

WHO Guidance Note: Engagement of private providers in immunization service delivery. Considerations for National Immunization Programmes

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1. Introduction and aims

Vaccinations are a core component of the human right to health, preventing communicable disease at the individual and population levels. In 2012, the World Health Assembly adopted the Global Vaccine Action Plan (GVAP) with the goal of providing equitable access to vaccines by 2020 (1). The GVAP sets ambitious goals that may only be attainable through shared responsibility and partnerships of the various groups that are involved in providing healthcare. One the recommendations to achieve its strategic objective 4 (i.e. Strong immunization systems that are an integral part of a well -functioning health system) is to: *“Ensure coordination between the public and private sectors for new vaccine introduction, reporting of vaccine-preventable diseases and administration of vaccines, and ensure quality of vaccination in the public and private sectors”*. Furthermore, the global routine immunization strategies and practice (GRISP) a companion document to the GVAP (3), recommends activities to: *Enable and harmonize routine immunization services provided by the private and nongovernmental sector*. Healthcare systems in countries involve different combinations of public and private funding and delivery models. In April 2016, the WHO’s Strategic Advisory Group of Experts on Immunization (SAGE) stressed that the implementation of immunizations in the context of health system strengthening and Universal Health Coverage¹ requires integration between various healthcare sectors.

Indeed, successful implementation and reaching the goals of the GVAP and necessary improvements in vaccine coverage rates at all levels require the optimization of the interaction between public and private (for- profit and not-for-profit) healthcare sectors. The challenge of national vaccination programmes (NIPs) is to achieve the goal of high vaccination coverage and reducing equity gaps, often in resource-constrained settings. Engagement with the private sector to optimize effective vaccination services, has the potential to help improve the programme and increase coverage, but only if the roles are clearly defined and the services are collaborative with the existing health system and standards (4, 5). In countries where there is both public and private immunization delivery, there is often variation in coverage and accessibility of providers. The variation can be geographic and/or related to socioeconomic and/or insurance status (4, 5). As each country performs differently, and is faced with a myriad of characteristics that make it unique, a single standard approach to engaging the private sector is not realistic or appropriate. The role of the private sector (contribution to coverage, service quality, disease and adverse events following immunization (AEFI) surveillance), and its engagement with national immunization programmes varies within and between countries and remains poorly understood (4–6). This applies not only to the direct contribution of the private sector to the delivery of vaccines and the provision of health care, but also to the interaction between sectors, its impact on equity of services, level of monitoring, and degree of regulations on private providers.

¹ Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicine and vaccines for all.

This guidance note aims to:

- 1 Present considerations related to private providers involved in vaccine delivery, including potential contributions to coverage (including equity issues), vaccination practices and service quality, program monitoring, and safety and disease surveillance reporting.**
- 2 Propose a framework for facilitating the engagement of private providers, and**
- 3 Provide recommendations to support optimal engagement of private providers in immunization service delivery.**

Although recommendations are provided, recognizing the need to adapt to the specific country circumstances, the document does not intend to prescribe the type of engagement of the private providers. It does not attempt to quantify the impact of the private sector itself or create a hierarchy proposing that one system of delivery (i.e. private, mixed, or public model) is better than another. The intent is not to advocate for a greater or smaller role of the private sector in health care, but for a closer collaboration between the public and private sectors and a stronger contribution of the private sector toward national immunization programme priorities.

2. Background and definitions

A broad definition describes the private sector as, “comprising all health care providers who exist outside of the public sector, whether their aim is for philanthropic or commercial purposes” (7,8). However, there is a need to further differentiate provision and financing of health services outside of the public sector as there can be considerable overlap (5,8). In some cases, a system can be funded by the public sector through a national healthcare system, but care provided by the private sector. There are also systems that are funded by private insurance, but with care provided by public providers. Additionally, a system can exist that is dependent on a mixed-scheme of public and private funding and public and private providers as typically seen in most lower and middle income countries (LMICs) (5). This document considers the provision of vaccination and other health services provided by any entity outside of the government either by an individual or by an institution. This encompasses full-time or part-time private practitioners, private for-profit and not-for profit primary care organizations and hospitals, civil society organizations (CSOs), non-governmental organizations (NGOs), faith-based organizations (FBOs), community-based organizations (CBOs), and private companies such as mining or other large industries that provide internal medical services for their employees and their families (5). Not included in the scope of this document are the private vaccine and vaccine delivery technologies manufacturing industries, and private practitioners in the informal sector (e.g., traditional healers and informal drug retailers).

Private sector engagement (PSE) can be defined as the deliberate, systematic collaboration of the government and the private sector to move national health priorities forward, beyond individual interventions and programs(9). The process of PSE has been described for vaccine supply chains, and engagement guidance documents specific to that process have been developed (9,10), but guidance on other aspects of immunization service delivery has not been developed. Private sector health services exist in all countries to some degree, and government engagement with the private sector is underway in all countries, to variable degrees. A variety of models are being utilized to deliver immunization services between public and private providers. In some countries, FBO-managed or NGO-managed hospitals are integrated and at times nearly indistinguishable from the public sector (11). In the majority of LMICs, publicly funded immunization services are provided by public providers but in many countries private providers also contribute to the delivery of these services

(5). Private providers can work full-time in the private sector or be based out of the public sector and serve as part time private service providers. Private providers may also provide services in school and occupational health settings (12). Many high-income countries rely on private providers as their primary means for immunization delivery with established health insurance schemes. Increasingly, LMIC countries are also using the private sector to deliver core health care services funded by Universal Health Coverage programs (5,6). The private sector is sometimes perceived as serving the wealthy, but this is not strictly true. Private sector providers, including for-profit and FBOs and NGOs, often provide services to poor and rural underserved populations (5).

