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Health policy in emerging economies: Innovations and challenges

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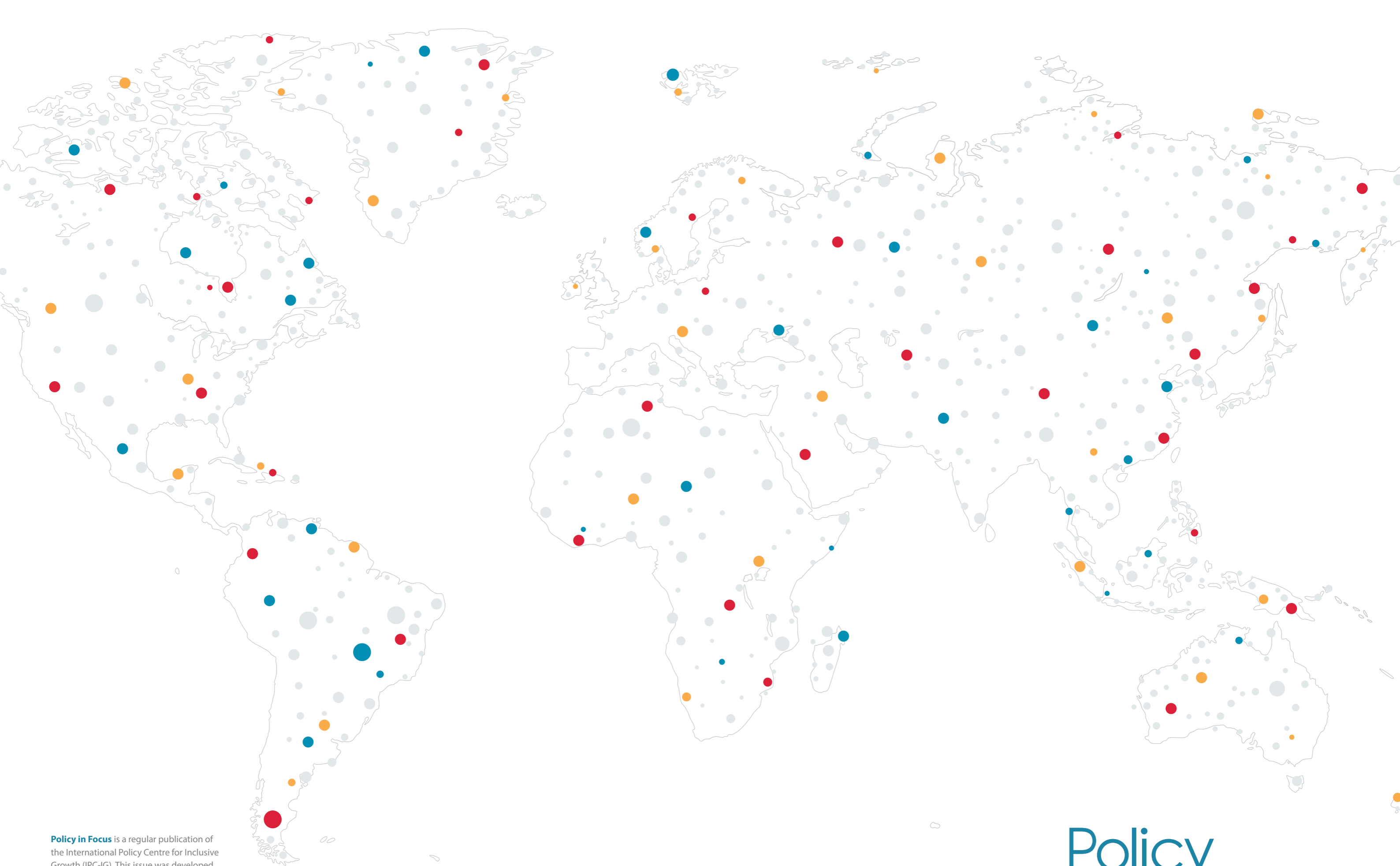
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Health policy in emerging economies: innovations and challenges



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Policy in Focus is a regular publication of the International Policy Centre for Inclusive Growth (IPC-IG). This issue was developed in partnership with the Oswaldo Cruz Foundation (Fiocruz), highlighting health care challenges and innovations across the Global South.

Policy
in Focus



The International Policy Centre for Inclusive Growth (IPC-IG) is a partnership between the United Nations and the Government of Brazil to promote South–South learning on social policies. The Centre specialises in research-based policy recommendations to foster the reduction of poverty and inequality as well as promote inclusive growth. The IPC-IG is linked to the United Nations Development Programme (UNDP) in Brazil, the Ministry of Planning, Budget and Management of Brazil (MPOG) and the Institute for Applied Economic Research (Ipea) of the Government of Brazil.

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Over the last decade, the global health agenda has converged around proposals for the construction of policies and interventions towards greater equity. Despite the great diversity in their historical and institutional contexts, developing countries face similar health care challenges, including inequity regarding access to services and to quality medicines, the prevention and control of communicable and non-communicable diseases, and the strengthening of capacities in scientific and technological development.

