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Summary

Many low and middle-income countries have pluralistic health systems with a variety of providers of health-related goods and services in terms of their level of training, their ownership (public or private) and their relationship with the regulatory system. The development of institutional arrangements to influence their performance has lagged behind the spread of these markets. This paper presents a framework for analysing a pluralistic health system. The relationships between private providers of health services and government, or other organisations that represent the public interest, strongly influence their performance in meeting the needs of the poor. Their impact on the pattern of service delivery depends on how the relationships are managed and the degree to which they respond to the interests of the population. Many governments of low and middle-income countries are under pressure to increase access to safe, effective and affordable health services. In a context of economic growth, it should be possible to improve access by the poor to health services substantially. Innovations in information technologies and in low cost diagnostics are creating important new opportunities for achieving this. It will be important to mobilise both public and private providers of health-related goods and services. This will involve big changes in the roles and responsibilities of all health sector actors. Governments, businesses and civil society organizations will need to learn how to make pluralist health systems work better through experimentation and systematic learning about what works and why.

Keywords: health markets; private health sector; health system regulation.

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Introduction

The Centre for Business and Development has several reasons for making health one of its priority sectors. These include the size of the health sector, the importance of access to safe, effective and affordable health services to individuals and to the businesses, which employ them, and the degree to which health systems are changing in a context of rapid, market-led economic growth, technological innovation and globalization.

According to data published by the WHO (2014), expenditure on health services accounted for 10 percent of global GDP in 2011, varying from 3.6 percent in the Southeast Asia Region (SEARO) to 14.8 percent in the Region of the Americas (PAHO). A significant proportion of this expenditure (40.2 percent) was from non-government sources, varying from 24.6 percent in EURO to 63.0 percent in SEARO. These percentages underestimate the economic importance of health and health services since they do not include the value of unpaid time that family members spend caring for the sick and they do not include the loss of productivity when someone falls ill. This highlights the potential significance of measures to improve health sector performance.

Health and health services are important to all social groups, including the poor. Almost all governments in the immediate post-colonial and post-revolutionary periods promised to provide universal access to health services. These commitments were expressed in national policies and global commitments to the achievement of “Health for All”, although in many cases, these ambitious goals were not reached. Studies of the viewpoints of the poor have consistently found that they give high priority to services that help them cope with major illnesses, which can disrupt livelihood strategies and drive them deeper into poverty. These factors have made health a political issue in many countries and a number of governments have made renewed commitments to achieve universal health coverage (UHC). Many international organisations, donor agencies and foundations have made support for UHC a priority. Substantial progress towards this goal will require, amongst other things, big improvements in the performance of markets for the medical care and drugs that poor people need.

Sickness and poor health affects businesses through reduced productivity of their employees and the loss of skilled personnel. Where businesses provide their employees with health care or access to health insurance, they bear a share of the costs of ineffective and unnecessarily costly services. These employers have a direct interest in measures to improve health system performance. Businesses can also have a negative impact on the health of their employees or of the wider community if they do not pay attention to occupational health or environmental pollution.

Market relations have spread rapidly within the health sectors of many countries (Bloom et al 2013). In 2011 out-of-pocket payments accounted for 25.5 and 50 percent of total health expenditure from the Africa and Southeast Asia regions of WHO, respectively (WHO 2014). Although some of these funds were paid as fees to government facilities they were also used to purchase health-related goods and services in the market. A number of studies suggest that more than half of health care visits are to informal providers in a number of countries (Sudhinaraset et al 2013) The spread of health markets has been associated with a variety of factors that include economic crisis and prolonged financial constraints in the public sector, major increases in the role of markets in development strategies and growing demand for health services linked to rising incomes, ageing populations and rapid growth in access to communications media (Bloom and Standing 2008). The creation of appropriate institutional arrangements to encourage good performance by market actors has lagged behind this development. The spread of health-related markets has created both opportunities and challenges. It has enabled many people to get better access to drugs and some form of

medical advice at a relatively small cost. But, it has been associated with a number of problems with the safety, effectiveness and cost of basic health care and with the lack of an effective referral system for the poor (Peters and Bloom 2012).

The demand for health goods and services has risen substantially in countries that are experiencing rapid and sustained economic growth. This is creating important market opportunities to which firms are responding. It is also opening up big opportunities for testing new ways of organising the health sector, without the major constraints to innovation that the complex institutional arrangements in the advanced market economies represent (Ehrbeck et al 2010). The new technologies and new organisations that emerge are likely to have a significant impact on national and global markets for health-related goods and services.

Technologies, such as use of mobile phones and low cost point of care diagnostic tests, are evolving rapidly, as are private companies that are trying to build new markets, based on these technologies. Some analysts argue that disruptive innovations, such as these, could lead to a major transformation in health system organisation. This is contributing to a growing interest in strategies for encouraging the development of innovations, which could benefit the poor, and in strategies for managing major health system changes to ensure that the needs of the poor are taken into account (Christensen et al 2009).

There is a high degree of inter-connection between local, national and global market actors and between health and related sectors. Large international companies from the advanced market economies and the rising powers are increasingly operating in markets about which they know very little. Meanwhile, poorly functioning markets in one locality can have major global consequences, such as the emergence of treatment resistant organisms and the undetected spread of a pandemic disease. It is becoming increasingly difficult to separate national and global levels of regulation and standard-setting (van Zwanenberg et al 2012)

Until recently, discussions about health markets have largely been about the appropriate roles of public and private actors in the delivery of health services. These discussions were strongly influenced by competing ideological preferences. One result is that most research on health systems in low and middle-income countries has focused on the public sector. Studies of the private sector have tended to be concerned with quantifying its size and comparing the quality of its services with those of the public sector. But health systems in these countries have increasingly been characterised by pluralism and marketisation, where the boundaries between public and private are porous and many actors with different relationships to states and markets provide goods and services to different population groups (Mackintosh and Koivusalo 2005; Bloom and Standing 2008). A recent systematic review of evidence on strategies for improving the performance of health markets in low- and middle-income countries (Leonard et al 2013) noted that there has been much less analysis of the pluralistic health systems that have spread so widely and of effective strategies for managing them.