PSE in the health system has been shown to add value at various levels, including increased access to skills and expertise, operational efficiencies, increased innovation, shared risk, and allowing the government to focus on its core competencies (9). PSE is particularly important in LMICs, where government resources may lack the capacity to achieve national health and vaccination goals (11). More effective engagement between the public and private health care sectors in terms of better policies, regulations, information sharing, and financing mechanisms, could improve the performance of health systems (12).

There are a number of reasons why one may seek immunization services from the private sector. Immunization services may be more convenient given proximity to a private provider as frequently seen in urban densely populated locations (4). People may consider immunization services to be of better quality with increased efficiency (e.g. shorter wait times) when delivered by a private provider even if the service incurs a fee (4,11). Also, in a growing number of countries, the private sector is used by a fraction of the population who wish to have access to vaccines not provided in the national schedule (see below for further details) (4). While in some countries the use of the private sector is limited to a small portion of the population such as the wealthy, expatriates, and employees of large corporations, or people in large cities, in other countries there is an increasing share of health delivery occurring in this sector (4,5).

The NIP in countries typically leads immunization service delivery with varying contributions from the private sector. In most lower and middle income (LMIC) countries, the NIP is part of a basic public package of health services provided and financed by the government, often supplemented by international donors. A country's ability to deliver these services is affected by its economic level and governance capacity (4). Frequently, in low income countries, the ability to provide preventative services is challenged by financial constraints, a limited health infrastructure, and competing health priorities (5,12).

3. Considerations related to the engagement of the private sector in national immunization programmes

There are several considerations related to private providers involved in vaccine delivery. Limited information only exists for several of these considerations, and is summarized below.

3.1 Contribution to vaccination service delivery and coverage

Provision of health care by private providers

Standardized country-specific information about the *share of overall health expenditures* in the private sector shows that the private sector has a major role in health care delivery. For example in 2014, the proportion of private sector share total expenditure on health care exceeded 20% in 82%

of 192 countries globally and exceeded 50% in 30 % of countries², with large variation by WHO region and country income status (Figure 1). However, overall expenditures include those for curative care, which outweigh preventive care expenditures. Participation of the private sector in *preventive services* (most commonly vaccination and prenatal care) is usually more limited. For example, in Africa, private sector participation in preventive services was 45 percent in Nigeria, 30 percent in Uganda, but less than 20 percent elsewhere (13). FBOs and NGOs are the main providers of private activity, often in partnership with the public sector (13).

Provision of vaccination services by private providers

Relative to the contribution of private providers to immunization service delivery specifically, currently available data do not allow for a comprehensive quantification. The location of vaccination (private vs public sector) is not captured in demographic health surveys (DHS). Service provision assessment (SPA) health facility surveys include both public and private facilities, enabling some comparison of vaccination service delivery characteristics by public and private ownership categories (14). However, vaccination coverage is not included, and SPAs have been done in a limited number of countries. Thus the private sector contribution to vaccination service delivery remains largely unknown, as noted in both the 2011(4) and more recent review (5), and is limited to a small number of studies. The proportion of private providers that offer vaccination services varies across countries (Table 1). Generally, the proportion of private for-profit facilities offering vaccinations is lower than the proportion of private not-for-profit facilities (14). The proportion of vaccines provided by the private sector also varies widely (Table 1). The limited number of studies that compared vaccination coverage between private and public sectors used different methodologies and found both lower, higher or no difference in coverage (Table 2).

3.2 Immunization practices, service quality, and missed opportunities

A previous review found that the few studies (in Cambodia, Mauritania and Malaysia) that addressed quality of vaccination service delivery by private providers in vaccination delivery in low- and middle-income countries generally found suboptimal immunization practices and knowledge levels among private sector providers (4). More recent studies that addressed these issues are limited in number, but likewise found service quality issues. However systematic assessments that compare vaccination practices among private and public sectors over a larger number of countries are lacking. A recent study of the knowledge, attitudes, and practices of private immunization providers (paediatricians and general practitioners) in urban settings in Gujarat, India, identified several practices with safety and quality concerns and practices potentially leading to missed opportunities for vaccination (MOV). Cold-chain quality varied greatly. In almost all cases, vaccines were stored in domestic refrigerators and some stored vaccine vials in unrefrigerated thermal boxes. Expired vaccine vial monitors were noted in 18% of observed refrigerators. Vaccine schedules were not strictly followed by 45% of participants if there were concerns about ability to pay, and 60% of practitioners responded that they do not administer more than two injections in the same visit. Half of the providers responded that they would not vaccinate a child who presented for immunizations without their home-based vaccination card and half reported that they would not administer

² Analysis using Global Health Observatory data, available at <http://www.who.int/gho>

vaccines if the child was mildly ill. Few (22%) providers used a vaccine register to record vaccine doses, rendering identification of defaulters difficult (15).

Surveys in representative samples of 3,219 health facilities in four African countries (Kenya, Malawi, Senegal, Tanzania) found barriers to vaccination and missed opportunities in both private and public health facilities (14). A smaller proportion of for-profit facilities offered child vaccination services (country range, 25-37%) than did public facilities (range, 90-96%). Less than a third of for-profit facilities offered measles vaccination daily. A minority of both private and public providers assessed the child's vaccination status during a sick child visit (range by country and facility type, 14-44%), or offered tetanus toxoid during antenatal visits (range, 19-51%). Among for-profit providers, 18-32% (range across countries) assessed the child's vaccination status during a sick child visit.

3.3 Vaccination schedule

A private provider's choice of routine vaccines and administration schedule should follow those dictated by their country's national scheme. However, private providers administering vaccines outside of a contractual agreement may choose to offer different vaccines or utilize new ones that have yet to be introduced by the Ministry of Health (MOH) (5). The for-profit sector is often targeted by vaccine manufacturer marketing campaigns for new vaccines. New vaccine introduction in the private sector can place pressure on the public sector to introduce these vaccines into the NIP (5). Besides being incentivized by vaccine manufacturers to offer new vaccines, private providers may also feel market pressures to meet the requests of the client e.g., when the client requests a new vaccine, an alternate schedule or expatriates request schedules used in their own countries. While some countries have started to penalize public physicians who deviate from the recommended national schedule, this type of control can be difficult to extend to the private sector and its impact has yet to be documented (5).

