and highest in Malawi (29%), and waiting times at facilities were a source of dissatisfaction among clients.

Private providers have made an important contribution to Sudan's improved vaccination coverage, which went from 62% for diphtheria-tetanus-pertussis third dose in 2000 to 95% for Penta3 in 2017 (using WHO–UNICEF estimates). Moreover, private facilities in Sudan participate in 'cost sharing', by providing the venues, health personnel, and some of the cold chain and running costs. Without the private sector, the government would need to significantly increase its capital investment in health facilities and recurring personnel cost, to fill gaps in services, especially in states like Khartoum (123). Private health providers of immunisation services are seen as critical in filling the gaps in government services in hard-to-reach or conflict-affected areas and among marginalised populations in Sudan, and thus in reducing inequities in access (Ahmed et al., 2019). At the time of the study by Ahmed et al. (2019), 55% of private health facilities (411 out of 752) provided immunisation services, with 75% (307 out of 411) based in Khartoum state and the Darfur region. In 2017, private providers administered around 16% of all third doses of pentavalent vaccines to children. It is believed that private health facilities have leveraged this partnership with the federal and state immunisation programmes to promote their health services, and subsequently increase their client base. However, there have been no studies or evaluations to substantiate this assertion (123).

In one study of adolescent health services (37), the private sector was perceived as enabling improved and reliable access to commodities, such as contraception. Improved physical facilities and environments of private clinics were identified, particularly in Mongolia. Some participants in the study identified the private sector as being 'closer' to adolescents, and therefore in a better position to advocate for their needs. Participants across countries also identified that the private sector could provide services (such as contraception and testing/treating for sexually transmitted infections and HIV) that were more accessible and efficient, and less judgemental, working through schools and other settings that adolescents frequent. The private sector was able to fill gaps in public care, in staffing, skills, and technology, but also to address needs that the public sector was restricted in tackling (e.g. in the Philippines a Temporary Restraining Order prohibited the public sector – but not necessarily the private – from providing contraceptive pills and implants). For the private sector, strengthened linkages with the public health system were seen to improve their public image and potentially increase corporations' market share. For private clinicians, stronger engagement with the public sector was seen as a means of recognising their role in and contribution to adolescent health, and of improving the quality of care they provided through linkages with broader services, but also access to training and guidelines (37).

In relation to the COVID-19 response, Thailand's engagement of the private sector was facilitated by a near-seamless integration of public and private care prior to the pandemic (63). Building on previous experience with SARS-CoV-1 and other infectious disease outbreaks, the country's Ministry of Public Health moved quickly to expand its cooperation and capacities across government ministries and the private sector. For instance, the Department of Disease Control produced guidelines and a protocol for case management that applied to both public and private hospitals. As part of this, private hospitals were required to report cases daily to the Centre for COVID-19 Situation Administration, chaired by the Prime Minister.

In other countries (Bangladesh, Nepal, and Sri Lanka), the pandemic exposed limited public–private engagement and governance mechanisms (63). In these cases, engagement of the private sector appeared to have been hampered by a lack of trust as some governments initially refused to allow private hospitals to provide COVID-19-related care, due to fears of profiteering. However, with a surge in demand and low testing rates, many governments were left with little option but to engage the private sector to expeditiously expand access by leveraging existing private testing and treatment facilities and resources. In Bangladesh, Sri Lanka, and Nepal, a small number of private hospitals were allowed to provide COVID-19 testing, subject to tight restrictions, and this number gradually expanded over time. In India, reports suggest that the state's ability to engage private providers was constrained by limited regulatory and purchasing capacity. Despite this, the national flagship health insurance scheme AB-PMJAY vastly increased the number of hospitals empanelled under the scheme to provide free COVID-19 tests and treatment. The National Health Authority introduced a Hospital Empanelment Module Lite, a new online system for rapidly on-boarding hospitals. Of the total facilities (20, 257) empanelled under the scheme in 2020, 40% were private for-profit and 4% were private not-for-profit entities.

Relatively little information was identified on adherence to regulations around referral practices and emergency care (see also the section on Enable Stakeholders). One study in the United Republic of Tanzania noted that private facilities often bypassed established referral systems and failed to follow regulations on treating emergency patients, regardless of their ability to pay, citing resource constraints (43). Equally, in India, the Karnataka Private Medical Establishments Act says that no private health facility can insist on advance payment for initiating emergency treatment and, in the event of the death of a patient, must hand over the body of the deceased immediately without a demand to pay the dues; however, this has been hard to enforce (68).

3.6.3 What are the key enablers of, and barriers to, aligning structures?

Quality of care initiatives

Enabling factors for ensuring compliance with clinical guidelines and standards overlap with those of regulation, in terms of incentives, subsidies, and sanctions (such as disclosure for poor performers) (53). In regard to the ongoing Kerala Antimicrobial Resistance Strategic Action Plan, it is highlighted that the intensive co-development and implementation process is contributing to its success, along with engaging multiple partners and champions at multiple levels, including from the private sector (120). The engagement of private hospitals, professional bodies, and medical colleges is highlighted as an important part of the action plan. These partners in turn are tasked with sensitising medical practitioners, pharmacists, and other stakeholders regarding the short-term and long-term objectives of antibiotic stewardship. Key strengths of the PPP include the collaborative work of 18 professional medical societies to formulate clinical guidelines on antibiotic prescription. Training curricula have also been developed, and a task force constituted to monitor the ongoing work. In addition, the authors highlight the importance of structural measures to ensure accountability. Capacity building at both public and private institutions is seen as important in order to address practical implementation challenges, and sharing of best practices though international and national platforms is highlighted as a key to success (120).

The main challenges noted for this initiative include the following: the effort required to bring the various groups (public and private) together; initial criticism of the initiative, as there was no data to support the cause; changes in political leadership, which have delayed the programme; a lack of dedicated funding; and a lack of dedicated staff in the public and private sectors to work on the initiative (120).

Inclusion in priority health programmes

While the government is responsible for setting policy and norms for vaccination, it can improve public–private engagement by involving private sector providers in decision-making on policies that affect vaccination programmes (124). For example, private sector provid-

ers can be invited to participate in discussions about vaccination policy, paediatric association meetings, or during training sessions. The experience of Sudan demonstrates the importance of making private providers feel that they are part of, or have ownership in, the delivery system, and are accountable to it, through taking part in regular planning, training, review, and decision-making activities, to ensure their compliance with immunisation guidelines and the overall quality of services (123). In Sudan, for-profit providers and NGOs were represented on both state-level technical immunisation committees and health coordinating task forces. Representatives of national and international NGOs served on the country's Interagency Coordinating Committee/National Health Sector Coordinating Committee, which oversees immunisation activities at the national level, while the national immunisation technical advisory group included representatives of professional associations (123).

High-quality data on adolescent health needs, as well as on sectors, their current activities, and their capacity to respond, have also been identified as important for informing effective partnerships in adolescent health (37).