This paper draws on the findings of several years of collaboration between the authors and partners in the DFID-funded Future Health Systems Consortium of research institutes in Africa and Asia, under the leadership of the Johns Hopkins School of Public Health. During 2006-11 the consortium's work on health markets focused on the role of informal providers in Nigeria, India and Bangladesh (Bloom et al 2013). In December 2012 it organised a meeting in Bellagio with government policy-makers, health system entrepreneurs, researchers and funders of intervention research to review the state of knowledge and identify priorities for engaging with health markets. Many of the findings are available in a special issue of Globalization and Health, which focuses on the challenge of regulation and on strategies for facilitating learning about the functioning of rapidly changing health markets (Bennett et al 2014; Bloom et al 2014 and Stallworthy et al 2014). The second phase of work, until 2016,

focuses on the emergence and diffusion of potentially disruptive innovations and on managing change in complex and dynamic contexts.

The remainder of the paper is structured as follows: section 2 introduces health markets and the pluralistic health systems of low and middle-income countries; section 3 focuses on potential strategies for engaging with and bringing order to these markets; section 4 explores selected technological developments that have the potential to disrupt health markets and section 5 concludes with a brief discussion of activities for generating knowledge for more effective engagement with health-related markets.

1 Analysing a pluralistic health system

Analysts almost unanimously agree that unregulated markets perform badly in meeting a population's health needs. Table 1 lists widely acknowledged failures of health markets. This paper focuses on curative medicine, which is largely a transaction between providers and recipients of services (Harding and Preker 2002). It pays little attention to health promotion and prevention, which have a substantial public goods element. It also does not discuss alternative ways to provide financial protection and reduce economic barriers to care, although these are essential elements of a health system that meets social needs. The market failure especially relevant to personal medical care concerns asymmetry of information between providers and users of health-related goods and services (Bloom et al 2008; Leonard et al 2013). This refers to the differences between them in the levels of expert knowledge they possess. Potential users need to be able to identify providers who have the necessary expertise and can be trusted to act in the interest of their patients (Gilson 2003). Providers of services need to be confident they will be rewarded for providing high quality and trustworthy advice and services. In the absence of appropriate institutions to manage information asymmetry, there is a risk that experts will use their power to charge patients for unnecessary services and/or clients will be unwilling to pay fees to health workers, whose knowledge and expertise they cannot assess. Both outcomes are commonly found.

Table 1.1 'Market failures' in the health sector

- ✓ Health-related services include public goods such as public sewerage and water supply systems, which are often undersupplied if left to the market.
- ✓ Health decisions based only on individual needs are likely to result in sub-optimal funding patterns, as some services – such as immunisations – have wider societal benefits.
- ✓ Markets tend to under-insure against major health expenditure because they cannot control costs effectively and there is little incentive for a healthy person to join an insurance scheme.
- ✓ Markets may not adequately reflect the greater willingness of the population to finance basic health care as compared to non-health goods and services.
- ✓ Markets can worsen distributive outcomes and hence health inequities.
- ✓ Markets for goods and services that embody expert knowledge produce information asymmetry between providers and clients that can make clients vulnerable to abuse of provider power and/or reduce the level of trust that clients have in providers.

The advanced market economies have addressed these problems with powerful professions, government purchase and provision of services and highly regulated pharmaceutical and medical equipment industries, all underpinned by social and ethical norms of behaviour. These arrangements have evolved over decades and reflect local social and political history (Bloom and Standing 2008). A number of analysts have argued that health systems are highly path dependent, because of political pressure to avoid changes that might threaten the ability of a health system to meet the established expectations of the population. Low and

middle-income countries need to build on their own institutional inheritance to find innovative solutions to the challenge of asymmetric information (Leonard et al 2013).

The view that health is a 'special case', guided by the principles of 'do no harm' and 'put the needs of a patient first', has led many health policy analysts to view engagement with markets as inappropriate. Yet, market relationships have become pervasive in the health systems of many low- and middle-income countries. In the pluralistic systems that have emerged, there are a wide variety of providers of services and drugs in terms of their training, their skills and their relationship with the formal regulatory system. The boundaries between public and private sectors have become porous as government health workers accept cash payments (official or informal), practise privately and establish informal links with the private sector. Policy interventions that ignore this reality may fail to exploit its potential and can have unintended outcomes (Bloom et al 2008). However, the effective management of pluralistic health systems requires new understandings of the influences on their performance and of the governance and stewardship roles of the state (Ahmed et al 2013; Lagomarsino et al 2009).

Figure 1 provides a framework for analysing a pluralistic health system. At the centre are the users and providers of health advice, services and/or drugs. They are influenced by a variety of actors, which perform a number of functions. This influence is mediated through different types of formal and informal relationship. An intervention aimed at improving the performance of particular health service providers needs to take these relationships, and the likely responses of different actors, into account.

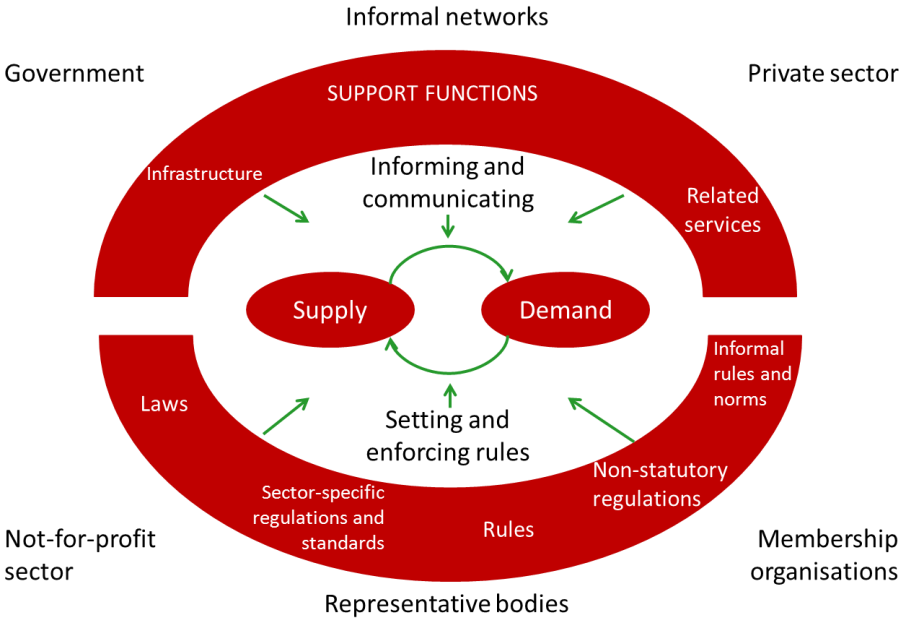
The boundaries of a health system and the actors included in an analysis depend on the particular goods and services the analyst is studying. For example, providers of services for common health problems, for reproductive health services and for mental illness may be quite different. The boundaries also depend on the problems to be solved, or social objectives to be achieved. This paper takes a normative position which prioritises the provision of access to safe, effective and affordable health care for the common health problems of the poor. This is consistent with the current global objective of universal health coverage.