Modifications to vaccination schedules and use of different vaccines in the private sector have the capability to create epidemiological gaps which can lead to increased risks for the vaccine preventable diseases in populations not covered by the private sector (16). For example, the use of rubella-containing vaccines in a subset of the population without achieving high population immunity in the whole population can shift the overall risk of the disease to older ages (child bearing age women) where the complication rate for those not protected is higher. Further, there is a risk that different vaccine schedules being used by different providers may generate confusion, questioning and lack of trust by the population. Recently, despite a synchronized global withdrawal of OPV2 and switch from trivalent to bivalent OPV vaccine, use of trivalent OPV by some private physicians in India long after the switch was discovered, resulting in a global threat. Another potential source of confusion or mistrust is the use of full dose IPV in the private sector and fractional dose in the public sector in India, driven by IPV global shortages. Harmonization of vaccine use and schedules between sectors minimizes epidemiological gaps and risks and supports equity of services between sectors as well as the credibility of the programme.

3.4 Equity of services

Ensuring equitable access to immunization services is instrumental in achieving coverage goals. Equity not only applies to access, but also extends to vaccines that are only offered in the private sector, or where the private sector might use vaccines that offer different spectrums of individual protection than their public sector counterparts. Typically, private-for-profit services favour those in urban areas and of higher socio-economic status (5, 6,11). This has the potential to

create inequity if the poorest populations are unable to access public sector or NGO services. When immunization services are covered by the national insurance scheme, inequity poses less of a threat (6). In countries where immunization services are low performing and challenged by lack of infrastructure, contracting with NGO's has shown to decrease inequity by increasing access to services in the world's poorest, most vulnerable populations (3, 6). Areas with contracted NGOs are often seen to be positively associated with the likelihood of children being immunized regardless of household wealth (6).

Inequity can also be seen at the institutional level. Governments may favour the private sector due to the perception that private healthcare is more efficient than maintaining an exclusive public healthcare system (5). The private sector's involvement can potentially undermine the public sector by diverting public health sector financing to the private sector, reducing resources available in the public sector (6). In a country where a healthcare provider may be both a government and private provider, questions may arise concerning financial incentives for providers to defer vaccination in a public setting and refer their client to a fee-based immunization programme in a private setting. Issues of equity can also arise in a setting where the private sector reaches higher vaccination coverage rates in the population it serves because of financial incentives to the provider by an insurance company or vaccine manufacturing companies (6).

3.5 Advocacy

Health workers serve as an important source of information for parents. A health worker's perception of and communication about effectiveness and safety of vaccines is important in motivating them to encourage parents to vaccinate their children (17). If a provider, private or public, is unable to communicate the need for vaccination or lacks pertinent information, this will likely have a negative impact on vaccine uptake. Additionally, if immunization services are divided between two sectors and messages are divergent, this could contribute to a loss of public confidence and possible vaccine hesitancy (5). It has been noted that improper knowledge among private providers and hesitancy is greatest for new vaccines, administration of multiple vaccines in one visit, conjugate vaccines, and where more than one vaccine type (e.g. OPV versus IPV) is currently in use (5).

3.6 Programme monitoring, coverage reporting and disease and adverse event surveillance

Monitoring of vaccine coverage and disease and adverse event surveillance are key components of a vaccination program and should include the private sector. Collection, analysis, and interpretation of surveillance data guides vaccination policies and programmes to ensure GVAP immunization targets are being reached (5). Monitoring and supervision of private provider vaccination delivery and participation in adverse event and disease surveillance activities is often inadequate (4,5). For example, the study in urban Gujarat India found that a minority of private providers (31%) reported vaccine doses to the government, and providers commonly responded that they would not report AEFIs or cases that met surveillance definitions for vaccine preventable notifiable diseases, including measles and polio. The most common reason given was unawareness of any reporting requirement (15). Particularly in LMICs, monitoring and surveillance systems put in place through contractual agreements, are often insufficient with evident gaps in enforcement and adherence (6). In high-income countries where governments have infrastructure and mechanisms in place to capture this data, it is often left to the discretion of the provider, insurance company, or manufacturer to perform data collection (6).

Assessment of the contribution of the private sector to vaccination coverage rates in LMICs can be difficult as doses delivered are often unaccounted for and reporting to the government can be sporadic and not standardized (5). Published studies on the private provision of immunization services typically focus on an individual vaccine, most commonly hepatitis B and tetanus toxoid, or a defined geographical location providing only a limited picture of the situation (5). There is often also a lack of funding and support from the MOH for documentation and information management, despite its importance in system oversight and planning (18).

Inadequate reporting from the private sector has implications for loss of information on vaccines administered and thus on coverage and disease incidence, which can affect resource allocation (5). Additionally, inadequate reporting of AEFI can lead to underreporting and inaccurate post-market safety surveillance. Lack of reporting of vaccine preventable diseases impacts detection and investigation of selected disease syndromes affecting indicators for overall immunization programme performance (5). Even if the private sector is not directly delivering vaccines, they need to be engaged in vaccine preventable diseases surveillance and AEFI reporting to help address problems that may arise at the population level. Engaging private providers through professional associations, providing professional development support, immunization forums, and creating health-information communication linkages can support a collaborative relationship and build understanding between the two sectors.