The recognition that universal access to health care and to medicines has an impact on poverty and social inclusion has led to the formulation and implementation of diverse interventions to improve the provision, access and quality of health services and products.

This issue focuses on developing countries that have exhibited significant progress across various health indicators. However, shortcomings remain regarding not only the financing of public health and social assistance interventions but also the regulatory and coordination capacities of governments, with the aim of ensuring complete, universal access to services and medicines. Domestic and international aspects (especially regarding regulatory frameworks, property rights and procedures for structured purchases) can translate into gaps and a lack of capacity to develop medicines, vaccines and other medical technologies.

The globalisation of health issues demands a global response towards the production of multidisciplinary and collaborative knowledge, which can only occur as a result of quick mobilisation and cooperation among research institutions and multilateral agencies, both in the elaboration of biomedical solutions and the development of social research capable of generating evidence regarding the effectiveness of actions and the determinants of the challenges being tackled.

These and other aspects are brought to light by this special issue of *Policy in Focus*, a collaboration between

the International Policy Centre for Inclusive Growth (IPC-IG) and the Centre for Strategic Studies of the Oswaldo Cruz Foundation (Fiocruz). This compilation of articles from leading experts in the field introduces readers to some of the many ways through which public health policies can substantially contribute to the reduction of poverty and inequality and the promotion of inclusive growth.

This issue is divided into four thematic blocks, arranged to guide the reader from an analysis of broader aspects towards more specific aspects of health systems and policies. The first block presents general aspects of health systems and policies that determine the nature and quality of the health services on offer in developing countries of Latin America and the BRICS, focusing on public health. The second block introduces articles that analyse more specific challenges and policies, especially those geared towards containment measures for epidemics such as hepatitis B, HIV/AIDS, dengue, Zika and chikungunya. The third block is a collection of articles discussing specific policies for more equitable access to medicines, dealing with price control regulations and how to work around the intellectual property rights of large pharmaceutical companies. Finally, the edition concludes with a block of articles evidencing the potential of the use of telemedicine initiatives across various health fields, from the training of new professionals to the performance of examinations and differential diagnoses, to improve the quality of health care in remote areas.

We hope this special edition can spark new debates about points of convergence between the promotion of health care, inclusive growth and development more broadly, and that the diversity of experiences presented by the articles can help to systematise the best practices and negative experiences arising from emerging health systems and models.

by **Jeni Vaitsman and Pedro Lara de Arruda**

Latin American pathways to achieve universal health coverage

by *Olga Lucía Acosta and Simone Cecchini¹*

Achieving universal health care coverage not only means fulfilling a fundamental social right, but it can also have a significant impact on the improvement of the distribution of income and on the construction of a more equitable and cohesive society.

The reforms carried out over the last decade and a half by Latin American countries concerning their health systems—which were sustained by an increase in health expenditure from 2.4 per cent of gross domestic product (GDP) at the end of the 1990s to 3.6 per cent in 2014—have contributed to greater coverage rates and equity in access (Atun et al. 2014; see Figure 1).

Strengthening the solidarity pillar of social protection systems has been key to providing health care coverage to populations without access to contributory social protection, such as informal workers and poor households, often in rural areas. Additionally, the past decade of sustained economic growth was accompanied by policies oriented towards the formalisation of employment, which

led to the broadening of coverage through traditional social security systems. However, fragmentation and overlap of benefits and coverage persist and are made evident by the disparate quality of services for different population groups: health systems in the Latin American region are typically organised around public-sector services for the poor, social security services for formal workers and private services for those who can afford them (Titelman, Cetrángolo, and Acosta 2014).

Although progress towards universal health coverage has been made throughout the region, the characteristics of health systems in terms of investment effort, out-of-pocket expenditures of households, integration of the public health and social security systems, coverage of the population and health impact indicators are quite uneven, depending on the country (see Table 1). Many of these differences are related to the historical evolution of the welfare state, which in turn is influenced by economic, social, demographic and political variables within each national context.