Although individual providers are typically located near to their clients, they are often linked to larger organisations. It is therefore important to include relevant aspects of the local, national and global levels in a health system analysis. The following paragraphs describe the types of actors commonly involved in the provision of drugs and outpatient services in countries with pluralistic health systems.

By users we mean the general public who make up the 'demand side'. There are many ways to categorise users and the factors shaping their health and health seeking. At different times users may interact with the health system as patients, as individuals 'at risk' of a disease, or as healthy individuals. As countries develop economically and living standards rise, the threat of infectious disease tends to lessen, people live longer and non-communicable diseases account for more of the disease burden. Many countries now face a double burden of disease, where infectious diseases remain a problem, but chronic and non-communicable diseases are increasingly prevalent. Age, gender, cohort and genetic factors fundamentally shape demand-side need and behaviour. Within societies there is usually a social gradient to morbidity, with the rich tending to be healthier. As well as the determinants of disease there are important economic determinants of health-seeking behaviour. Cost of healthcare, and the cost of transport to healthcare, can be a significant demand-side barrier. As a result, in many healthcare markets the poor tend to rely on informal private healthcare providers, who may not charge for consultations or who will accept delayed payment. Typically, health-seeking behaviour and treatment preferences are also influenced by a patient's knowledge and experience of the local health system: past illness episodes, their education, their social

networks, and the perceived quality and attitude of healthcare providers. In short, a complex and interacting range of social, political, economic and biological determinants influence user demand.

Figure 1.1 Conceptualizing a pluralistic health system



Source: Adapted from Elliot et al. (2008)

The supply side includes individuals and organisations that define themselves primarily as service providers or drug sellers, although providers frequently sell drugs and pharmacies advise clients on which drugs to use. It is difficult to define what qualifies as a “business” in a pluralistic health system, where the regulatory arrangements are neither highly developed nor rigorously enforced. The formal status of an organisation as publicly owned, a large or small enterprise, a not-for-profit organisation, a faith-based organisation or a social enterprise is often not a good predictor of behaviour. For example, a recent study in India found no difference between public, private and informal health workers in the quality of care of some common conditions (Das et al 2013). The performance of both public and private providers is influenced by factors such as the internal “mission” of the organisation, the terms and conditions of employment and career progress, financial and other incentives, formal and informal rules, prevalent ethical norms of behaviour, accountability mechanisms and widely accepted social norms (Macintosh and Tibandebage 2002; Leonard et al 2013).

An explicit or implicit acceptance of a variety of market-like activities has blurred the boundaries between public and private sectors in many countries. In China, for example, government-owned facilities rely heavily on payments by patients and compete fiercely for business. The Chinese Government uses a combination of regulation, direct management intervention and strategies for engaging with markets, such as performance-related contracts, to influence their behaviour. Elsewhere, the inter-connections between public and private providers are largely informal, in the sense that regulation is either lacking or poorly implemented. Governments of these countries face a choice between implementing major reforms to the public sector to (re-) establish a fully salaried public service, a very expensive and difficult to enforce option in many countries, or taking measures that recognise the influence of market relationships in the public sector. These measures might include signing contracts with individuals or facilities and the production and dissemination of monitoring indicators.

A large proportion of economic activity takes place outside the legal framework in many low and middle-income countries. This certainly applies to the health sector, with poor people relying largely on unlicensed suppliers of health services and drugs for treatment of common diseases in a number of cases (Sudhinaraset et al 2013). The degree to which these providers meet health needs is unclear. On the one hand, a recent study in Bangladesh suggests that the supply of antibiotics by informal village doctors has contributed to falls in maternal and childhood mortality from infections (National Institute of Population Research and Training 2012). On the other hand, other studies have revealed problems with sub-standard drugs, inappropriate prescriptions, high levels of unnecessary spending and weak links with the rest of the health sector, leading to delayed referral and lack of notification of potential epidemics (Bhuiya 2009; Ali et al 2012). One policy option would be to eliminate these unorganised markets, but this would only be politically feasible if higher quality sources of health care were made at least as accessible and acceptable to potential clients. The alternative is to find ways to improve their performance (Shah et al 2011; Peters and Bloom 2012).

The existence of unorganised markets makes it necessary to differentiate between a legitimate business and a criminal enterprise. In India and Bangladesh, for example, many licensed doctors refer to informal providers as “quacks” and “thugs”, citing examples of highly exploitative behaviour. But, the clients of many of these providers trust them and hold them in high esteem for their accessibility, flexibility over payments and better interpersonal attitudes (Gautham et al 2013; Bhuiya et al 2009; Oladepo and Lucas 2013) This may explain their persistence for decades, despite illegally selling prescription drugs. This contrasts with attitudes towards producers and suppliers of sub-standard drugs or addictive narcotics, who are widely perceived to be profiting from harmful activities. This difference in public understanding and tolerance may partially explain why the drug regulatory agency in Nigeria was able to pursue a concerted campaign to eliminate counterfeit drugs in a context of generally weak governance (Garuba et al 2009). Measures to influence health markets need to be based on both an objective assessment of the technical quality of provider performance and a contextual understanding of trust and what is regarded as legitimate and illegitimate behaviour.