To ensure that private providers are offering quality services, governments should guarantee adequate training on improving vaccination service delivery in private facilities (Levin et al., 2019). It is particularly important that they provide clear guidance on how to purchase appropriate cold chain equipment for vaccine storage, and information on how to maintain the cold chain. To the extent possible, national improvement plans should also frequently supervise the private facilities that provide vaccination services, to ensure high-quality services. Governments should engage in monitoring the quality of private sector service provision by requiring annual licensing, or at least some type of monitoring of quality metrics that is tied to government provision of vaccines (124). It is also important to monitor charging by providers, to ensure that households are not being charged for national vaccination services (123).

Across all programme areas, having clear incentives for all actors involved is identified as foundational (37). These incentives may be different for different sectors, but nonetheless they need to be articulated. In Ethiopia, for example, some for-profit providers showed a lack of enthusiasm in continuing certain services, such as TB treatment, due to a perceived lack of incentives. The implementation of the Public–Private Mix (PPM) TB guidelines initially provided opportunities for capacity building and attracting more patients to private health facilities, but additional costs and uncompensated staff time may have discouraged the long-term retention of TB patients (39). Delays in funds and lack of recognition of their contribution are demotivating, as highlighted in relation to NGOs working on TB in India (122).

Challenges in accessing training for adolescent health, and difficulty in accessing regulations and policy documents relating to it, have been highlighted as barriers for private providers in a number of settings (37).

Referral systems

No studies were identified which discuss enablers of, and barriers to, strengthening the role of the private sector in referral systems.

3.7 Nurture Trust

Nurture trust is defined as 'government takes action to safeguard 'patients' human rights, health and financial welfare in relation to their interaction with the private sector' (3).

3.7.1 What approaches to nurturing trust have been adopted to govern the private sector?

A range of mechanisms have been used to strengthen the voice of the public in private sector governance, to address patient complaints, and to provide opportunities for legal redress. Many of these mechanisms concern accountability across both the public and private sectors, although some are specific to the private sector.

In some cases, these mechanisms are underpinned by patients' rights charters or laws (66)(70)(105). For example, the Indian federal government developed a Charter of Patients' Rights encompassing 17 rights, including the right to a second opinion, to transparency in fee rates, to choose the source when obtaining medicines and tests, and 'to be heard and [to] seek redressal' (49).

Opportunities for patient voice may occur through participation in annual general meetings of social insurance organisations, by including patient representatives on hospital boards, or through other public consultation fora, such as Thailand's National Health Assembly (60)(64)(71)(95). Gatome-Munyya et al. report that in several African countries members of the public have been consulted in the design of purchasing arrangements, including benefits specification, selection of providers, and performance monitoring (95). For example, in Kenya the Health Benefits Advisory Panel included patient groups (100). Other patient voice approaches include patient feedback surveys or review apps (95)(97).

Patients can make complaints and seek their resolution through various structures. This may involve contacting the healthcare provider or insurer concerned directly, or it may involve external bodies, such as provider organisations or regulators, sometimes through a telephone hotline or patient complaints portal (51)(96). For example, in Brazil there was a complaints procedure for users to raise concerns about health insurance companies, which the regulator was required to respond to (125). In some settings complaints are addressed through a hospital ombudsman or ombuds office (2)(66)(105). For example, in Malawi in 2018 the Ministry of Health created a new role of hospital ombudsman in public hospitals and in hospitals run by FBOs (110).
Patients may also choose to address their grievances through the legal system by suing providers in connection with adverse experiences and outcomes (51)(57)(60). There have also been cases of medical negligence suits being brought through suo motu action by legal courts as a result of judicial activism: for example, in Pakistan (62).

3.7.2 How effective are approaches to nurturing trust?

The identification in the literature of examples of public voice and complaints mechanisms that were perceived as well-functioning was relatively rare, with concerns that appropriate mechanisms were often absent, non-functional, or not trusted, or that they had low levels of public participation (50)(70)(121). In Brazil 'health councils' at federal, state, and municipal levels were said to have been unable to address inequalities in access and quality, despite having 50% beneficiary membership (84). Low and diffuse public participation was also noted in social accountability mechanisms relating to Brazil's private health insurance market, in contrast to the active and organised participation of insurance agencies and healthcare providers (126). In Malawi there was little public awareness about the charter of patients' rights, and any implementation of these rights was described as ad hoc (110). In Mongolia it was reported that the Consumer Rights Protection Law 2003 covered only basic consumer rights, without any specific rights related to health, and it was reported that although the law gave consumers the right to seek redress, there was no health sector mechanism in place to facilitate this (72). Hanson et al. drew on ex-

perience with purchasing mechanisms across multiple countries to argue that, while citizen and civil society representation can help take account of beneficiary preferences, in practice engagement is often ad hoc and ineffective: one example being a complaints and feedback telephone number for Kenya's National Hospital Insurance Fund that was not functional (101).

Some notable exceptions appear in the literature, with some cases of positive experiences being reported. Indonesia's LAPOR! (REPORT!) platform was reportedly widely used by citizens to voice their views and submit complaints about public services, including health, and was said to provide a means to monitor performance of government authorities (65). In Thailand the annual National Health Assembly was described as a 'participatory governance mechanism', which provided a forum for the public to voice concerns and influence policy. Harris and Maia argue that the Assembly has constrained the influence of the private sector on policy, for example, leading to the elimination of a tax subsidy for private hospitals that was perceived to undermine the national healthcare system (73). Thailand was also said to have robust systems for involving patient interest groups on particular diseases, and a well-functioning telephone helpline for social health insurance members (101).

Experience with legal redress is variable across countries. In some contexts, consumer litigation has become a prominent regulatory tool (49), with a medico-legal fraternity developing in countries such as India and Thailand, in line with that observed in the United States (62). In India, the application of consumer protection laws has been said to be a significant concern for private healthcare providers, and many complaints have been lodged under the 1986 Consumer Protection Act (47)(65).

While litigation provides financial redress for some patients, a number of potentially negative consequences are also noted. Fear of being sued could lead to increasingly precautionary and 'defensive' medical practices, with incentives to over-test and over-intervene pushing up costs for patients (47)(60). It has also been argued that such mechanisms emphasise individual rights and claims, potentially side-lining considerations of social equity (49).

In the absence of effective mechanisms for redress, patients and their families may use more direct routes. Disgruntled users may share their grievances through social or press media, and, worryingly, violent attacks on healthcare workers have become a concern, with examples cited in the literature from India and Yemen (47)(50). In 2019 doctors in India even went on strike to protest against this violence, and some have felt the need to enhance security at their facilities (49).

3.7.3 What are the key enablers of, and barriers to, nurturing trust?

An underlying barrier to public accountability in healthcare is the inherently imperfect and asymmetric information held by providers and patients, with patients often lacking good-quality information or understanding about the need for and quality of healthcare (53). In addition, patients often have limited information on their rights, on healthcare regulations, and on the accountability mechanisms that exist (101). To counter this, it has been argued that there should be a concerted effort to inform the public about rights and regulations (65). For example, in the Indian State of Karnataka the Private Medical Establishments Act requires that health facilities display the patient rights and responsibilities charter and contact details of the facility owner (68). Information on care quality can also be provided to users through facility scorecards or surgical outcome comparisons, though their use in LMIC contexts is still limited (2)(57).