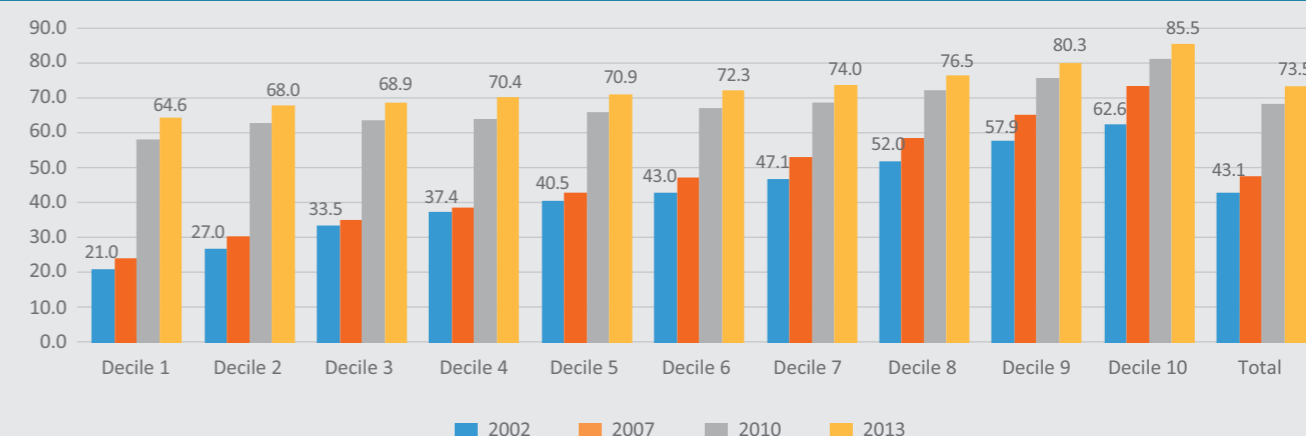
Cuba and Brazil are exemplary in the region for guaranteeing free universal health

coverage, funded by general taxation. Cuba established the National Health Service in 1961, consolidating it over the 1970s, and Brazil created the Unified Health System, a result of the enactment of the 1988 Constitution. In Costa Rica, the social security fund has been the only provider of comprehensive health care for the entire population, including informal workers and poor families since the 1980s (Atun et al. 2014; Cecchini, Filgueira, and Robles 2014; Cotlear et al. 2014).

More recently, to strengthen the solidarity pillar, countries have followed a variety of approaches, including:

- adopting universal health benefit plans, establishing guarantees and prioritising certain diseases and services (such as in Chile, Colombia, Uruguay);
- expanding health insurance to formerly excluded population categories, especially the poorest (Mexico, Peru); and
- strengthening health plans for mothers and children (Argentina and Honduras) (Gledion, Bitrán, and Tristao 2014; Vega and Frenz 2014).

FIGURE 1: Latin America – affiliation with health care systems among workers aged 15 and older, by income decile, national total, 2002–2013 (percentages)*



Source: Economic Commission for Latin America (ECLAC 2015), based on special tabulations of data from household surveys conducted in the respective countries.
Note: * Weighted average of 13 countries.

“ Strengthening the solidarity pillar of social protection systems has been key to providing health care coverage to populations without access to contributory social protection.



Photo: Nahuel Berger/World Bank. Baby receives care through the Nacer programme, Argentina, 2007 <<https://goo.gl/P1G0nN>>.

In Chile, the Explicit Health Guarantees were established in 2005, featuring legally enforceable entitlements to a comprehensive set of services for a prioritised group of diseases, the number of which has grown from 40 to 80 over time. In Colombia, since 2012, all citizens have had full access to the Compulsory Health Benefit Plan (*Plan Obligatorio de Salud*—POS). In Uruguay, with the Comprehensive Health Care Plan (PIAS) adopted in 2006, all individuals are entitled to the same health care plan, financed by a single pool of resources to which citizens contribute according to their financial ability to pay. Furthermore, in Mexico, the *Seguro Popular* programme was established in 2004 to provide health coverage for people with no access to the social security system.

In Peru, the Essential Health Insurance Plan (PEAS) was adopted in 2009 to provide a minimum level of coverage for all citizens as part of a universal insurance plan, with an emphasis on paediatric, obstetric and gynaecological conditions. In Argentina, where all citizens are entitled to services provided by hospitals and public health services, there are also additional initiatives to prevent barriers to access that exist on the ground. The *Nacer* plan was established in 2004 to facilitate access to public health care for mothers and children; in 2012, it was turned into the expanded *Sumar* plan, covering women and men up to 64 years old. The federal *Incluir Salud* programme covers elderly people and people with disabilities who are beneficiaries of non-contributory pensions.

“ Cuba and Brazil are exemplary in the region for guaranteeing free universal health coverage.



Photo: Marco Antonio Teixeira/World Bank. Zilda Arns Health Clinic at Complexo do Alemão, Rio de Janeiro, 2015 <<https://goo.gl/P1G0nN>>.