3.7 Private providers' role in policy and decision-making

Currently, the majority of industrialized and many LMICs have formally established National Technical Advisory Groups (NITAGs) to guide immunization policies and decision-making while other countries are working towards forming these groups. NITAGs serve as both a technical resource and deliberative body to guide immunization policies and decision-making (19). NITAGs are made up of core members who should be independent and credible experts serving in their own capacity and who do not represent the interests of a particular group or stakeholder (19). A credible NITAG and related processes can have a very positive impact on perceptions about vaccination and the NIP, both within government but also among professional organizations, funders and the private sector and ensure a comprehensive and cohesive country immunization service delivery perspective (19). Representation of private sector partners through liaison members representing various professional organizations, insurers or individual experts serving as core NITAG members can be extremely beneficial (5,19). Liaison members do not participate in the decision making process but they can contribute to the discussion. Including private sector members in NITAGs can allow them to share their experiences and propose solutions to addressing the barriers to comprehensive vaccine coverage. When private sector representation is low on the NITAG, this can be a barrier to regular updating of knowledge pertaining to new scientific evidence, recommendations, and changes to policies due to the absence of a communication pathway (6). The NITAG can also serve as a means to seek formal agreements with private providers who deliver vaccines. Countries with professional bodies often have an established national advisory process to issue recommendations on vaccine use for their members (19). It is important to ensure close collaboration between these professional bodies and NITAGs to avoid conflicting recommendations that may undermine the credibility of both groups and to ensure uptake of, and adherence to, the national immunization schedule in both private and public health sectors (e.g. in the past those from the US National Academy of Paediatrics and Advisory Committee on Immunization Practices) (5,19).

3.8 Private sector interaction with manufacturers

Both the 2011 review and the more recent review of the private sector's in immunization found scant literature on the relationship between vaccine manufacturers and private providers (4, 5). It is known that the for-profit sector is often targeted by vaccine manufacturer marketing campaigns for new vaccines. Regulatory requirements and standard operating procedures should apply for both private and public sectors, including regulations for vaccines that are donated or offered "free" to the private sector (5). Additionally, it has been feared that some private providers may be reluctant for vaccine manufacturers to lower vaccine prices as this could result in decreased profit margins in settings where client charges are based on a percentage of vaccine costs.

4. Framework for engaging the Private Sector to Support National Immunization Programmes

Engagement with the private sector can improve the use and effectiveness of existing resources. Suggested steps for a strategy of the NIPs to engage private providers include the following:

4.1 Assessment of private providers in immunization service delivery

4.1.1 Review existing information about the private sector contribution to immunization coverage, adverse events and disease surveillance, and service quality issues.

Limited information about the private sector role in immunization delivery may exist, but may be available from administrative data (if private providers receive vaccine from the government), coverage surveys, facility surveys (e.g., service provision assessments) or specific studies. If private sector already provides a significant proportion of vaccinations, engagement could focus on service quality issues. If private sector providers do not contribute a significant proportion of vaccinations a potential role for them to expand the reach of the public sector could be considered.

4.1.2 Identify and inventory key stakeholders in private sector involved or potentially involved in vaccination

The NIP should identify and inventory the potential players and stakeholders from the private sector, e.g., "who is doing what and where", covering all aspects of the immunization programme (vaccine manufacture, import, procurement, education and social mobilization, vaccine programme delivery, to post-market surveillance including surveillance of vaccine preventable diseases and AEFIs). This exercise can be useful to foster conversations with private sector players to include in the engagement process and also to flag major system challenges relevant to private sector players and allow identification of policy reforms, system changes and potential activities that could address these challenges (11, 12). Governments could begin by initially targeting highly influential stakeholders who favour collaboration, then target stakeholders who are in favour but less influential, and finally, inform or co-opt those who are not in favour and are influential by keeping them informed (12).

4.2 Determination of optimal model of public private engagement

There are a number of countries that have engaged well with private providers and have used it as an engine to increase the reach of their immunization programme. Regardless of whether the public sector proactively engages with the private sector, the latter is already playing a role in immunization in most, if not all, countries (10). CSOs, NGOs and FBOs often play several roles in NIPs, e.g., education, advocacy, awareness raising and demand creation, resource mobilization, vaccine-preventable disease surveillance, provision of immunization services (11,18). In many LMIC countries these organizations, typically not-for-profit, have had longstanding arrangements with NIPs to provide vaccination services. Specific arrangements relative to technical and financial support vary. The government of Afghanistan contracts out the bulk of health service provision, including immunization, to CSOs. Health Net TPO, a health-focused NGO and key partner of the Ministry of Public Health in Afghanistan, runs the entire health system in 3 provinces (18). CSO leadership has been credited as playing a key role in the success of immunization coverage in spite of the country being ravaged by war (18). In a different type of arrangement vaccines are sourced by the MOH and then distributed to private providers for administration (5), an arrangement that has the advantage of increased control and standardization of the messaging about the vaccine. Providers report on the number of vaccines given, or participate in national immunization registries (4). This collaboration may stipulate that the private sector adheres to national standards of immunization service provision including reporting, monitoring, and quality service delivery (4, 6). Contracts that encompass technical support, or well-defined programme goals and consistent monitoring generally have a greater chance of producing higher coverage rates (3,4). Of note however, there is little information on the extent of government support to and successful arrangements with the private sector in LMICs. A survey of in Ghana and Kenya found that few private clinics reported receiving assistance for immunization service delivery. In Ghana, only 12% of private clinics, and in Kenya, only 20% reported financial or technical assistance from the government for childhood vaccinations (13).

High-income countries typically utilize the private sector to deliver the majority of their vaccinations and have mechanisms in place to capture vaccine coverage data (4). Private sector data is either submitted to the public sector at established time points, or to private physician associations who in turn report claims data to assess coverage (4). This leads to more complete information on vaccine coverage compared to LMICs, though gaps in reporting have been identified (4).