Front-line providers of health-related goods and services are influenced by other organisations. These include providers of more sophisticated health services with whom they compete but to whom they refer patients, often in return for payment. They are also influenced by the producers and distributors of drugs and diagnostic services. A recent study in Bangladesh documented how representatives of pharmaceutical companies supply informal village doctors with information on their products and offer financial incentives to stock them (Rahman et al 2010). Another study found that one of the large Bangladeshi pharmaceutical companies maintains a database of more than 180,000 informal drug sellers and organises regular meetings with them (Bloom et al 2014). A study in Tanzania also found that rural pharmacies were more likely to stock products produced and distributed in that country than imported products (Mujinja et al 2014). These studies demonstrate the influence of the organisation of the drug value chain on both the availability of drugs to poor clients and the type of advice the drug sellers provide.

The flow of health information and advice has been undergoing rapid change in recent years. A very high proportion of people have access to radio and, increasingly, to television. There has been a growth in advertising agencies and advocacy organisations that produce content aimed at informing and influencing health-related decisions. More recently the spread of mobile phones has led to a growing influence on the content and sources of health information of mobile phone operators, internet providers and other types of knowledge intermediary. These developments are increasingly influencing providers and users of health services and mark a departure from the more traditional form of health advice mediated by

medical professionals. They raise important questions about quality and about whose interests are being promoted or represented.

As the integration of the global economy has proceeded, it has become important to take into account the role of transnational pharmaceutical and service delivery companies (both for-profit and not-for-profit). These organisations are influenced by their home country's legal frameworks and their relationships with their own government. Companies and NGOs from rapidly growing large low and middle-income countries are becoming global actors.
At the local level, a number of civil society organisations also influence the performance of pluralistic health systems. These include representative bodies, such as professional bodies, trade associations and, in some countries, associations of informal providers and drug sellers (Oladepo and Lucas 2013; Gautham et al 2013). These bodies represent the interests of their members, but they may also play a role in assuring the quality of their members' performance. There are often strong conflicts of interest between the associations that represent different types of provider. In a number of countries, for example, the representatives of medical doctors have successfully opposed measures that could strengthen their competitors, including paraprofessionals and informal providers (Dussault 2008).

Organisations that represent people as citizens, patients and/or carers are becoming increasingly important. The most prominent have been the diverse advocacy groups that successfully lobbied for governments and the global community to provide access to antiretroviral therapy for people with HIV/AIDS. The rapid growth in access to communications media, especially mobile phones, has accelerated the development of a multiplicity of such organisations at local, national and international levels, often promoting the interests of those with a very specific health condition and composed of a diverse range of stakeholders that may include not only patients, carers and clinicians but pharmaceutical and health care companies. There are also examples of consumer groups and community organisations, for example Health Watch in Bangladesh, that advocate for improvements in the performance of health markets.

Finally, a wide variety of government agencies influence pluralistic health systems. These include agencies that license health workers and accredit facilities, national regulators of trade and industry and sub-national regulators of small and medium enterprises. There is often a gap between the formal regulations and their enforcement. Countries with relatively weak governance structures often have detailed regulatory frameworks that strictly define the rules within which those operating in the health sector must function. However, they typically do not have the capacity, or in some cases the will, to ensure that these frameworks are effective. In many countries the formal health sector is so restricted in accessibility that strict enforcement of existing regulations would severely limit access to any form of health services by the poor.

The previous paragraphs note the stakeholders that influence the performance of pluralistic health systems. They vary in their power, their short and long-term interests and their understandings of the context within which they operate. A number of analysts have highlighted the need for government to play a stewardship role in ensuring that the interests of all stakeholders, including the poor and politically weak, are taken into account (Lagomarsino et al 2010). The capacity of government to play this role depends on its technical expertise and the degree to which it has legitimacy as a representative of the common good. It also depends on the capacity of other stakeholders to play an effective role in building relationships and creating effective institutional arrangements. The following section explores these issues.

2 Engaging with health markets

This section is concerned with the relationships between providers of health-related goods and services and a variety of entities that influence their performance. These include other private providers of drugs and health services, membership organisations, not-for-profit organizations, representative bodies and government agencies (figure 1). It focuses on the outpatient services used by the majority of the population. It argues that the institutional arrangements within which health markets are embedded are co-constructed by stakeholders. These arrangements include formal regulations and informal rules, backed by widely accepted norms of what constitutes socially acceptable behaviour (Leonard et al 2013). It is important to recognise the dynamic nature of these arrangements and the political nature of co-construction. Health institutions are highly path dependent, reflecting the historical legacy and beliefs about basic rights, entitlements and responsibilities. They are also dynamic; new structures can emerge as a result of constant testing of new ways to address problems. The challenge for governments and political leaders is to oversee the creation of institutions that support markets in meeting social objectives, such as the provision of access to safe, effective and affordable health services, whilst reducing the risk of harmful activities, such as the sale of sub-standard drugs or the provision of damaging treatments. The following paragraphs use the lenses of regulation and partnership to explore institution-building in pluralistic health systems.

Regulation

A number of studies have shown the lack of appropriate and effective health regulatory systems in many low and middle-income countries (Alfifi et al 2005; Ensor and Weinzierl 2006; Sheik et al 2012; Bloom et al 2014). A narrow view of regulation views it as a government function involving administrative and bureaucratic controls to correct market failures (OECD 1997).This kind of regulation plays an important role in protecting the public against incompetent medical practices and dangerous medicines in many countries. However, it has limitations because of the paucity of information about health markets available to the state, the lack of capacity to enforce regulations and the potential for capture of the state by special interests or by its own rent-seeking officials. Another view is that regulation is the outcome of a series of relationships between states, enterprises and civil society organisations (Black 2002; Smith 2004; Bourgon 2011). This “decentred” understanding of regulation recognises that states, on their own, cannot ensure the effective functioning of complex markets that involve relationships between a number of stakeholders. It also recognises that regulatory systems are co-constructed by the state and other stakeholders. The capacity of the state to participate effectively in this co-construction strongly influences outcomes.