TABLE 1: Latin America – indicators for health systems, latest available year

Country	Public health expenditure (% of GDP)		Public health expenditure per capita (2010 USD)		Out-of-pocket health expenditure (% of total household expenditure)	Integration of public health system and social security	Population health coverage by sub-system				Maternal mortality ratio (deaths per 100,000 live births)	
							Public (%)	Social security (%)	Private (%)	Other (%)		
	1998	2014	1998	2014			2000	2015				
Argentina	3.8	5.0	349	535	5.0	Segmented	Universal	51.0	7.9	3.2	60	52
Brazil	3.7	5.2	327	622	5.0	Integrated	Universal (Unified Health System)	0.0	19.6	0.0	66	44
Chile	2.4	3.9	226	569	4.3	Integrated	Universal (Explicit Health Guarantees)	73.5	16.3	6.7	31	22
Colombia	2.0 ^a	2.1	95 ^{a d}	146 ^d	1.9	Integration under implementation	Universal (Basic Health Care Plan)	91.1	...	3.9	97	64
Costa Rica	4.7	6.5	263	560	2.1	Integrated	Universal	0.0	0.0	0.0	38	25
Cuba	5.1	10.4	159	650	...	Integrated	0.0	100.0	0.0	0.0	43	39
Honduras	1.8	3.4	30	70	11.2	Segmented	60.0	18.0	2.9	...	133	129
Mexico	2.0	2.7	156	251	4.7	Segmented	47.0 (<i>Seguro Popular</i>)	42.9	4.5	4.5	77	38
Peru	1.5 ^a	2.4	48 ^a	128	7.0	Segmented	37.0	24.0	5.5	...	140	68
Uruguay	2.9	5.9	259	736	2.8	Integrated	45.3	45.0	1.8	7.6	31	15
Venezuela	2.0	3.9	159	343	3.1	Segmented	Universal (<i>Barrio Adentro</i>)	17.5	11.7	...	90	95
Latin America	2.4 ^b	3.6 ^b	131 ^b	292 ^b	4.7 ^c	91 ^b	60 ^b

Source: Authors’ elaboration, based on ECLAC Social Panorama of Latin America 2013 and 2015; CEPALSTAT; Atun et al. (2014); Bermúdez-Madriz et al. (2011); Cotlear et al. (2014). Notes: ^a 2000. ^b Simple average of 21 countries. ^c Simple average of 18 countries. ^d Data for Colombia only provide general government expenditure on health; adding social security expenditure on health, Colombian public health expenditure per capita was USD117 in 2000 and USD405 in 2013 (WHO Global Health Expenditure Database).

Looking forward, the complex and uncertain economic scenario that Latin America is now confronting brings new challenges to its efforts to improve equity, universalise health coverage and achieve Sustainable Development Goal (SDG) 3, to “ensure healthy lives and promote well-being for all at all ages”. However, it is important for the countries to retain the progress made in recent decades, while at the same time continuing to advance in areas where further gains can be made (ECLAC 2015).

Most countries need to continue increasing the financial resources flowing into the health sector and to improve solidarity-based schemes, while at the same time reducing out-of-pocket expenditures. This requires increased fiscal resources (Titelman, Cetrángolo,

and Acosta 2014)—something that has happened over the last decade and a half (total tax revenue in Latin America increased from 17.2 per cent of GDP in 2000 to 21.7 per cent in 2014) but which is more difficult to accomplish during times of less favourable economic conditions. ●

Atun, R. et al. 2014. “Health-system reform and universal health coverage in Latin America.” *Lancet, Universal health coverage in Latin America*, October.

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1. Economic Commission for Latin America and the Caribbean (ECLAC).

The health systems of the BRICS countries and their performance regarding the health-related MDGs

by Pedro Lara de Arruda¹
and Mary MacLennan²

Despite legal and political tendencies towards providing universal health care, in practice, the BRICS countries (Brazil, Russia, India, China, South Africa) face a number of structural bottlenecks that challenge the delivery of and access to these services. This is especially the case regarding the distribution of services within the countries, particularly in rural and less developed regions.

The following article provides a review of recent changes to the health systems of the BRICS countries and an account of recent progress against health-related Millennium Development Goal (MDG) indicators. It brings up select points but is not intended to be an exhaustive review of the literature nor a comprehensive description of each health system. As there are many aspects outside the health care system that affect health outcomes, we are careful not to imply causation but hope that this information colours and provides some context to the description of the various BRICS health care systems.

Health systems of the BRICS countries

South Africa has a two-tier health system that relies on public and private sectors. Since 1996, the public sector has provided primary care free at the point of use (i.e. no user fees required), though the network of health professionals and the overall funding of the system are insufficient to meet the demand. The country's health care system faces a particularly challenging degree of inequity in practice, due in part to the structural issues resulting from public funding of private health care and health insurance systems (5 of the 8 per cent of gross domestic product (GDP) dedicated to health care subsidises private health care). Despite being highly subsidised, private health care and health insurance schemes still demand high user fees, which are beyond the contributive

capacity of most vulnerable populations (Centre d'Analyse Stratégique 2012).

India, on the other hand, attempts to increase health care progressivity through its vast public-private partnerships. It compels service providers to create more flexible participation criteria with the aim of accommodating vulnerable groups and poor people. A flagship initiative in this regard is the *Rashtriya Swasthya Bima Yojana* (RSBY), a scheme funded by federal (75 per cent) and state (25 per cent) governments, under which households living below the national poverty line only need to contribute a small amount of money (just enough to cover registration costs). Coverage is provided by public and private companies through guidelines established by a public regulatory agency. Launched in 2008, the initiative aims to benefit 60 million households, and, in its first two years, 18 million households classified as living below the poverty line (about 50 million people) had been included in the programme (Krishnaswamy and Ruchismita 2011). Although there have been recent efforts to coordinate existing policies and services, the Indian system is still based on several public schemes operationalised by private partners with scarce coordination, facing duplication and efficiency challenges (Centre d'Analyse Stratégique 2012).