4.3 Development or expansion of collaboration and dialogue to achieve common immunization goals

In order to overcome preconceived misconceptions and biases between the public and private sector, private sector engagement must be approached in a way to maximise trust and predictability (11). Unpredictable policy changes, including changes in legislation, regulatory enforcement or subsidy allocations prevent long-term, scaled-up investments with the private sector (11). To build trust and foster dialogue, it is important to build engagement step by step through transparency, sharing united visions and long-term goals; with realistic expectations on both sides of relative contributions, capacities and timelines (9). Using approaches in change management can help alter attitudes and foster collaborative partnerships in PSE (20). Starting with small collaborative projects and building overtime, with the opportunity for quick wins to demonstrate progress, is part of this relationship-building process and allows partners to demonstrate commitment (9).

According to the World Bank's Healthy Partnerships guide, policy and dialogue are the foundations of effective private-public engagement (11). Meaningful dialogue between the public and private sectors around mutual goals, expectations and limitations is necessary to build trust and understanding (11). In order to foster collaborative engagement between the public and private sectors, there are 4 elements of good practice in policy and dialogue:

1. a high level of on-going implementation of engagement policy,
2. formally instituted dialogue mechanisms,
3. on-going dialogue between the government and the private sector, and
4. government policy to work with the private sector as a partner in the delivery of services (11).

In order to foster policy that supports PSE, many governments must revise existing immunization policy, or design new policies (12). Clarifying roles to support collaboration through policy frameworks may alleviate suspicion and mistrust between the government and the private sector, while improving effectiveness (12). The policy revision process involves developing public-private dialogue structures, identifying dialogue opportunities, and gaining stakeholder consensus (12). The opportunities for structured dialogue include participation in task forces, leadership committees, information sharing, and involvement in policy changes and prioritization (11). Involvement in task forces at various administrative levels allows private sector members to stay current with issues and play a part in offering solutions (21). One important way of collaborating with the private sector is its involvement in National Immunization Technical Advisory Groups (NITAGs).

4.4 Development of collaborative activities, agreements and contracts

One of the most important elements for engaging with the private sector in developing PSE policy, besides dialogue, is the development collaborative activities and formal agreements. National and regional immunization plans, programmes and strategies should not only be developed in collaboration with the private sector, but should also clearly articulate the private sector's role and expected contributions to both implementation and monitoring (21). Signed agreements, memorandums of understanding (MOU), or contracts can be developed between governments, development partners, and the private sector to formalize and clarify relationships, which can allow the private sector to expand their reach and contribution to immunization plans and programmes (21). This can be complex in view of the multiplicity of providers and it is clearly best if agreement can be negotiated with professional or umbrella organization. Governments may need to build capacity around contract development, negotiation and enforcement (9). MOUs are formalized statements of mutual expectations between two organizations or groups (22) MOUs can be useful for coordination of services: to specify services provided, facilitate communication processes, formalize partnership statuses, specify responsibilities and transfer authority within a partnership (22, 23). Contracts are more formal, and considered legally binding documents compared to MOUs. Contracts are one way for governments to collaborate with the private sector in order to achieve national vaccination goals (12). There are definite benefits of contracting the private sector to deliver various aspects of immunization services (9,13). Contractual agreements that encompass technical support, or well-defined programme goals with consistent monitoring, evaluation, as well as financial incentives, can be successful in producing high vaccination coverage rates (5). The private sector is more inclined to seriously consider collaboration and dialogue if there is a likelihood of being contracted to provide vaccination services (11). It is essential for all parties to enter contracts with clear expectations on performance, including performance measurement and consequences (9,20). However, contract development for PSE can be challenging. The contracting public sector needs to

know how to write, enforce and monitor a contract that includes important elements including payment terms, performance expectations, assessment, and contract renewal (9,20). The contract manager on the public side must be a senior official with project management experience, support and authority (20). There are practical toolkits available to help governments with the process of contracting (11). There is a tendency for governments to limit PSE to short-term contracts, such as 1 to 2 years in length, for various reasons including government funding cycles (9,20). However, this short time period is not long enough to allow for stable cash flow to justify the risk for many in the private sector (9,19). The other aspects that are necessary for successful PSE contracts are realistic key performance indicators, flexibility in allocation of resources, and payment (9). Further, appropriate contract oversight is necessary in order to ensure that deliverables are being met, issues are being resolved, and communication among stakeholders is effective (9). In some countries, NGOs and CSOs have umbrella organizations, platforms or coalitions representing multiple entities in the private sector that can participate in the PSE process (11,21). Coalitions also provide an opportunity for the private sector to shift some oversight responsibility from the government to the representative body (11).

4.5 Training and capacity building

Enhancing professional knowledge and skills through training and competency exams ensures accurate knowledge transfer and directly supports the success of immunization programmes and particularly the quality of the vaccination programme and its monitoring as well as disease surveillance. When providers have up-to-date information on changes in immunization theory, practice, and policy they can vaccinate safely and within their scope of practice (4). Training and quality standards not only apply to delivery mechanisms and immunization schedules, but extend to the safe and appropriate use of injections, proper vaccine storage and handling, screening for contraindications, proper recording, and safety surveillance.

Quality standards not only apply to vaccine information communication, but extend to the safe and appropriate use of injections including pain mitigation steps on immunization, proper vaccine storage and handling, screening for contraindications, proper recording, and safety surveillance. This also includes adhering to vaccine expiry dates. In most LMICs mechanisms to enforce quality standards for vaccine storage and administration in the private sector are limited due to human and financial resource constraints (4,5). NIP standards may only extend to contracted private sector services that have training and guidelines incorporated into their MOU (4,5). However, training accreditation and regulation does not have to be carried out by the government (11). In the Dominican Republic, INSALUD, a coordinating organization for more than 100 NGOs, participates in a National Commission for NGO Qualification and Accreditation, ensuring that NGOs receiving public funding are in compliance with requirements, standards and norms (11).