It can be particularly challenging to reach the poorer and more vulnerable consumers with enhanced information (53), and these consumers may also lack physical access to accountability mechanisms. In Yemen it was found that most complaints mechanisms were centralised at the Ministry of Health, and it was unclear how accessible they were to the vast majority of the rural population (52). A potential solution where rates of internet access are high is to take the mechanisms online. Indonesia has used a platform known as eParticipation to engage citizens in regulatory activities across multiple sectors, with the aim of increasing transparency and inclusiveness, as well as using the

online LAPOR! platform described above for managing complaints (65).
CSOs, NGOs, and patient groups can also play a key enabling role in representing a diffuse public, facilitating interaction between community members, healthcare providers, and government, and in some cases they have been given official monitoring roles (2)(95). However, there is considerable variation in how well different communities are represented, and the capture of such mechanisms by local elites is possible (53).

The independence of complaints procedures is also mentioned in the literature as having a potential influence on the effectiveness of mechanisms. For example, in Malawi it was seen as an advantage that hospital ombudsmen were new recruits and not current or previous Ministry of Health staff, thus implying a degree of impartiality, but this was felt to be limited as they still reported to the District Health Officer, meaning it was 'very difficult for the subordinates to play watchdog over their seniors' (110).

Legal redress requires that citizens have sufficient resources to pursue claims, or that class action is possible, and is dependent on relating cases of harm to specific health products or services (53). India's Consumer Protection Act is designed to enable accountability because it operates through dedicated district-level consumer courts, which should have resulted in quick and local resolution of consumer complaints (62). However, in practice the process could be lengthy and costly for consumers, with some arguing that outcomes were weighted in favour of the clinicians (57)(65).

While the Thai examples of public accountability mechanisms were described as being well-functioning and effective (see above), the papers in the review provided little detail on why these mechanisms had worked well. However, their very existence and the commitment to their functioning perhaps reflects the sustained political commitment to a predominantly publicly financed and provided health service, and to UHC, in Thailand, as well as reflecting the Ministry of Health's willingness to take on the role of 'arbiter' between the interests of the private sector and civil society (73).

3.8 Capacities for governance

A strong theme that emerges across all of the Governance Behaviours is the capacity of both the public and private sectors to effectively operationalise governance mechanisms, with the skills and human and financial resources for governance within the public sector almost always described as inadequate.

Specific skills and knowledge mentioned as necessary for contracting include legal, contracting, clinical and financial risk management, claims data analysis, clinical coding and pricing, contract management, and performance monitoring and enforcement (34)(40)(43)(45)(54)(60)(66)(79)(96)(101)(104)(105)(122)(123). A 2015 review of reviews across Asian-Pacific countries found that public sector governance capacity was inadequate, despite it being a key factor in the operation and success of voucher schemes and purchasing arrangements, particularly when rolled out at scale (25). Similarly, a 2018 study looking at contracting of non-state providers across Africa, Asia, and eastern Europe found that government's capacity to monitor contractual arrangements is critical for the success of contracting and, without this, these arrangements can experience many of the resource and management challenges of public sector delivery (94).

Specific skills mentioned in relation to *regulation and accreditation* include facility registration, facility inspection, accreditation and enforcement (42)(68)(72)(102)(110)(129), and quality improvement/assurance (43)(45)(102)(129). A 2017 study looking at the emergence of private hospitals in a post-Soviet mixed health system found that the government's lack of technical and financial resources to conduct a facility needs-based assessment resulted in duplication of providers and services, particularly in urban areas where facilities were more financially viable. This lack of capacity, together with perverse incentives, saw a concomitant shift towards more expensive inpatient care (46).

A WHO review of governance for strategic purchasing across 10 countries in eastern Europe and central Asia that have undergone health financing reforms highlights that in addition to the technical and analytical skills mix listed above, higher-order management and leadership skills are also important enablers for governance across both the public and private sectors, such as the ability to weigh up options and make good-quality decisions, and the ability to innovate and manage change (55).

The literature focuses not only on the human resource skills required, but also the underlying *organisational processes, systems, and standard operating procedures* needed to enable regulatory mechanisms (34)(40)(41)(43)(45)(101)(105)(123). A 2011 review across 45 sub-Saharan African countries found that while most countries had explicit policies in relation to the private sector, the majority of these countries did not have the capacity for policy implementation, or to enforce regulation (42). A recent 2022 landscape analysis across five African regions found that the public sector lacked technical skills in drafting private sector policy, but that even where such a policy existed, it had not been implemented, monitored, or evaluated (36). The review found stronger public sector capacity to govern the private sector within some vertical disease programmes, supported by additional resources from external funding. Although these programmes were found to fragment service delivery, the finding does suggest that capacity may manifest with focused implementation and ongoing monitoring support, as well as additional financial and human resources (36). This is borne out by a similar finding from a WHO landscape analysis of countries with well-developed engagement with the private sector, noting that programme-specific learnings could be applied to system-wide initiatives (2).

In addition to a lack of skills and organisational processes, common public sector capacity challenges include high staff turnover, the lack of succession planning, and the loss of institutional memory (66)(105). For example, an Indian case study looking at sub-national implementation of private facility regu-

lation found that government officials shifted positions frequently, and the loss of institutional knowledge, especially in the absence of regular training on the implementation of the regulation, meant that newly appointed staff were left to 'learn on their own' (68).

The literature highlights that local public actors face a number of specific challenges when *operationalising governance in decentralised contexts*. One issue is the lack of appropriate skills at the local level: in the United Republic of Tanzania responsibility for service agreements with FBO facilities rested with district authorities but their staff were said to lack the ability to oversee the delivery of quality health services in the contracted hospitals (109). In Brazil it was argued that local public managers should be recruited and trained to ensure they have a good understanding of contracts, and the ability to discuss, debate, and question the relationships with the private sector (128). Local regulatory entities, although empowered to regulate, almost always report insufficient human and financial resources to effectively implement, monitor, and enforce private sector regulatory mechanisms (2)(5)(50)(52)(68)(71)(74)(104)(116). Another challenge is insufficient or absent training on the policy or regulation itself: local actors are distanced from the policy intent, are not involved in policy development, and sometimes do not even clearly understand policy objectives, and they are not in themselves regulators but rather administrative or clinical staff, and hence may not be invested in the policy, or have little incentive to be invested in it (2). This distance may also render local actors vulnerable to undue influence from local relationships, which are far more 'present', and may result in power imbalances during contracting and compliance, as discussed in the section on Foster Relations (2)(53)(56)(71)(116). An evaluation of regulatory failures in two Indian states recommends the separation of the public health and regulatory functions at the local level, as they require distinct skill sets, as well as a fundamentally different relationship with local providers (67).