Since its 1988 Constitution, **Brazil** has relied on the Unified Health System (*Sistema Único de Saúde*—SUS), a federal structure that provides both basic and specialised health services free at the point of use, through a vast network of public hospitals and clinics fully funded by the State through taxes. However, there are areas where demand for these services is greater than the supply, mostly in rural/ sparsely populated and less developed municipalities (ISSA 2013). The Workers Party's government was particularly committed to ameliorating the shortage

of health care professionals in such areas through special programmes to attract Brazilian professionals (e.g. *Programa de Valorização do Profissional da Atenção Básica*—Provab) as well as those from abroad (e.g. *Programa Mais Médicos*).

Russia's health care system has relatively high indicators of coverage and quality of services compared to the other BRICS countries. The country has a vast number of hospitals and clinics, both public and private. Since private hospitals charge user fees, health insurance is of utmost importance. The management and operation of health services devolves to federation units, although they are guided by a central government strategy. To mitigate user fees and barriers to access, the country has two separate health insurance (funding) systems.

First, the Mandatory Health Insurance Fund covers basic health services and is subsidised by central government funds, covering about 98 per cent of the population. With their share of the national funds, local and regional governments are responsible for subcontracting private insurance packages to be chosen by the beneficiaries. Even though this set-up is meant to provide users with a variety of choices, often the subcontracting by local and regional governments is monopolistic or oligopolistic, and in such cases beneficiaries have to accept benefit packages ostensibly more limited than what could be achieved if actual competition existed among the various subcontracted insurers (Popovich et al. 2011).

Second, the Voluntary Health Insurance Fund covers relatively specialised health services and reaches only around 5 per cent of the population. In addition, there are private health insurance plans available, where risk pooling is smaller, but contributions and premiums can be suited more accordingly to the needs and demands of consumers. It is worth noting

FIGURE 1: Performance of the BRICS countries regarding selected health targets of the Millenium Development Goals. Nutritional status, maternal and child care

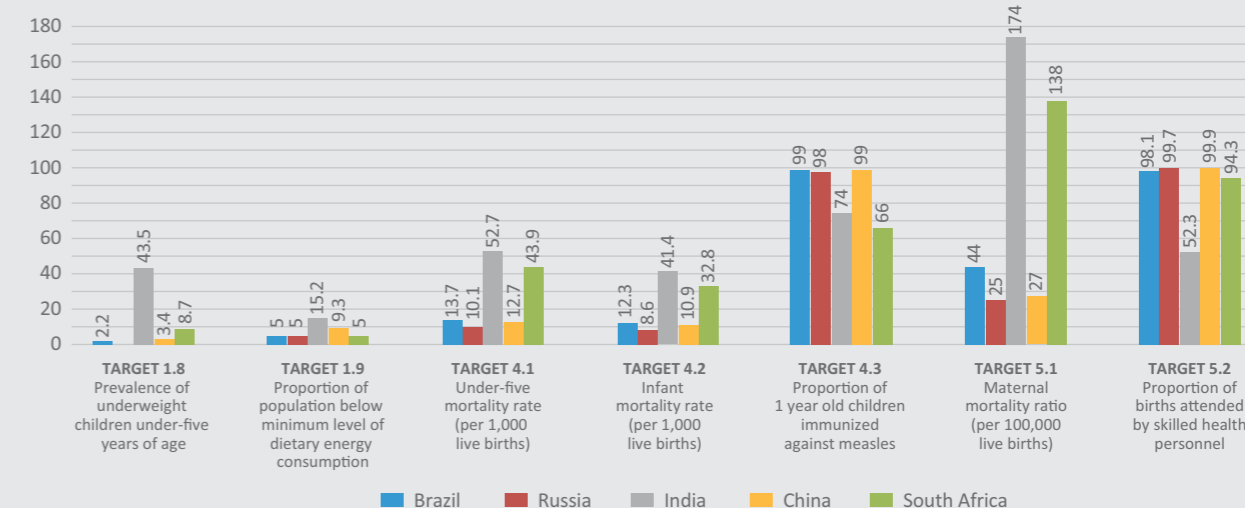
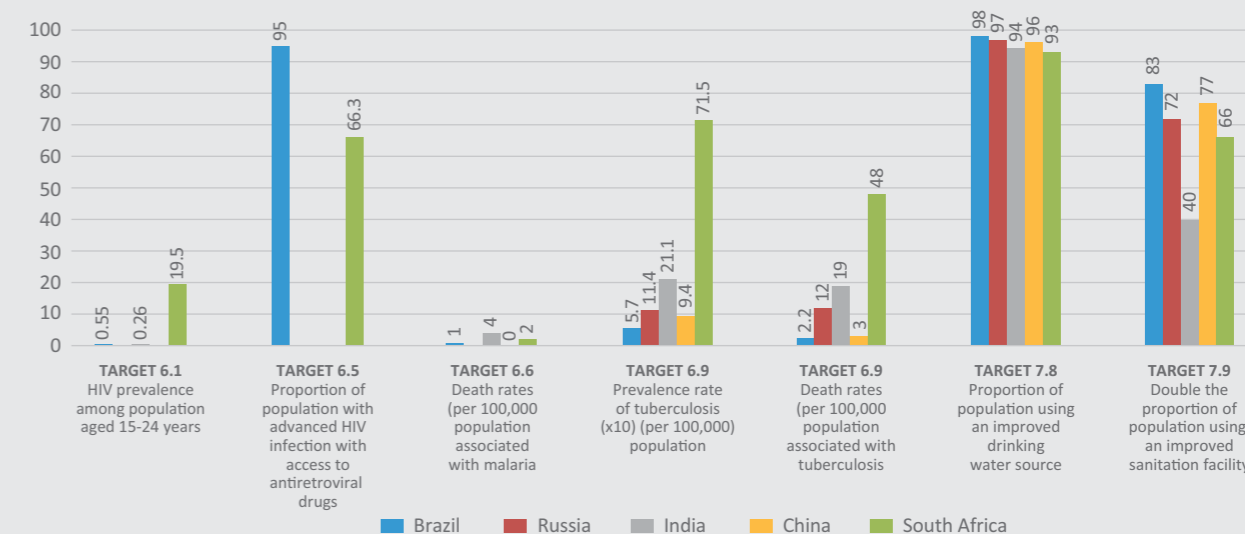