4.6 Regulation, standards and quality control

The three core aspects of regulatory functions include: registration and recording of new players in the health market, a quality regulatory framework for requirements of opening new facilities and inspections that do not discriminate between public and private, and effective enforcement of regulations (11). Regulations and standards can include (but are not limited to): vaccine schedules, licensing requirements, price controls, regulation of vaccines, regulation of private insurance, and fee waivers for those in poverty (12). Regulation can also require health professionals to attend continuing medical education (CME) before being able to renew their license

to practice (11). To be able to enforce regulation, governments must have a registry in order to know who is operating where (11). In many cases, professional self-regulation or third-party accreditation can relieve government of the burden of standards and enforcement (11). While the public sector is typically required to follow to the national schedule, without requirements the private sector may choose to offer different services based on a variety of factors including cost, supply, and client demand. One way this can manifest is when the client requests an alternate schedule or expatriates demand schedules used in their own countries (5,22). Some countries have started to penalize public physicians who deviate from the recommended national schedule, however, this type of control is difficult to extend to the private sector (5).

In most LMICs mechanisms to enforce quality standard for vaccine storage and administration are absent due to limited human and financial resources (4, 6). NIP standards only extend to contracted private sector services that have training and guidelines incorporated into their Memorandum of Understanding (MOU) (4, 6). In some settings, this can lead to private sector services being inferior to those administered in the public sector (4). Areas most commonly identified with breakdowns in quality standards include temperature chain management, immunization schedules, consent, and waste management (4,5,21). However, supply chain maintenance contracting with the private sector for the public sector has also had success and improved vaccination system efficiency (9,24). In the majority of high-income countries, infrastructure is in place to support private sector provision of vaccines (4). Here, information is more commonly exchanged between the public and private sector supporting quality standards and more frequent trainings and competency exams (16). There is a need to unify the standards between the public and private sector and for private providers to be routinely trained on immunization related topics to ensure even standards across sectors. Private providers can use a variety of mechanisms to procure vaccines and injection supplies through government channels or private suppliers and distributors. In some countries vaccines are sourced by MOHs and then dispatched to private providers for administration (5). There may be attempts from vaccine manufacturing industry to influence the private providers through advocacy promoting the use of their products even if not in agreement with the national immunization programme, unless it is carefully regulated.

Information disclosure and availability is essential in health systems planning, evaluation and surveillance, but currently in many countries the private system is not integrated or non-compliant with reporting (11). Reporting requirements must be reasonable, aligned with national priorities, and a single comprehensive system for both public and private sectors (11). There must be a legal requirement for the private sector to provide information to the government, and accountability systems to ensure that the data reaches the appropriate department (11). The private sector must be included in national vaccine coverage, vaccine preventable diseases and AEFI surveillance systems (11). Information must flow in both directions: data is collected and submitted to the government, and the government distributes regular surveillance, regulation and policy updates to the private sector (11,21). Currently information exchange between the public and private sector is weak in most countries, despite legal requirements existing in most (11). To strengthen reporting, the private sector can be involved in surveillance activities. The private sector must also be adequately trained to fulfil these tasks and be reimbursed for the investment of time.

Assessment of provider performance and feedback interventions are powerful strategies to improve vaccination practices and coverage.

5. Recommendations

NIPs should increase collaboration and communication with private providers delivering vaccination services regardless of the relative contribution of private providers to the delivery of vaccination.

Assess

- Countries should conduct an assessment of the current role of private providers in immunization service delivery, including their contribution to coverage, immunization advocacy, adverse events surveillance and vaccine preventable disease surveillance.
- An inventory of key players/stakeholders should be done to identify problems, strengths and challenges, and to identify what is needed to address the issues identified in the assessment.

Optimize service delivery

- The NIP should determine the optimal model for engagement with private sector that addresses identified issues and is tailored to the country immunization system (e.g., whether government supplies vaccines to private provider or not, existence and role of active professional bodies).
- The NIP should ensure that appropriate schedules and high-quality practices are implemented by private providers and that they are held to appropriate vaccine handling and storage standards. If vaccines administered in the private sector are provided by the public sector, they should be provided free of charge and private provider should comply with national reporting requirements and approved cold chain and vaccine handling practices. Measures should be taken to harmonize the private sector and government vaccination schedules ensure that all public and private vaccine providers are adhering to the national immunization schedule. This can be aided by having national vaccine procurement schemes, financial incentives through vaccine subsidy, capitalizing on the credibility of the NITAG and its involvement of the private sector, and appropriate communication.
- The NIP should consider feasibility of contracting portions of vaccination service delivery or supply chain to private providers to optimize capacity and efficiency, but this should be approached at a pace that minimizes risk.
- To prevent missed opportunities, private and public providers should use all clinical encounters to assess vaccination status and vaccinate clients as appropriate.
- Private providers should educate clients, parents, and guardians on the importance of vaccination and advocate for vaccination. Communication and advocacy efforts should align with and be supportive to the NIP.

Facilitate dialogue and decision making

- The NIP should provide the private sector with guidance on advocacy, AEFI and vaccine preventable disease reporting, and communication regarding immunization practices.
- Countries are encouraged to include private provider representation in NITAGs both as core members and as liaison members representing professional bodies and important NGOs. This will support two-way communication flow and ensure that private sector issues are considered at the time when recommendations and policy guidance are being developed.
- Professional bodies and NITAGs should work with one another to ensure harmonized immunization schedules.

Ensure data management and reporting

- Governments or professional organizations should develop a database with information on all providers offering immunizations at the district and state level. The database should include the providers' contact information, list of vaccines provided, target population/catchment area, vaccine schedule, if the service is fee based, and where vaccines are procured. Health system mapping is important for identification of inefficiencies and the need for additional activities to achieve national immunization goals. The database is also critical for determining what regulations are needed.
- Countries that provide free vaccines to the private providers for administration should require those providers to report vaccine doses administered in a standard format using data recording tools and reporting processes from the NIP.
- Countries should establish clear reporting mechanisms between the private providers and the NIP to ensure that immunizations and related information (e.g. vaccine doses administered and disease and AEFI surveillance) are reported according to the same standards. The NIP should provide training and supervision on data recording and reporting to ensure appropriate and timely use by private providers leading to complete reporting.
- The private sector should be provided with adequate supplies of the national immunization/health cards recording tools, including home-based records, and health-education materials including checklists for systematic screening and vaccination job aides.