Capacity constraints also affect private sector actors themselves, and their ability to engage with governance mechanisms. Private sector capacity challenges are most often described in the literature in relation to small, individual, or rural providers, who lack the financial and time resources to comply with regulatory requirements (2)(9)(53)(96)(104)(123). These private providers report not receiving training on government reporting systems and processes, and lack the capacity to collect, maintain, and share mandatory data with regulators (38)(104)(125). Experience in Ethiopia indicates that despite public-led training of private facility staff in clinical and administrative procedures, ongoing mentorship and 'supportive oversight' was required (39). Similarly, in Kenya a national quality improvement and accreditation programme reported that facilities needed training on the accreditation framework, and additional guidance throughout the process (129). A donor-funded initiative in Kenya sought to address this through the use of intermediary organisations to assist less formal private providers to navigate onerous National Health Insurance Fund accreditation requirements (107). A 2021 qualitative evaluation found these organisations helpful in reducing 'street-level bureaucracy' and improving efficiency and consistency in application (107).

Historic mutual mistrust between the sectors and a lack of collaborative capacity emerges within and between both the public and private sectors (38)(46)(104). An Ethiopian case study highlights that despite required skills, processes, and resources, intentional efforts and 'persistent advocacy', supported by a donor-funded public–private engagement programme, was still required to pursue activities that required working together, to start shifting perceptions (39). A study in Kenya evaluated a facility inspection reform and found that in addition to the inspection tools, operational processes and skills, 'Cultural, relational and institutional "software" are also crucial for legitimacy, feasibility of implementation and enforceability, and should be carefully integrated into regulatory reforms' (91). Effective governance was reported as requiring trust, cooperation, and collaboration capacity not only across the sectors but also between the different health and financing agencies,

networks, civil society, and communities (23)(65). An Indian case study recommends that implementation of cross-sectoral regulation with a diverse set of stakeholders should be accompanied by information sessions for public sector staff to explain the objectives of the regulation and foster collaborative capacity (68).

At one time there was a strong emphasis on creating PPP units within Ministries of Health, and these were set up in multiple sub-Saharan African countries and Afghanistan, mainly during the 1990s and 2000s, though in Ethiopia this occurred as recently as 2018 (37)(39)(116). PPP units typically comprise three to six staff, with expertise in business, law, or economics, serving as a focal point for engaging the private sector, and as an internal Ministry of Health resource for data, technical assistance, capacity building, and general oversight of private sector engagement (121). In Ghana a PPP unit was set up at municipal level (38). In the United Republic of Tanzania it is argued that the national PPP unit led to strong technical coordination of PPPs (69). However, in some cases the units are said to be small and under-resourced (34)(36). In Ghana, the unit was reportedly positioned at a low level in the administrative hierarchy and was said to lack sufficient staff and funding (38). In Ethiopia stakeholders noted that the PPP unit was not integrated into the Ministry of Health organogram, nor well-coordinated with private sector engagement activities in specific disease areas, meaning that the approach to the private sector remained fragmented (39). 'While some authors continue to advocate for the establishment of such units (45), there is increasing emphasis on the role of designated agencies in handling healthcare regulation, accreditation and/or strategic purchasing' (70)(97). Several papers stress that these agencies should be strong and have clear independence from the Ministry of Health, to avoid ministerial interference, and conflicts of interest where the bodies are responsible for governance of/purchasing from public as well as private facilities (43)(45)(70)(97).

Efforts to enhance governance capacity described in the literature generally involve some kind of *donor-supported technical assistance programme*. National programmes to strengthen governance without donor support are not described in the literature, though this could be because externally funded programmes have greater resources for evaluating and writing up their work. Four donor-supported programmes are described. In Afghanistan, the Ministry of Population Health's and private associations' stewardship-building activities were largely supported by external aid agencies (mainly USAID). This included subsidising salaries, equipment, and communications, training programmes and operating costs, as well as technical assistance and training (41). In Ethiopia the USAID-funded Private Health Sector Programme implemented a series of PPP projects from 2004 to 2020, including in the areas of TB, malaria, HIV/Aids, and family planning (39). Cisek et al. describe the implementation of the 'total market approach' to strengthen governance practices across family planning services in Mali, Uganda, and Kenya (44). The approach emphasises multisectoral coordination and private sector engagement, and has been supported in several contexts by USAID, the United Nations Population Fund, and the government of the United Kingdom of Great Britain and Northern Ireland. (44). Finally, the Strengthening Mixed Health Systems project was implemented in Kakamega County in Kenya, with funding from MSD for Mothers, with the aim of 'integrating quality private maternity care into government stewarded health systems' (113). Interventions included the formation of a private sector association, setting up a stakeholder forum, increasing private sector representation in county planning, and building the capacity of the County Health Management Team to engage with the private sector (113).

All four of the aforementioned papers describing donor support to capacity report improvements in various dimensions of governance, as well as ongoing challenges (it is notable that the authors of at least some of these papers are from the technical assistance teams implementing the projects). None of the papers provide information on the cost of the capacity strengthening activities or the impact on UHC outcomes. Concerns are raised about the vulnerabil-

ities to reductions in aid which such donor-funded activities could engender (41). In Ethiopia, the federal and regional governments faced challenges in independently implementing and effectively engaging the private sector at a large scale without donor support (39). Concerns have also been raised in the literature about the degree of public ownership in governance strategies that have had strong external input, as highlighted in the section on contracting.

Whilst donor-funded initiatives may have had some success in increasing government capacity, in LMICs the cost to fully capacitate government entities to effectively govern the private sector may be prohibitive. This has led to proposals for, or de facto, reliance on alternative approaches, such as self-regulation, consumer-based regulation, incentives, and subsidies (see the sections on Enable Stakeholders and Nurture Trust), as well as taking advantage of possible regional regulatory capacities, while recognising that large-scale public health application of such alternative mechanisms will have their own capacity requirements, and may not be feasible in low-income contexts (16)(51)(57).