Bloom et al (2014) advocate a multi-pronged approach to health market regulation, which takes into account the different types of relationship with a regulatory aspect. These include relationships between the state and enterprises, between enterprises, between enterprises and other organisations and within an enterprise. They argue that this approach needs to be tailored to local contexts and adjusted as a market system develops and evolves. New ideas may emerge out of local innovations or they may be introduced as experimental interventions. There is likely to be an extended period of testing and revision as new ways of doing business go to scale. They identify four complementary regulatory strategies.

- Administrative and bureaucratic controls such as the criminalization of malpractice, licensing and accreditation of providers and facilities and registration of products
- Market-supply oriented approaches such as self-regulation, contracting, creation of franchises, incentives and subsidies, disclosure and management improvement

- Consumer or citizen-oriented approaches such as consumer education, a right to information by citizens, consumer rights, patient redress, citizen empowerment and liability norms
- Collaboration oriented approaches including co-production of services and regulation across key stakeholders and partnerships for transparency and accountability.

Regulation takes place at local, national, regional and international levels. Global and regional initiatives play an important role in generating agreement on broad objectives, involving global actors such as national governments, transnational organisations (for profit and not-for-profit), and global bodies that establish regional or international standards. However, it is important to recognise the significant influence of the advanced market economies in setting standards which rarely take into account the context of informal markets (van Zwanenberg et al 2010).

Reforming a regulatory system cannot be driven from outside national boundaries. The ultimate aim is to establish rules that the majority of stakeholders consider to be legitimate and that they internalise as behavioural norms. The outcome of this kind of institution-building will be strongly influenced by the degree to which different social groups can mobilise to ensure that political leaders take their interests and perspectives into account. There is little systematic evidence on what works in building effective institutional solutions to the problem of asymmetric information in low and middle-income countries. These countries will have to pursue a learning-by-doing strategy, in which they test alternative interventions and build on what succeeds (Peters et al 2009).

Partnership

A second lens through which to examine health sector institutions is partnership. Interest in this perspective has been stimulated by action at global level to build public-private partnerships (PPPs) involving large international organisations, philanthropies, NGOs and corporations with a variety of aims as outlined below. The governments of many low and middle-income countries have managed a wide variety of partnerships with non-state organisations for years. These have included co-funding agreements with faith-based health facilities, contracting for a variety of services and regulatory partnerships. This paper uses a modified version of the working definition for PPPs proposed by Reich (2002): involving at least one private-for-profit organization and one not-for-profit or public organization with the partners having some shared objectives for the creation of social value and an agreement by the core partners to share efforts and benefits. We argue that governments and other stakeholders in countries with pluralistic health systems need to build on this experience to create and manage new partnerships to address major health system problems more quickly and at scale.

A wide variety of PPPs have emerged to address the health needs of low and middle-income countries (Widdus 2001; Brinkerhoff and Brinkerfoff 2011; Nishtar 2006). These include:

- Policy, public advocacy and education-building coalitions around developing specific health programmes or addressing specific regulatory challenges
- Public funding of private company research and development of drugs, vaccines and medical technology with the potential to improve access to services by the poor, at scale
- Investment in the construction of facilities, such as hospitals
- Partnerships for service delivery and strengthening of health services through public funding of services provided by non-state providers of health and through supply of subsidized drugs and other products by private companies

- Regulation and quality assurance through partnerships to regulate drug quality and safety, social franchising of service providers and private participation in governance bodies
- Global coordination of major initiatives such as by the Global Fund for HIV, malaria and TB and GAVI.

Partnerships intended to contribute to the provision of access to safe, effective and affordable health services may involve a variety of stakeholders. These relationships can be largely between private, for-profit and not-for-profit actors, they can involve associations of providers and they can involve citizens' organisations (figure 1). What is important is the degree to which the partnership addresses an agreed public purpose, as well as the specific objectives of each partner. The tensions between individual interests and the agreed partnership objectives are intrinsic to this kind of partnership.

The creation and maintenance of an effective partnership requires an investment of time and money. A review of health PPPs for the World Economic Forum (2005), for example, emphasised the effort needed to create governance arrangements, particularly when these partnerships go to scale. Brinkerhoff and Brinkerhoff (2011) propose several reasons why stakeholders invest in this kind of initiative (i) to enhance efficiency and effectiveness through reliance on comparative advantages; (ii) to provide the multi-actor resources needed to address particular problems:- (iii) to move towards compromise and potential win-win situations and (iv) to open decision-making processes to promote a broader operationalization of the public good.

For a partnership to survive it is important that each partner believe that the benefits it derives from the effort of creating and maintaining the partnership outweigh the potential losses from the constraints to pursuing its narrow interests. They also need to believe that the distribution of downside risk is shared fairly. The way a partnership balances the interests of its members reflects the governance arrangements put in place and the relative power of the different partners (Buse and Harmer 2004). Much of the debate about the desirability of PPPs reflects different views about the possible capture of a partnership by powerful stakeholders and of the capacity of governments and other stakeholders to provide an effective countervailing influence and protect the public interest. Buse and Harmer (2004) point out that there is little systematic evidence about the political economy of these partnerships and its influence on their outcome.

Building institutions for regulation and partnership

Discussions of regulation and partnership in the literature present alternative framings of the same issue: the role of trust-based relationships in ensuring the quality of health system performance and the need to build institutional arrangements to support these relationships. Previous efforts to build the institutions for a modern health system in low and middle-income countries have focused on the replication of the arrangements in advanced market economies. The results have often fallen well below expectations and in a number of countries the outcome has been the emergence of the largely unregulated pluralistic systems of health care described above. There is limited evidence about the approaches that work well in building institutions in low and middle-income countries (Fukiyama 2004; Chang 2007). This has led to a recognition of the inherent complexity of health systems and of the need for a learning-by-doing approach to the management of change (Peters et al 2009; Bloom and Wolcott 2013).