Provide adequate training and capacity building

- The NIP should increase communication and collaboration with private providers delivering vaccination services, tailored to the role and contribution of private providers to vaccine delivery. This includes information dissemination when new scientific findings are released, notification of changes to the national immunization schedule, private sector involvement during NIP trainings and consideration of designing specialized capacity building training programmes for health workers who provide vaccination at private facilities.
- All vaccinators in the private sector should undergo training on immunization. Initial training should be supplemented, ideally with yearly refresher courses followed by competency assessments. Key topics should include current schedules, new vaccines, storage, cold chain management, vaccine vial monitors, communication, advocacy, multiple injections, adverse events and notifiable disease reporting. If the private sector does not have the capacity to implement such training they should reach out to the NIP for support and guidance.

Facilitate accountability and performance oversight

- Countries are encouraged to engage the private sector through legislation regarding the development and implementation of immunization policies and laws. Policies and laws should include surveillance, monitoring, reporting, and regulations pertaining to immunization services. Regulations can include vaccine schedules, licensing requirements, price controls, regulation of vaccines, regulation of private insurance, and fee waivers for specific populations.
- In the absence of specific legislation, countries are also encouraged to engage the private sector via contractual agreements or memoranda of understanding (MOUs). Contracts and MOUs should clearly state the role of both the government and the private sector and include

supervision, surveillance, monitoring, training, and evaluation. They should explicitly note any payment that will be made to the private sector. Governments may need to increase capacity in development and negotiation of MOUs and contracts.

- Systems are needed to ensure adequate practices in all facilities delivering vaccines, including proper storage and handling, appropriate use of injections, screening for contraindications, proper recording and adherence to safety measures, and waste management and disposal. This may be managed by the health system through initial and/or periodic public health inspections, or by independent professional bodies.
- Countries should establish a system for the monitoring of quality standards by private providers. For countries that do not have infrastructure in place to implement regulations that are supported by monitoring and enforcement mechanisms, the NIP should provide documents to the private sector outlining guidance on regulations, enforcement, and compliance.
- There should be regulation and enforcement of adequate training of vaccine providers. This can be done through professional bodies or licensing legislation.
- Vaccines procured by private providers should be held to the same regulatory standards and oversight of the national regulatory authority (NRA) as those procured by the NIP. Regulatory requirements should not be waived for “free” or donated vaccines.
- NIPs should work through professional societies to develop and adopt standards of practice. NIPs should provide feedback to private providers on their performance relative to quality of services delivered
- Enforcement of the above recommendations can be achieved through a variety of mechanisms, but is challenging in resource-constrained settings. Professional self-regulation and third-party accreditation processes can relieve much of the regulatory burden from the government.

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Table 1. Proportion³ of private providers providing vaccination services and proportion of vaccinations provided by private providers, by World Health Organization (WHO) Region as reported in publications and expert interviews.

Data from recent review⁴ of papers since 2009, from 2011 literature review⁵ of papers before 2009 (shaded) and recent paper by Olorunsaiye et al 2017⁶

Country (year data collected)	% Private providers providing vaccinations		% Vaccinations provided by private providers	Source of information	Comment
WHO African Region					
	For profit	Not-for profit			
Kenya (2010)	37	80		Olorunsaiye et al 2017	Service provision assessment (SPA) facility surveys
Tanzania (2014-15)	27	79		“	“
Senegal (2012-13)	30	79		“	“
Malawi (2013-14)	25	95		“	“
Kenya (2010)	34	80		Sood & Wagner, 2013	SPA; community, provider surveys
Nigeria, Abia State, 4 LGAs , urban, peri-urban (2011)			21	Oluoha et al, 2014	Monthly administrative data; 45% of facilities offering vaccine were private.
Uganda, Kampala (2010)			30	Babirye et al. 2014	30% respondents reported using for-profit providers
Ghana (2006)			40	Bass 2006	Mission hospitals. Traditional EPI estimates
Ethiopia (2006)			1 (0-3 across regions)	Ethiopia government	Survey 2006
Kenya, some north and northeast districts (2000)			45-60	Bass 2006	Traditional EPI vaccines
Mauritania (2003)			10	Ouedrago 2003	Traditional EPI vaccines, Hep B, Hib
Zimbabwe (1998)			0-3	Madrid report 1998	Hib

³ Percentages rounded to whole number

⁴ Mitrovich R, Marti M, Watkins M, Duclos P. A Literature Review of Immunization Service Delivery by the Private Sector in Low, Middle, and High-Income Countries. Draft.

⁵ As reported in Levin A, Kaddar M. Role of the private sector in the provision of immunization services in low- and middle-income countries. Health Policy Plan. 2011;26(SUPPL. 1):4–12.