A strong theme that emerges across all of the Governance Behaviours is the capacity of both the public and private sectors to effectively operationalise governance mechanisms

Primary Health Care in Kazakhstan, 2019.
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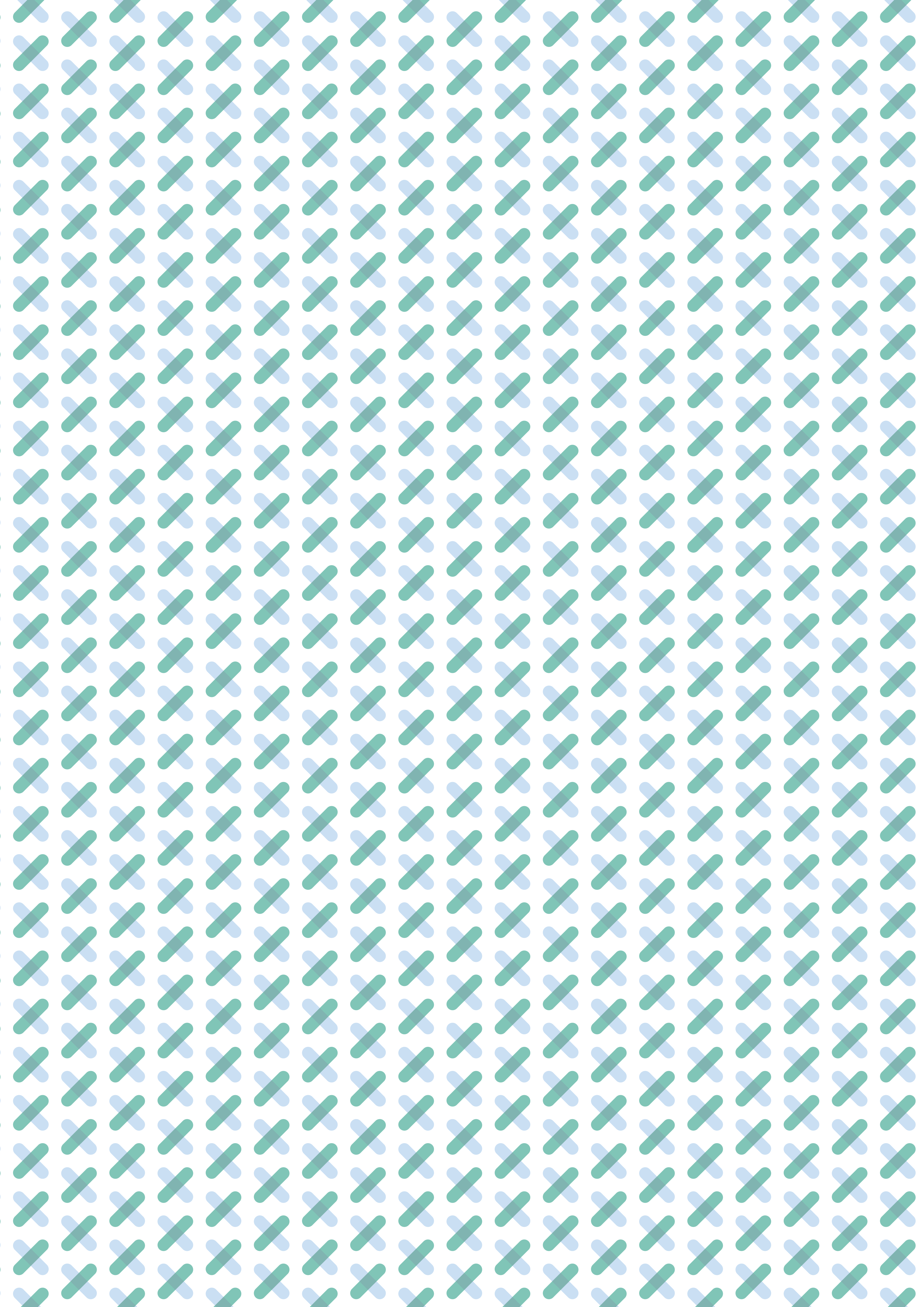

4 Discussion

This review aimed to synthesise the literature on governance of the private sector in mixed health systems in LMIC contexts. Its objectives were to describe the approaches that have been used under each of the WHO's Governance Behaviours, assess the available evidence on their effectiveness, and synthesise the literature on the enablers of, and barriers to, their effective implementation. In this discussion section we first consider the strengths and limitations of our review methods, before turning to an assessment of the nature and quality of the literature identified. We then summarise our findings in relation to each of the Governance Behaviours, before concluding with the key cross-cutting lessons for those involved in governance.

4.1 Strengths and limitations of the review methods

A strength of the review was the inclusion of a very wide range of literature in terms of study design, data collection methods, types of private sector actors, and both journal articles and grey literature or reports. While it is common for reviews to involve tighter methodological inclusion criteria, for this topic we were aware that valuable evidence may come not only from rigorous research studies but also from outputs that describe practical policy implementation, or that reflect and synthesise the views and experiences of actors who have been directly engaged in the practice of governance.

A principal methodological challenge for the review was defining the boundaries of the topic area. The term 'governance' has multiple definitions. In the context of the private sector in mixed health systems, it can be considered very broadly to cover anything that state authorities do to influence the operation and performance of the private health sector (including the specific policy mechanisms employed to do so), or more narrowly as high-level oversight of these activities. This means that it is hard to draw the boundary between what falls strictly under 'governance' and what falls under a potentially broader understanding of 'private sector engagement'. This inclusive approach to study selection presented some practical challenges, particularly for reviewing the Enable Stakeholders literature on regulation and contracting, as these are two extremely broad areas that could merit multiple individual reviews on aspects of these topics alone. To maintain feasibility, we drew where possible on existing literature reviews or evidence syntheses on these topics, while also including individual empirical papers to elaborate key issues.

A second methodological challenge was that the nature of the topic and terms used in relation to governance meant that it was not possible to define a very specific, well-targeted search strategy. In fact, using terms related to the two domains of 'private sector' and 'governance' led to the initial identification of over 11,000 articles. We considered restricting the search by also requiring at least one mention of terms related to specific Governance Behaviours but found that

this led to the omission of some key documents. We employed machine learning technology to order the screening of the papers, meaning that in practice we manually screened 2,052 articles. We cannot rule out the possibility that relevant articles were not screened before our stopping rule was reached but note that we supplemented database searches with articles identified by key informants who are well-versed in the governance and private sector literature, leading to some degree of confidence that the most significant articles have been included.

4.2 Strengths and limitations of the literature

The literature has considerable breadth, particularly geographically, and covers a high number of different LMICs, and with at least some literature on most types of private actors in the financing and service delivery domains, though the main focus was on health facilities. Some gaps were notable. There was very limited evidence on governance of the private sector in fragile and conflict-affected states. Some topics were relatively under-covered, particularly regulation of private health insurance, taxation policy, and public accountability mechanisms, though these could all be extremely important governance levers. It was also notable that there was little coverage of more recent market developments, such as telemedicine, perhaps reflecting the fact that these developments typically precede the strategies to govern them (131), which may therefore be in their infancy in many LMIC settings. Examples include medical tourism, digital health, growth of chain providers, and private equity investment in the health sector (51)(127). It is also worth noting that in drawing on the literature (rather than, say, key informant interviews), the findings may reflect practices at the time of the studies, which go back to 2010, and may miss some of the most recent developments and innovations that have not yet been written up.