In the context of the advanced market economies, Fligstein (2001) argues that successful private companies strive to achieve both immediate market advantage and the creation of an institutional framework that provides stability for future growth and development. This stability depends on attaining a degree of social legitimacy, which makes it possible to enforce rules

effectively. This means that their behaviour reflects the need to both protect and build their market share and co-produce a stable institutional framework that is perceived to be in the public interest. Governments play a central role in creating and enforcing the regulatory framework. Governments and other stakeholders face special challenges in promoting the development of appropriate institutional arrangements in countries with pluralistic health systems. The emergence of these systems has typically been in countries with either a history of weak governance or undertaking radical changes in development strategy, for example transition from command economies (Leonard et al 2013). In both cases, strategies for change need to take into account the lack of deeply embedded formal institutions and, in some cases, generally accepted behavioural norms. This often means that there is a lack of a shared vision of the roles and responsibilities of the different stakeholders, leading to a predominance of short-term considerations in decisions. One way of addressing this issue is to identify specific problems that lend themselves to attempts at consensus building around possible solutions in the hope that a successful experience will provide lessons for dealing with more difficult issues.

A second challenge is the imbalance of power and the different understandings and visions between the government and other national stakeholders and the transnational companies and other organisations that are increasingly engaged in their health economy. For example, there may be a conflict between the search by pharmaceutical companies for markets for their drugs and the needs of poor people for inexpensive ways to prevent or delay the complications of diabetes and hypertension. This raises questions about the degree to which these companies can be made accountable to local stakeholders and about the possible role of global institutions as influences on the behaviour of these companies. The increasing global presence of companies from rapidly growing middle-income countries and the consequent involvement of their governments in governance arrangements adds another level of complexity, especially since these important global actors are still in the process of building institutions to bring order to their own pluralistic health systems.

Large companies are increasingly aware of the tension between their immediate need to build market share and their longer-term interest in establishing a stable and long-term presence in new markets. In the advanced market economies, they have sought to secure their long-term interest through a combination of lobbying, communications efforts and promotion of the concept of corporate social responsibility. The rapid growth of markets for health-related goods and services has made it increasingly important for companies to find ways to build a long-term presence in them. However, in low and middle income countries, measures to provide immediate and visible benefits seems to have taken centre stage, with much less investment in market forming and stabilising activities. For example, pharmaceutical companies have focused mostly on tiered pricing and the provision of low-cost drugs for diseases of poverty. They have not engaged very much in building institutions for market stabilisation to address problems such as the large proportion of drugs that are counterfeit and the inappropriate use of many drugs. This balance of activities probably reflects a lack of contextual knowledge, the unwillingness of governments to engage with them and a lack of confidence in long-term growth and stability. It may also reflect a previous reliance on the governments of their home country to protect their interest in the so-called “developing world”.

Governments have been reluctant to engage with these companies, because of a concern that they are so powerful that they would use this engagement to build monopoly positions. Many countries have previous experience with the consequences of this kind of behaviour. This highlights the need for governments to build a capacity to lead a process of institutional development and to play an effective stewardship role (Lagomarsino et al 2009; Ahmed et al 2013).

The co-existence of highly ordered health systems in some countries and pluralistic systems, with chaotic health markets in others is an unstable arrangement. This is putting pressure on all actors to find ways to bring more order to national and global health systems. Each has a partial understanding of the complex reality and has a particular focus on its own interests. It is important to facilitate processes for building mutual understanding of the challenges and possible development pathways and to enable all stakeholders, including the poor and relatively powerless, to influence policy choices. The outcome of the engagement between businesses, government and other health sector stakeholders will be strongly influenced by political economy factors. The pathway of development will reflect the way that conflicting interests are mediated, the extent to which mutual understanding of the problems and a shared vision of the role of the partnership in a future health system can be achieved and the degree to which emergent institutions can win political legitimacy.

Governments, businesses and a wide variety of other stakeholders face a big challenge in managing and reforming pluralistic health systems. This will require a major effort of learning how to establish and manage new kinds of relationship between stakeholders and how to participate in the creation of appropriate institutional arrangements. The direction of development and the degree to which the health system addresses the needs of the poor for access to safe, effective and affordable health services will be strongly influenced by the way this process is managed. One of the major areas of research by the Centre for Business and Development will be to test possible strategies for this kind of effective engagement. It will select high priority problems, for which it will address the following questions:

- Is the problem clearly defined?
- Who are the key stakeholders with regard to the problem to be addressed and what are their interests in engaging in a partnership?
- How is the problem to be addressed framed by different stakeholders and how can a mutual understanding be built?
- Can stakeholders agree clearly defined roles and responsibilities concerning the problem?
- How is the tension between the agreed goal and specific stakeholder interests managed?
- Can the state play a stewardship role on its own or in partnership with key stakeholders and can the initiative win public legitimacy
- Is there a process for learning from emergent arrangements and disseminating lessons learned?

It is impossible to predict the outcome of any particular intervention. This suggests the advantages of beginning with rather focused local interventions to generate information on what works and why and then apply the lessons to take the intervention to scale. A focused intervention can also provide systematic learning about ways to extend partnerships to address other health system problems. Annex I illustrates with the example of the global effort to reduce the risk of emergence of resistance to antimicrobial drugs.

3 Innovation and health system development

There is a lot of international interest in the potential role of innovation in increasing access to safe, effective and affordable health services (Piot 2012). This has led donor agencies and foundations to invest in research and development of technological solutions.

One stimulus to this interest is the belief that new technologies are creating big opportunities for improving health services (Pauly 2008; Smith 2007). Christensen et al (2009) argue that a combination of developments in information technology and low-cost diagnostics and the development of evidence-based treatment protocols make it increasingly possible to employ a rules-based approach for diagnosing and managing illnesses. This means that less expensive personnel can take over these tasks from physicians. Many conditions can be swiftly and cheaply dealt with in walk-in clinics and people can increasingly manage their own health problems, particularly for chronic, lifelong conditions, such as diabetes and hypertension. These “disruptive innovations” have the potential to change health systems substantially. However, resistance by stakeholders and a myriad of complex regulations and payment mechanisms may preserve existing arrangements for a long time in the United States and other advanced market economies (Lee and Lansky 2008). There may be fewer constraints to change elsewhere.