FIGURE 2: Performance of the BRICS countries regarding selected health targets of the Millenium Development Goals. Specific diseases and environmental health factors



Source: Authors' elaboration based on data from the United Nations Statistics Division.

Note 1: Some of the MDG data presented on the United Nations Statistics Division website have been adjusted by the specialised agencies responsible, to ensure international comparability, in compliance with their shared mandate to assess progress towards the MDGs at the regional and global levels.

Note 2: Data refer to the latest available year for each country. Data on Targets 4.1, 4.2, 4.3, 6.1 and both of 6.9 (prevalence and death rates) are from 2013. Data on Target 6.6 are from 2012. Data on Target 6.5 are from 2011. Data on Target 1.8 for Brazil, India, China and South Africa are from, respectively, 2007, 2006, 2010 and 2008. Data on Target 5.2 for Brazil, Russia, India, China and South Africa are from, respectively, 2012, 2010, 2008, 2013 and 2008. All remaining data are from 2015.

that many of Russia's health outcome indicators are comparable to some of the best-performing countries of the Organisation for Economic Co-operation and Development (OECD) (ibid.).

Other than expanding health insurance coverage to more specialised health care services, Russia's main challenges include improving the cost-effectiveness of its services (which cost around 30 to

40 per cent more than in OECD countries with comparable health outcome indicators) and restructuring the network of mid-level health agents (ibid.).

“ Given the complexities and uniqueness of health contexts in each of the BRICS countries, there is no one-size-fits-all instrument that can adequately illustrate the health achievements and the health status of these countries.

In **China**, the supply of health care used to be provided by communes and state firms, but since the 1980s and a pro-market reorientation, the provision of these services has changed. Furthermore, in the past decade, the State restructured their supply. Currently, health care services are offered by central and local governments through rural and urban initiatives that have both contributory (e.g. the New Rural Cooperative Medical Scheme—NCMS—and the Urban Employee Basic Medical Insurance—UEBMI) and non-contributory streams (Resident-Based Basic Medical Insurance Scheme—URBMI). In addition, central government funds are provided to subsidise user fees (Medical Financial Assistance Programme—MFA) (Meng and Tang 2010).

As a result, in 2008, about 87 per cent of the entire population of China was covered by a health care plan—68 per cent of whom were covered by NCMS, 15 per cent by UEBMI, and 4 per cent by URBMI. Between 2005 and 2010, China increased the proportion of people covered by health insurance from 24 per cent to 94 per cent of its total population (around 16 million newly insured per month during this period) (Meng and Tang 2010).

Performance regarding some health-related MDG targets

Given the complexities and uniqueness of health contexts in each of the BRICS countries, there is no one-size-fits-all instrument that can adequately illustrate the health achievements and the health status of these countries. Nevertheless, a glance at the health-related targets of the MDGs can illustrate how these countries perform in relation to different health indicators, as well as cross-sectional changes in these dimensions from 1990 to 2015. For the purpose of this article, we have selected 14 health-related MDG targets and their respective indicators for monitoring (see Table 1). These were selected because they feature available data for most of the 15-year period of the MDGs, and because they refer to aspects that are neither too context-specific nor too dependent on surveys based on subjective perception. This is arguably the case with information on popular knowledge regarding HIV transmission mechanisms, the use of condoms and other aspects that are purposefully not analysed here.