An important observation concerns the nature of the methods used in the papers, and the nature of the evidence produced. We did not perform a formal quality assessment of articles to determine their inclusion, as we wanted to be as inclusive as possible of different approaches to this topic, and different disciplines (which have different reporting customs), and to ensure we included the perspectives of those actually involved in policy and practice, even where these were not based on formal research approaches. However, some of the limitations in the literature overall merit careful discussion. First, the reviewed papers were nearly all primarily based on qualitative interviews and/or document review, typically including interviews with high-level stakeholders discussing their perceptions of governance. While most included some description of governance mechanisms, they typically lacked evidence on the intensity of their implementation (e.g. number of meetings, frequency of inspections, compliance with requirements, sanctions implemented, etc). There was a considerable body of evidence on the perceptions of stakeholders about problems with existing governance approaches, but rather less evidence on how these could be improved (despite many opinions on this being presented). There was a particular lack of quantitative data on effectiveness in terms of impact on governance (no quantitative measures of governance were presented), or in terms of quantitative outcomes related to the operation of health systems or UHC. There were exceptions, such as two recent RCTs on facility inspection (57) and facility certification (80), but such studies are unusual. In some ways, the nature of the literature reflects the challenges of conducting research in this area. Governance is a difficult concept to define, let alone measure in a rigorous and meaningful way, and some would likely argue that quantitative measurement of governance may be difficult. In addition, there are challenges in conducting controlled evaluations of legal changes or health system reforms that cannot be easily piloted or withheld from comparison/control groups. Any governance changes that do occur often happen at the same time as multiple other health system and contextual changes, making their impact on UHC outcomes hard to isolate. While these factors may explain the limited number of quantitative evaluations, there was also a lack of rigorous studies that draw on in-depth qualitative methods and careful triangulation with process data, with some exceptions. Some papers had a very limited description of methods, or none at all. The literature emphasises the im-

portance of considering the costs as well as the benefits of governance mechanisms, such as regulation (57)(103), but only one paper providing any rigorous cost data was identified (associated with the RCT on facility inspection (76)).

Most studies drew on interviews with stakeholders, yet there are potential challenges in interpreting these data in the light of social desirability bias. Private providers and their representatives may want to be seen as good corporate citizens, and their responses may be strategic: for example, they may have a strong interest in claiming that regulation is too strict, or tariffs for social health insurance reimbursement are too low. Government staff may want to be seen as performing their governance roles well, or at least as not being blameworthy for any shortcomings; and donor-funded technical assistance staff supporting governance will want to be seen as effective. In a number of cases government and technical assistance actors were also authors of the papers in the review. Having a well-informed, insider perspective can be very valuable in understanding the complexities of governance but could also be a further source of bias. The views of the public or patients or their representatives were much less frequently included, perhaps reflecting the challenges of asking them about upstream processes that may not be visible to them. However, having acknowledged the potential for social desirability bias, it is notable that the literature is heavily focused on the problems of governance strategies, and some papers where authors were implementers appear to take a balanced approach to their assessments. In sum, considerable care is needed in interpreting the literature to identify what credible evidence there is of 'what works well', as opposed to the claims of those involved in implementation or the many opinions on offer of what could be improved.

4.3 Key findings from the literature

With those provisos, we now turn to identifying the key findings that can be taken from the literature in terms of the effectiveness, enablers of, and barriers to, each Governance Behaviour, and the recommendations that can be drawn from this.

Deliver Strategy: An important positive finding is that the practice of including the private sector in national policy is already very common, and many countries have specific policy objectives on private sector engagement. This reflects substantial changes in recent decades, in response to the growth and development of the private sector, a shift in mindset on the government's role in private sector governance, and, in some cases, donor influence. There is broad consensus on the importance of a strong strategic policy direction for the private sector, though it is likely that in many cases the mere inclusion of private actors in policy falls far short of clearly articulating the role of the private sector in achieving health system objectives, and how government policy will enable that. In fact, there are frequent reflections in the literature on failures to develop a clear vision for the private sector's role, and a lack of implementation. Having said that, a growing role of the government in private sector governance is evident in many contexts, particularly as a purchaser of care, though it is unclear how well this is linked to an overarching policy vision to ensure that private sector operations are aligned with national healthcare objectives.

Enable Stakeholders: There is considerable evidence of poor and uneven compliance with regulations across multiple countries and private provider types, with widespread infringements reported in health facilities and retail pharmacies in many contexts. This does not imply that regulation is entirely ineffective in imposing some basic minimum standards/compliance, though this may be well below the standards officially listed in regulatory documents. Given its central role in private sector governance, strengthening regulation should be considered a priority area for greater intervention and research. However, studies on strategies to improve regulation are rare; a few RCTs indicate that it is possible to improve compliance through a package of reforms, though the generalisability of these findings to situations without substantial external support is yet to be demonstrated.

The literature suggests that improving regulation could begin with a careful mapping of all relevant laws and rules, in order to identify gaps, contradictions, and areas for potential reform. Other potential enablers include appropriately resourcing regulatory bodies to reflect the scale of the private sector; streamlining licensing and inspection processes; enhancing the perceived legitimacy of regulation through greater transparency and fair application of rules; and shifting from a punitive culture to one providing greater support for compliance. Much can be learnt from insights relating to responsive regulation, risk-based regulation, and smart regulation, which are rarely discussed in the LMIC literature (86)(128)(129). However, the literature indicates the need to go beyond a focus on greater enforcement of existing standards to apply a systems perspective to regulation that acknowledges the economic realities of operation in private markets, wider cultures of corruption and informal payments, and the role of powerful vested interests. Moreover, effective enforcement is only likely to be possible when affordable (likely subsidised), reasonable quality alternatives to non-compliant providers are available.

Contracting mechanisms are potentially powerful opportunities to influence private provider behaviour: for example, through requiring minimum quality standards, use of incentive-compatible payment mechanisms, and performance monitoring. Studies comparing contracting with public sector provision indicate that contracting can increase utilisation, and potentially patient satisfaction, and reduce out-of-pocket payments, though the impact on clinical quality of care is unclear. However, given that a substantial increase in contracting is taking place, particularly associated with the expansion of social health insurance, attention is increasingly focused not on whether to contract, but how best to do it. Drawing on an array of experiences across multiple countries, the literature provides a range of credible, though rarely evaluated, recommendations. These include well-defined policy objectives, and clear roles across a 'task network' of government actors at a central and devolved level. They also concern detailed consideration of the incentives from payment mechanisms; the inclusion of quality and service targets in contracts; coordination – or preferably consolidation – among purchasers, and potentially facilities; and investment in digitised and automated processes. The importance of well-functioning governance mechanisms and enhanced capacity for purchasing agencies is also stressed. As with regulatory strategies, contracting cannot be understood outside of the dynamics of the broader health system, with some of the most important influences on contracting outcomes being the overall funding of the purchasing mechanism, the coordinated development of purchasing with complementary policies on quality and financing, and the containment of vested interests in influencing policy.

Foster Relations: In much of the literature, inclusive policy processes are considered to be a positive component of governance, being key for information exchange, building trust, and balancing interests. It is critical that such policy platforms are purposeful and are institutionalised, such that they can be sustained beyond the timeframe of any specific health programme. In addition, it is important that steps are taken to ensure that policy processes are open, inclusive, and transparent. In particular, where such processes take place 'behind closed doors', this can create risks of state capture, bias, and corruption – including in ways that compromise the government's strategic objectives.