Analysts of markets in rapidly growing middle-income countries have documented the emergence of low cost goods and services to meet rapidly rising demand by people, whose incomes are rising above subsistence level (Prahalad 2005; Clark et al 2009). There are already a number of examples of innovative approaches for providing safe, effective and affordable health services. These include: (i) protocol-driven management processes within hospitals or primary care providers, (ii) the use of branding, franchising, and accreditation to influence the performance of large numbers of dispersed providers of health services and drugs and (iii) the growing availability of health information and advice through mobile phones and the internet (Ehrbeck et al 2010; Bhattacharya et al 2008; Lowe and Montagu 2009). Most of these innovations are relatively small-scale and it is difficult to predict how quickly they will spread. The rapid take-up of mobile telephone banking is an indicator of the rapidity with which new ways of doing business can become established (Batchelor 2012).

These developments have stimulated interest in strategies for stimulating potentially beneficial innovations and/or for accelerating their diffusion. A number of agencies are financing the development of new drugs, vaccines and ICT applications. These investments have had mixed results in improving access by the poor to health services (Frost and Reich 2008). This has led to greater interest in downstream innovations that improve the delivery of the benefits of new technologies to poor people (Batavia et al 2011). One response has been the creation by donor agencies of challenge funds in a number of low-income countries to support this kind of innovation. There is little systematic evidence on the impact of these funds on the diffusion of new approaches at scale.

These findings are consistent with the experience of innovation in other sectors. A number of authors employ a systemic approach which views innovation as the outcome of the relationships between firms, governments, research organisations and other actors, which could include NGOs and activists (Mowery and Rosenberg, 1979; Nelson, 1993, Lundvall, 1998; Carlsson et al., 2002). The translation of a new scientific idea or technological application into improved benefits for large numbers of people requires innovative activities by many different actors. A few analysts have applied this perspective to health (Consoli and Mina, 2009). Some have focused on the biotechnology industries, arguing for strengthening the capacity of developing countries for technological innovation (Thorsteinsdottir et al., 2004, Engel et al., 2012). Others have focused on the diffusion of innovation in health systems (Atun and Sheridan 2007; Greenhalgh et al 2004). A few papers have analysed how

health systems co-evolve with institutions, products and services (Consoli and Mina, 2009, Thorsteinsdóttir, 2007).

Several analysts have focused on the degree to which technological change is path dependent. The health sector can be viewed as a "socio-technical system" which brings together products, knowledge, regulation, user practices, markets, cultural meanings, infrastructure and production and supply networks (Geels, 2004). The technologies and institutions that comprise a socio-technical system include norms, attitudes and infrastructural arrangements, which make them resistant to radical change (Geels and Schot, 2007, Berkhout et al., 2004). One example from the health sector is the use of point of care diagnostics for malaria. Their revolutionary potential has been limited by entrenched socio-cultural diagnostic practices and test results are commonly rejected when they differ from a doctor's or patient's opinion (Chandler et al., 2008, Chandler et al., 2012).

A number of authors are exploring how relatively stable socio-technical regimes are destabilised or transformed (Turnheim and Geels, 2012, Geels et al., 2004, Geels and Schot 2007; Smith et al., 2005). They reach similar conclusions to the analysts of disruptive innovation (Christensen et al 2009). In both cases they identify different transition pathways, which depend on the degree to which new actors disrupt existing markets and the ability of established actors to adopt new practices. The major lesson that emerges is that a sequence of small changes and adaptations can eventually lead to a tipping point after which substantial changes happen. Investments in innovations need to have an eye on both the immediate impact and the potential contribution to long term transformation. Government actions to create a regulatory framework and encourage new ways of doing business can also have an important influence on the longer-term development pathway.

One needs to be cautious in applying concepts developed in OECD countries to the different context of a pluralistic health system in a low or middle-income country. On the one hand, this context may not display the coherence and alignment implied in the concept of a regime. Thus, while pluralistic health systems may provide a fertile ground for incremental innovations, large scale change may be harder to govern. On the other hand, there may be fewer constraints to major transformation. Romijn and Caniëls (2011), for example, suggest that advances in biotechnology and platform technologies, such as ICTs, mean that the pathways open to developing countries are fundamentally different to those of the past. The trajectory of a development pathway and the degree to which it provides benefits to the poor is influenced by the actions of a number of stakeholders and by the regulatory framework they put in place (Stirling 2009). It is possible to imagine an ICT-enabled health system that provides easy access to trustworthy health information and enables people to manage many health problems very inexpensively. It is equally possible to imagine a system that induces people to purchase unnecessary and potentially harmful drugs, or that is too expensive for most people to use. Governments and other stakeholders need to be able to identify and respond to problems as they emerge to reduce the risk of undesirable developments.

The work of the Centre for Business and Development will focus on innovations aimed at increasing access to safe, effective and affordable outpatient care for common conditions of the poor. These include a combination of new information and communications technologies and of low cost point-of-care diagnostics. We will address the following questions:

- Who are the potential innovators at local, national and global levels and how are potentially important innovations spreading?
- What factors constrain the development and diffusion of appropriate technologies and what kinds of investment in innovation can help overcome these constraints? What is the evidence from the experiences of "grand challenges" and national innovation challenge funds

- What new types of knowledge brokers and mediators are emerging and what are the implications of these for managing knowledge asymmetries?
- How can governments and other stakeholders increase their capacity to ensure that technological innovations meet the needs of the poor?
- What are the potential unintended and deleterious outcomes of the spread of new technologies and what measures can be taken to reduce the risk of them occurring?