Looking at some of the recent data for the indicators analysed for each BRICS country (Figures 1 and 2), it is easy to notice that Russia stands out for having the most positive figures related to nutrition and child, maternal and newborn health care. Communicable disease-specific indicators related to HIV and malaria have relatively little relevance for the country, although tuberculosis is a serious challenge. Indicators related to environmental health aspects show almost universal access to improved drinking water sources, although there is still much work to do to increase access to improved sanitation facilities.

Brazil and China perform similarly and/or almost as well as Russia regarding most nutritional and maternal, child and newborn health indicators, and their challenges related to tuberculosis are less pronounced. China provides no data on HIV and malaria, while Brazil faces challenges in both of these areas; however, it relies on a policy that provides access to antiretroviral medicines to 95 per cent of people living with HIV.

Whereas China’s indicators for environmental health are similar to those of Russia, Brazil actually achieves better figures than its BRICS peers. India and South Africa are different from the group, as they have relatively worse indicators. Among them, India has the worst indicators for nutritional, maternal and child outcomes, as well as access to improved sanitation facilities, whereas South Africa faces more challenges than India regarding HIV, malaria and tuberculosis. South Africa faces a particularly stark challenge due to its very high prevalence of HIV (the highest in the world) in a context where over 30 per cent of people living with HIV have no access to antiretroviral medications.

With the exception of MDG Target 6.5—which calls for universal access to antiretroviral medicines—all the others refer to relative goals (e.g. halving, improving proportions and rates of reference etc.). Brazil and China exhibited the highest rates of targets fulfilled (progress rate) of the BRICS countries: 83 per cent and 82 per cent, respectively. They are also the countries with most data available for the period 1990–2015. Rates of targets fulfilled (or progress rate) refer to the number of

TABLE 1: Progress of the BRICS countries regarding selected MDG health targets							
	Target 1.8: Halve prevalence of underweight children under five years of age	Target 1.9: Halve proportion of population below minimum level of dietary energy consumption	Target 4.1: Reduce under-five mortality rate (per 1,000 live births) by two thirds	Target 4.2: Reduce infant mortality rate (per 1,000 live births) by two thirds	Target 4.3: Increase the proportion of one-year-old children immunised against measles by two thirds	Target 5.1: Reduce maternal mortality ratio (per 100,000 live births) by three quarters	Target 5.2: Increase the proportion of births attended by skilled health personnel by three quarters
Brazil	✓	✓	✓	✓	✓ - Universal	X	✓ - Universal
Russia	✓	X	X	X	✓ - Universal	X	✓ - Universal
India	X	X	X	X	✓	X	X
China	✓	✓	✓	✓	✓ - Universal	X	✓ - Universal
South Africa	X	X	X	X	X - Worsened	X - Worsened	✓ - Universal

	Target 6.1: Halve HIV prevalence among population aged 15–24 years	Target 6.5: Proportion of population with advanced HIV infection with access to antiretroviral drugs (universal access)	Target 6.6: Halve the death rates (per 100,000 population) associated with malaria	Target 6.9: Halve the prevalence of tuberculosis (x10) (per 100,000 population)	Target 6.9: Halve the death rates (per 100,000 population) associated with tuberculosis	Target 7.8: Double the proportion of population using an improved drinking water source	Target 7.9: Double the proportion of population using an improved sanitation facility
Brazil	NO BASELINE	✓ - Universal	NO BASELINE	✓	✓	✓ - Universal	X
Russia	NO DATA	NO DATA	NO BASELINE	X - Worsened	X - Worsened	✓ - Universal	X
India	X - Worsened	NO DATA	NO BASELINE	✓	✓	✓ - Universal	✓
China	NO DATA	NO DATA	NO BASELINE	✓	✓	✓ - Universal	X
South Africa	X - Worsened	X	NO BASELINE	X - Worsened	X - Worsened	✓ - Universal	X

Source: Authors’ elaboration based on data from the United Nations Statistics Division.

targets fulfilled by each country divided by the number of targets for which the country has available data for 1990–2015.

Given that Russia was the sole BRICS country whose favourable health conditions date back to before the 1990s, it can be intuitively understood that its progress rate over the period was only 37 percent, even though it holds some of the best current indicators. The same logic explains how, on the other hand, India has a progress rate of 42 per cent, even though most of its current indicators still have far to go to catch up with the levels observed for Russia, Brazil and China.

Brazil and China not only have similar rates of progress regarding the same MDG targets, they also show very similar behaviour regarding the improvement curves for most indicators. They also both fall short of the MDGs in regards to the same two indicators: maternal mortality rate and access to improved sanitation facilities. It is a matter of

concern that India and Russia have exhibited worsening indicators related to the prevalence of HIV and tuberculosis compared to their 1990 levels.

Finally, it is worth noting that this article purposefully neglects to provide an analysis of the progress of South Africa, as we believe there may be some limitations to the comparability of data, given the transition from Apartheid to democracy, and because we understand that the disease-specific (HIV/AIDS) epidemiological burden faced by South Africa is disproportionately higher than the ones faced by other countries, and that it has particularly troubling effects for a progress analysis, since it relates to a pandemic that started to spread at the beginning of the period under scrutiny.