From this perspective, it is generally considered desirable for governments to engage with representative private sector associations, rather than individual private actors – albeit this depends on whether such associations exist. For example, the literature indicates that it can be challenging to ensure that such organisations are representative of the full range of private sector stakeholders, with small-scale primary care providers, including those in rural areas, likely to be excluded – to the potential detriment both of their specific interests and the success of policies and programmes. More generally, without including other interests, such as patients, social insurance recipients, and CSOs, etc, it is difficult for state authorities involved in the governance of the policy process to balance legitimate stakeholder interests. It is therefore perhaps better to emphasise the importance of multi-stakeholder policy processes,

rather than public–private dialogue, on matters related to mixed health system governance.

Build Understanding: The evidence shows that many LMIC governments have limited data on what the private sector does, for whom, on what terms, and at what level of quality. Even in countries where the data available to government are reasonably complete and up to date, they are often not organised in a way that facilitates policy analysis and decisions – being fragmented across datasets and not easily accessible to Ministries of Health or sub-national health authorities. In addition, government agencies often lack sufficient capacity to use the information for policymaking purposes.

Although there is some evidence that the situation is improving, in part due to technological developments, more and better data are needed to enable stronger governance of mixed health systems. Efforts are needed to strengthen enforcement of regulations that require the private sector to provide data, but barriers to compliance also need to be addressed. Government, sub-national state authorities, and other stakeholders (including donors) can make compliance less costly, complicated, and burdensome, including by adopting a flexible approach to data submission, investing in digital reporting tools to facilitate reporting, and providing feedback and support.

Align Structures: The inclusion of the private sector in quality of care initiatives is commonly linked to regulatory and contracting approaches, including for participation in social health insurance. In addition, to encourage the use of standard treatment guidelines, the inclusion of private providers in free or subsidised publicly funded training programmes is common. PPPs focused on tackling specific issues, such as reducing antimicrobial resistance, can also be a vehicle for developing and applying clinical guidelines to the private sector. Many disease programmes have also set up referral and notification systems from private health providers to the public sector, especially for infectious diseases. Another common point of engagement is with national immunisation programmes, which provide vaccines and sometimes cold chain equipment to facilitate provision of services, with clear reporting requirements and also rules about charging (making services free to clients). Lessons are also emerging on similar partnerships for adolescent mental health and tackling COVID-19. Encouraging referrals from private providers is a key component in some of the strategies used to engage private providers in vertical programmes, especially for TB. However, the literature on engagement of the private sector in more general referrals is limited.

In general, if there is no routine process of inspection or monitoring (e.g. through regulatory or contractual approaches), the incentive to comply with evidence-based guidelines is limited or negligible. For inclusion in vertical programmes, the evidence is mixed but suggests that the private sector can contribute, particularly in areas where public sector capacity is low (e.g. in conflict-affected areas) or where attention to particular user groups is needed (e.g. to reach adolescents). Overall, the literature indicates that initiatives to Align Structures need to be clear and transparent about the incentives for both sides to participate, as well as establishing good engagement of all stakeholders, making roles clear, and providing regular material support, training, monitoring, and supervision.
Nurture Trust: Approaches for enhancing public accountability encompass voice mechanisms for eliciting patient views, complaints mechanisms, and opportunities for legal redress. Most approaches are not specific to the private sector, and indeed from a patient's perspective one would want to see similar opportunities for accountability across all sectors. Although these strategies are strongly advocated, the identification of well-functioning examples is rare, with more frequent reports of mechanisms that are non-functional, or have low public participation. While a couple of examples of mechanisms said to be well-performing were identified in the literature reviewed, greater information on how this is achieved would be needed to learn from these examples. The wider literature suggests possible strategies around improving provision of information to patients, increasing the accessibility of complaints portals, ensuring the independence of complaints procedures, and greater involvement of civil society, NGOs, and patient groups, all of which merit greater testing and rigorous study.

Several cross-cutting lessons emerge from the literature:

Develop

a clear vision for the private sector's role in the delivery of key health system goals and objectives. While clearly stressed under Deliver Strategy, this emerges as a fundamental requirement influencing all the governance behaviours: governments need to understand the roles that the private sector will play in the delivery of the overarching objectives set for the health system, and what specific policy mechanisms are required to enable the private sector to realise these roles.

Optimise

synergies between Governance Behaviours. Governance mechanisms can be strengthened by creating synergies between them, such as linking contracting mechanisms with regulatory compliance or accreditation, or including in eligibility criteria for licensing or contracting contingent requirements for timely submission of data. Effective use of data and multi-stakeholder dialogue, highlighted under Build Understanding and Foster Relations, can be considered as foundational to all governance mechanisms.

Coordinate

and sequence governance strategies with other health sector reforms. A clear and well-sequenced policy direction is essential, and it must be coherent – for example, between governance and financing policies.

Consider

the devolution/decentralisation context. A clear take-home message is the importance of the devolution/decentralisation context in designing effective governance. While there are many possible options for allocating decision space and governance powers across levels, this must be carefully articulated to avoid either over-centralisation of roles or delegation of roles to levels that lack the capacity to perform them.

Address

capacity for effective governance. Inadequate capacity is one of the most prominent themes in the literature, cutting across all Governance Behaviours, and including both individual level skills and organisational systems. The types of skills argued to be required are well-documented, but greater evidence is needed on how these can be achieved in practice, especially in contexts without substantial donor support. Greater emphasis is also needed on developing strong (and ideally independent) institutions for regulation, purchasing, and quality assurance across both the public and private sectors.

Design

governance mechanisms that are robust to the influence of powerful vested interests. A message that emerges from the literature is the importance of ensuring that policy processes are open, inclusive, and transparent. Where public–private dialogue takes place 'behind closed doors', this can create risks of state capture, bias, and corruption – and can undermine core health system goals, such as primary healthcare and UHC. To mitigate such risks, and to enable state authorities to balance legitimate stakeholder interests, the focus should be on multi-stakeholder platforms (rather than public–private dialogue alone) and including patients, social insurance recipients, CSOs, in purposeful deliberation.

Ensure

that the government is also held to account. While there is considerable emphasis on holding the private sector accountable through effective governance, the public sector also needs to be accountable in its governance actions. This encompasses adherence to contract terms, transparency in tender and regulatory practices, and control over favouritism and other corrupt practices – an area which merits much greater innovation and evaluation, as indicated by the growing literature on corruption in the health sector (130)(131).

Be mindful

of path dependence. A final cross-cutting lesson is that governance choices shape not just the current behaviour of private actors, but also the future development of the health system as a whole. Once a large and powerful constituency of private facilities or health insurers has developed, it can be particularly challenging to make progress towards UHC. Conversely, sustained effective governance can shape market development in line with health system goals.

4.4 Priorities for further evidence generation

The findings from this review have been used to inform the *Progression Pathway for the Governance of Mixed Health Systems* – which, in turn, is intended to provide a standardised qualitative approach for assessing a country's current governance arrangements in relation to the private sector in health, informing policies and prioritisation, building institutional capacity, and scaling up existing examples of effective governance practice. Tracking progress against the *Progression Pathway* and the narratives that accompany it will generate important data on current and needed governance approaches.