4 A learning approach towards engaging with health markets

Many governments of low and middle-income countries are under political pressure to increase access to safe, effective and affordable health services rapidly. At the international level this pressure is expressed in the proposal of multi-lateral organisations, such as the World Health Organization and the World Bank, to make universal health coverage (UHC) a global development goal. In order to move rapidly towards meeting the health needs of the poor it will be important to make good use of all health sector resources that provide services to them. In countries with pluralistic health systems this will involve major changes to the roles and responsibilities of all health sector actors. There is no blueprint for managing this kind of change (Peters et al 2009; Bloom and Wolcott 2013). Although strong leadership by the state is important, it is also important that local and international businesses and civil society organizations participate in the construction of effective institutions. There is relatively little systematic knowledge on strategies for managing change in a pluralistic health system. It requires mutual learning by all stakeholders (Bennett et al 2014). The Centre for Business and Development will contribute to this learning by supporting the generation and dissemination of systematic knowledge of what works and why through the following activities:

- Consultative meetings to facilitate sharing of knowledge, including tacit knowledge, between stakeholders and to build mutual learning between these stakeholders.
- Analytic studies of the organisation, functioning and political influences on the performance of health markets.
- Identification and assessment of the impact of emergent innovations on the performance of health systems in providing access to safe, effective and affordable services
- Participation in partnerships aimed at introducing innovations in information and communications technology and low cost diagnostics and systematic assessment of the experience
- Participation in studies of the creation of regulatory partnerships to address defined health sector problems.

Annex I

Addressing the challenge of anti-microbial resistance in pluralistic health systems

The problem
There is a large amount of evidence about the factors that contribute to the emergence of bacteria that are resistant to most common anti-microbial drugs. There is a growing global consensus that these bacteria represent a major public health challenge and could lead to the spread of infections for which there are not effective treatments. There is also a growing recognition of the risk of these infections spreading across national boundaries. The WHO has declared this to be a major global challenge. There is very little disagreement about the need for action.

Key stakeholders

- Producers and distributors of anti-microbial drugs at all levels in the value chain
- Health service providers and drug retailers who supply the drugs to clients including large numbers of informal providers
- Associations of service providers including professional bodies (doctors, pharmacists and so forth) and associations of informal providers.
- Users of anti-microbial drugs
- Associations representing service users
- Social entrepreneurs with a particular interest in health system reform
- Government regulatory agencies in countries with pluralistic health systems
- Government regulatory agencies in other countries, who are concerned about cross-border spread
- Global organizations such as the World Health Organization

Framing the issues
The dominant view is the need for regulatory action to reduce excessive use of anti-microbial drugs and ensure that people take a full course of treatment. In countries with pluralistic health systems, this would mean strict enforcement of laws that require a doctor's prescription to obtain a drug. In many countries professional associations have been lobbying for this kind of action for many years. However, for measures that deny people access to these drugs through existing channels to gain political legitimacy, alternative mechanisms would be needed to provide access to treatment of infections. This could be achieved by a well-funded government health service.

An alternative view begins by recognising the functioning of informal markets. They have made anti-microbial drugs widely available for many years although there are serious problems with the quality of the products, a tendency to over prescribe them and a willingness to supply partial doses. There is some evidence that the easy availability of anti-microbial products had contributed to reductions in mortality amongst the poor. This suggests that there is a tension between the need of the poor for easy access to anti-microbials and the concern by the global community about the emergence of drug resistance. Is it possible to create new kinds of partnership for providing access to drug treatment of common infections?

Roles and responsibilities of stakeholders
The combination of strict enforcement of laws to restrict access to anti-microbial drugs and of rapid expansion of publicly organised health services to provide universal access will mainly involve government regulatory agencies and major reforms to the management of public health services. Where this is unrealistic, an alternative approach will be needed that

engages with the existing health markets. This will begin by mapping the key stakeholders (figure 1):

- Providers of medical advice and common drugs mostly operate as small businesses. They have strong incentives to supply drugs that they believe will work. They frequently supply more than one anti-microbial drug plus an analgesic and or a steroid to reduce symptoms rapidly. Drug wholesalers often provide additional incentives for them to supply particular products. In many cases there is strong competition between informal businesses and pharmacies and private medical practices run by a licensed professional.

- Drug wholesalers are competing for markets for their products. They provide information to the retailers, but have little incentive to inform them about public goods issues, side-effects of drugs and so forth. In many pluralistic health systems there are a variety of wholesalers who compete on quality and price. If the regulatory system is weak, there may be a major problem with the quality of products.

- Drug producers are also competing for markets. Many common anti-microbial drugs are no longer covered by patents and are supplied by generic manufacturers. They have little incentive to worry about issues of the emergence of resistance

- Large R&D-based pharmaceutical companies have not given high priority to the development of new anti-microbial agents, because of a perceived lack of a market. They have little incentive to invest in products, and to withhold them from the market in anticipation of the emergence of resistance to existing products.

The challenge is to build a partnership for tackling anti-microbial resistance that will enable the existing market actors to supply easy access to appropriate drugs, while altering the structure of incentives to reduce oversupply of these products and to encourage people to take a full course of treatment. This would need to involve some of each of the following:

- Drug wholesalers who have direct contact with drug retailers
- Drug producers who are seeking stable markets for their products
- Large pharmaceutical companies, who do not have a major stake in the market for common anti-microbials, but who are seeking a long-term presence in these countries
- National regulatory agencies and the government health service
- Global governance arrangements, which could set norms and standards concerning the functioning of national anti-microbial markets

An initiative to alter the performance of markets for anti-microbials could apply all four regulatory strategies:

- Strengthening enforcement of regulation of drug quality and access to second or third line anti-microbials
- Partnerships between informal providers and the formal health and pharmaceutical sector to realign incentives regarding the supply of anti-microbials
- Consumer oriented approaches to increase awareness of when and how to use anti-microbials and of the threat of emergence of resistant organisms
- Collaboration-oriented approaches for a focused effort to find ways to provide universal access to antimicrobials while reducing the risk of resistance.

Management of conflicts of interest
The intervention would take place in the context of highly competitive markets for pharmaceuticals and for the provision of health services. The purpose of the proposed partnership would be to find ways to address a specific problem in this context. There is

always a risk that one member could use the partnership to promote its own interests. This risk can be reduced by widening the membership of the partnership and by agreeing ways to monitor its performance.

Stewardship
The government has an important role to play in overseeing the creation and management of this kind of partnership. However, it could involve other strong actors, who can express the interests of the different stakeholders. These could be strong NGOs, a variety of citizen organisations, faith based organisations, professional associations and so forth. There may be a need to organise activities aimed at strengthening the capacity of all stakeholders to participate effectively in this kind of partnership.

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