⁶ Olorunsaiye et al. Missed opportunities and barriers for vaccination: A descriptive analysis of private and public health facilities in four African countries, in press, Pan African Medical Journal. 2017

WHO South-East Asia Region				
India total (2009)		9	UNICEF Coverage Survey 2009	Household survey;% partially/fully immunized in private sector
India urban		21	"	"
India rural		6	"	"
India highest quintile		34	"	"
India range by state		1-28	"	1 (Sikkim)-28 (Delhi)
India,16 states.>90% India birth cohort.(2009-12)		5 (BCG)	Sharma et al. 2016	Estimate based on sales data. Weighted mean. Range 1 (Bihar)-17 (Punjab-Haryana)
		4 (Measles)	"	Range 1 (Assam)-19 (Kerala)
		2 (DTP3)	"	Range 1 (Orissa) - 7 (Kerala)
		4 (OPV)	"	Range 0.1 (W Bengal)-82 (Kerala) OPV3> actual due to likelihood of >4OPV doses/child
		4 (Hib)	Sharma et al. 2015	
Bangladesh, Dhaka city ()		95	Uddin et al. 2012	
Bangladesh (2005)		1 (for-profit) 4 (not-for-profit)	Bass 2006	
Bangladesh (2000)		22 urban, 3 rural	Bass 2006	
Bangladesh, Dhaka (1999)		2	Levin 1999	
Bangladesh, Dhaka		62	Kahn 2004	NGOs
India		10	Peters 2002	
India 1995-6		17 in children, 36 in women	Howard and Roy 2004	National coverage survey
India, Madha Pradesh		27 urban, 15 rural	Yoong 2007	
India, Chandigarh		66 (Hep B)	Puri 2007	
		45 (Hi)b	"	
		100 (typhoid)	"	
		100 (MMR)	"	
		100 (varicella)	"	
Sri Lanka 2007		15 national 34 (Columbo) 1 (Monaragala)	Agampodi and Amarasinghe 2007	0 in Anuradhapura Trincomalee, Matale
Thailand 1998		10 national, 33 urban	Madrid report, 1998	

WHO Western-Pacific Region				
Philippines		10	L Suy 2016	Estimate from interview
Republic of Korea	60		Cho et al. 2010	
Cambodia	65 (provided at least 1 antigen)		Soeung et al. 2008	% of for-profit facilities offering specific antigens: 56 (HepB), 35 (tetanus), 10 (BCG), 4 (DTP), 4 (measles), 36 (rabies), 12 (typhoid), 10 (JE)
Cambodia		30-40	Bass 2006	
WHO Eastern Mediterranean Region				
Bahrain		<10	J Jawad, 2016	Estimate from interview
Lebanon		60 (for profit 40 (not for profit)	A Rady 2016	Estimate from interview
Pakistan		3	Hasan Q et al as referenced in Zaidi. 2012	National coverage survey. 4% for women vaccination
Pakistan urban (Karachi)		25	Siddiqui N et al as referenced in Zaidi. 2012	
Morocco (1998)		5	Madrid report 1998	Hep B, Hib
WHO Region of the Americas				
Caribbean		10-20	Irons & Dobbins 2011	
Mexico		5	J Santos 2016	Estimate provided in interview
Quebec, Canada		20	M Landry 2016	Estimate provided in interview
United States		61- exclusively in private 23-combination public/private	Groom et al. 2007	61% children vaccinated exclusively in private sector; 23% combination of public and private
Brazil, Sao Paulo state (2008)		1.3	De Soarez 2008	
Honduras		1.6	Epi Newsletter 1998	
Nicaragua		5	Epi Newsletter 1998	
Panama		15	Epi Newsletter 1998	
El Salvador		5-10	Epi Newsletter 1998	
Costa Rica		1-2	Epi Newsletter 1998	

WHO European Region				
Catalonia, Spain (2003-4)		31 (EPI series) 63 (varicella) 47 (PCV7) 52 (Hep B)	Borras et al, 2009	Telephone survey of parents of 3 yr-olds.
Germany		90	O Wichmann 2016	Estimate from interview
Greece		33	Pavlopoulou et al. 2013	
Austria		90	O'Flanagan et al. 2012	Estimate reported in survey of vaccine program managers (children <3 yrs)
Belgium		20	"	"
Cyprus		57	"	"
Czech Republic		95	"	"
France		90	"	"
Greece		70	"	"
Hungary		<1	"	"
Ireland		100	"	"
Latvia		1	"	"
Luxemburg		100	"	"
Malta		10	"	"
Poland		5	"	"
Romania		10	"	"

Table 2. Summary of studies comparing vaccination coverage by private and public providers, as reported in literature

Country, Year, setting	Source	Vaccine	Study type	Coverage	Other finding
Kenya (2010)	Sood and Wagner 2013	No vaccination	Modelling from SPA and DHS surveys	Odds of not being vaccinated 4.8 times higher where facilities are for-profit compared to areas with no for-profit facilities.	
Sub-Saharan Africa	Wagner, 2014			BCG coverage for child born in private facility (45%), less than for child born in public facility (55%)	
Gabon, Libreville	Ategbo et al. 2011	EPI antigens		Private for-profit coverage higher than public sector. Coverage of 3rd dose DPT, polio vaccine (90%), and measles (83%) at private clinics, 75% and 64% at public clinics.	
Philippines 2011, 142 government clinics, hospitals and private hospitals in regions with low Hep B-birth dose coverage.	Patel MK et al 2013	Timely (within 24 hrs of birth) Hep B- birth dose coverage	KAP	Private hospitals had lowest median timely HepB-birth dose coverage, 50% among private hospitals, 90% among government clinics, 87% among government hospitals ($p = 0.02$)	Private sector delivered 18% newborns. Private hospitals less likely to receive supervision (6–31%) than government facilities (53%) and to report vaccination data to EPI (36% vs. 96%–100%)
Vietnam	Murakami et al. 2008	Timely (within 72 hr of birth) Hep B- birth dose coverage		Hep B-BD (within 72 hrs of birth) coverage lowest (47%) in province with the highest % deliveries in private facilities	
Pakistan 2015 2 remote rural districts	Zaidi, 2015	BCG		In 1 district BCG coverage was 11 percentage points higher in contracted NGO clinics than in government clinics ($p<.01$), but not significantly different in other district. No difference in TT coverage between NGO and government facilities in either district.	
Catalonia Spain (2003-4). Survey of parents	Borras et al 2009	Basic series + booster		No difference in coverage (basic series+booster), 88% for both private and public	

Figure 1. Proportion of countries with >50% Private Expenditure on Health of Total Expenditure by WHO Region and Income Level (n=192)