In terms of future research priorities, this whole field deserves further investigation, as gaps were identified in the evidence base under all Governance Behaviours. The review has acted as a spotlight, revealing areas where evidence falls short and where further research is needed. By learning from countries' best practices and addressing specific country needs, future research can bridge these gaps and foster more robust and responsive frameworks for the governance of the private sector in health. In particular, there is a need for rigorous quantitative and qualitative methods to provide a detailed understanding of specific mechanisms, especially those deemed to be successful to some degree. Consultation with country stakeholders during the introduction of the *Progression Pathway* could help to prioritise specific areas that are of most relevance to them in facilitating progress in governance. These could then be explored through purposive literature searches drilling down on specific topics in more detail than was possible in this scoping review. Given the limitations of the available literature in these areas, this would best be accompanied by key informant interviews with actors with in-depth experience and expertise in these areas, and focused primary data collection to document and validate these narratives. It will be important in undertaking these case studies to consider a range of settings as different approaches may be needed in fragile settings, for example, and across low-income, lower middle-income, and upper middle-income countries.

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Annex 1
Search strategy for published articles

A.1 Medline Ovid

S. No.	Theme	Search terms
1	Private sector	private healthcare OR private health OR Private sector OR informal sector OR for-profit OR not-for-profit OR public-private OR faith-based OR non-governmental organisation OR retail OR charity OR private organisation* OR profit-driven OR privatisation OR private provider OR private health insurance OR private medical insurance OR private hospital* OR private clinic* OR private pharmac* OR drug shop* OR drug seller*
2	Limit	2010- Present
3	Governance	Governance OR stewardship OR regulat* OR engagement OR oversight
4	Limit	2010- Present
5	MeSH terms	Public–private sector partnerships/
6	Limit	2010- Present
7	MeSH terms	Private sector/
8	Limit	2010- Present
	(2 OR 6 OR 8) AND 4	Private sector (including MeSH terms) and governance

A.2 Scopus

S. No.	Theme	Search terms
1	Private sector	(TITLE-ABS ({private healthcare} OR {private health} OR {private sector} OR {informal sector} OR {for-profit} OR {for profit} OR {not-for-profit} OR {not for profit} OR {not for-profit} OR {public-private} OR {public private} OR {faith-based} OR {faith based} OR {non-governmental organisation} OR {non-governmental organisations} OR retail OR charity OR {private organisation} OR {private organisations} OR {profit-driven} OR {profit driven} OR privatisation OR {private provider} OR {private providers} OR {private health insurance} OR {private medical insurance} OR {private hospital} OR {private hospitals} OR {private clinic} OR {private clinics} OR {private pharmacy} OR {private pharmacies} OR {drug shop} OR {drug shops} OR {drug seller} OR {drug sellers}))
2	Governance	(TITLE-ABS (governance OR stewardship OR regulat* OR engagement OR oversight))
3	Health specific	(TITLE-ABS (health OR medical))
4	Limit	PUBYEAR > 2009 AND PUBYEAR < 2023
5	(1 AND 2 AND 3) AND 4	Private sector and health and governance

A.3 Web of Science

S. No.	Theme	Search terms
1.	Private sector	(TI= ("private health*" OR "Private sector" OR "informal sector" OR "for-profit" OR "for profit" OR "not-for-profit" OR "not for profit" OR "not for-profit" OR "public-private" OR "public private" OR "faith-based" OR "faith based" OR "non-governmental organisation*" OR retail OR charity OR "private organisation*" OR "profit-driven" OR "profit driven" OR privatisation OR "private provider*" OR "private health insurance" OR "private medical insurance" OR "private hospital*" OR "private clinic*" OR "private pharmac*" OR "drug shop*" OR "drug seller*")) OR (AB=("Private sector" OR "informal sector" OR "for-profit" OR "for profit" OR "not-for-profit" OR "not for profit" OR "not for-profit" OR "public-private" OR "public private" OR "faith-based" OR "faith based" OR "non-governmental organisation*" OR retail OR charity OR "private organisation*" OR "profit-driven" OR "profit driven" OR privatisation OR "private provider*" OR "private health insurance" OR "private medical insurance" OR "private hospital*" OR "private clinic*" OR "private pharmac*" OR "drug shop*" OR "drug seller*"))
2.	Governance	(TI=(Governance OR stewardship OR regulat* OR engagement OR oversight)) OR (AB=(Governance OR stewardship OR regulat* OR engagement OR oversight))
3.	Health specific	(TI= (health or medical)) or (AB= (health or medical))
4.	Limit	Manually install in 2010-2023 limit
5.	(1 AND 2 AND 3) AND 4	Private sector and health and governance

Annex 2
Amendments to the protocol

During the development of this output and our ongoing consultations with the core team at WHO, several changes were made to the original protocol for this review, as follows.

1. **Review type**: The original commission was for a systematic review, and a protocol was developed on this basis. As the work progressed, and our understanding of both the nature of the literature and WHO's evidence needs evolved, it became clear that the topic was not suitable for a systematic review, as it was much broader than the specific focused questions which systematic reviews typically address. Rather, it was agreed that a scoping review would be more appropriate for the three research questions, including a description of governance approaches and enablers/barriers to implementation, as well as assessment of effectiveness on any outcome type.
2. **Assessing papers for relevance**: On assessing papers for eligibility, we noted that many papers, while strictly meeting the inclusion criteria, contained very little detail on governance: for example, just a couple of general sentences on governance within the results, or a general recommendation for better governance but with no empirical evidence or detail on this topic. In selecting the final set of papers for inclusion, we therefore decided to only include articles containing a substantial amount of useful information on our research questions and/or information on a topic not widely covered by other papers. This was done in consultation with the screening team and the senior authors, with the support of the WHO core team members.
3. **Expanded set of extraction categories**: The protocol proposed to extract information from articles on the following: study type/design, geographical setting, governance mechanism, types of private actors, data collection dates, data collection methods, design and implementation of mechanisms, effectiveness of mechanisms, enablers, barriers, study limitations, recommendations, and other notes. Subsequently, this was expanded to also classify studies by the WHO Governance Behaviour covered.
4. **Geographical coverage**: The original protocol did not specify any geographic limitations to our search. However, it was decided to focus the synthesis on LMICs only, as most of the relevant literature identified was from LMICs, and given the major differences in the nature of health systems across income levels it was challenging to extract lessons from the available high-income country literature for LMIC contexts.
5. **Quality assessment**: The protocol proposed the use of the Mixed Methods Appraisal Tool (MMAT) to assess the methodological quality of individual studies. Given the wish to include a very wide range of study designs, some of which are more descriptive and some more evaluative, and which also include policy pieces drawing on the reflections of actors engaged in governance, we concluded that it would be challenging to conduct a meaningful quality assessment, and this was not pursued. To note: a quality assessment is not a requirement for a scoping review.

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