Phillips (1999) provides comprehensive analysis of such problems featuring demographic survey data gathered during the Apartheid regime, whereas Bhorat and Kanbur (2005) illustrate the challenges

inherent to the process of consolidation of new data-sets in the first post-Apartheid years. Also relevant is the Jeremy Seekings article (2006) that discusses these data-related aspects while also drawing attention to the fact that comparisons of periods before and after the 1990s have to take into consideration the emergence of HIV/AIDS pandemics, which deteriorate life expectancy and death rates, and how such effects are particularly pronounced in South Africa (the country with the highest prevalence of the disease in the world, with rates over 1500 per cent higher than those of the other BRICS countries). For these reasons, we advise caution on the interpretation of South African nominal performance as illustrated in Table 1.

Concluding remarks

India and South Africa depend greatly on public–private partnerships, although they differ largely in that India has a more progressive set-up for ensuring access to health care. However, that country also has room to improve in terms of cost-

“All of the BRICS countries should strive to provide their people with access to improved sanitation facilities, a major environmental factor related to preventable diseases.



Photo: Dmitry Kirillov/World Bank. General practitioner taking blood test, Russia, 2011 <<https://goo.gl/cefU8>>.

effectiveness and coordination. Among the countries whose health policies are more dependent on the direct provision of the services by the State, Brazil stands out as the one that does not charge user fees, while China is developing subsidy funds and non-contributory streams to mitigate the coverage gaps of its contributory initiatives. Russia's large formal labour market makes it somehow easier to increase adherence to the mandatory, contributory basic health insurance, although the country still faces the challenge of expanding the coverage of the voluntary health insurance set up to mitigate the costs of more-specialised health care services.

In terms of their performance regarding the health MDG targets, there is a clear divide separating Russia, Brazil and China from India and South Africa. The first group has relatively better health indicators, including almost universal immunisation rates against measles, although they all face major challenges due to specific disease burdens, such as tuberculosis in Russia and HIV in Brazil. These diseases represent even more severe challenges in India and, especially, South Africa.

From our select group of indicators, it is evident that all of the BRICS countries should strive to provide their people with access to improved sanitation facilities, a major environmental factor related to preventable diseases. This is a particular challenge for India, whose coverage is

still below 50 per cent of the population. Brazil and China achieved by far the most progress in relative terms during the 15-year period of the MDGs. The worsening scenarios related to diseases such as HIV and/or tuberculosis in Russia, India and South Africa deserve political attention. Specifically regarding HIV, the Brazilian trajectory may be of interest to India and, especially, South Africa, since Brazil performs well not only regarding the target related to reduction in prevalence but also the one related to the provision of universal access to antiretroviral medicines.

Although this article discusses key elements of the health systems and MDG-related progress in the BRICS countries, any policy recommendation must be the result of more in-depth studies. This is because we have only considered health care systems in a somewhat isolated manner, and progress and setbacks in health are often related to many interconnected external factors such as disease burden—which in South Africa's case is very high in terms of HIV/AIDS. ●

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Improving access and reducing health inequities in India, Brazil and South Africa: financing, human resources and private-sector strategies

by Venkat Raman,¹ Gert van Zyl,² Jeni Vaitsman,³ Lenaura Lobato,⁴ José Mendes Ribeiro⁵ and James W. Björkman⁶

Analysing the inequities in the health sector is a significant topic for researchers, development partners, social entrepreneurs, and governments across the globe. Cooperation among researchers in India, Brazil and South Africa was established in 2014 to study policies aimed at tackling three key issues that might improve access to health care and, as a consequence, equity: financing, human resources and public-private partnerships.

The three countries have tried to address their context-specific inequities, each in their own way. Evidence about the potential causes of inequity, and how equity might be enhanced, can provide valuable lessons for learning across the countries. Best practices and innovations in financing, human resource management and private-sector engagement (and regulation) may improve evidence-based policymaking in each country.

Despite diverse social settings and differences in economic, demographic and health indicators, India, Brazil and South Africa share democratic political systems and an avowed commitment to achieving equitable access to affordable health care for all their citizens. Access to health services is a core determinant for equity in health, as it involves social, geographic, economic, organisational and individual characteristics—specifically, the organisation of service delivery, geographic availability, affordability and acceptability. Brazil has a constitutionally guaranteed universal (public) national health system as well as a strong private insurance subsystem. India's large network of state-funded health facilities suffers from severe resource constraints (funds, equipment and

human resources); therefore, a substantial portion of its population seeks services from an unregulated private sector. In the absence of insurance, Indians either pay out of pocket or refrain from seeking medical care. South Africa has initiated a scheme for national health insurance that is moving towards universal coverage, but disparities still exist in the use of services among different social groups. Capacity to pay for services is one of the major causes of inequity.

Given their large and diverse populations, all three countries experience the challenge of guaranteeing equitable access to health care. Brazil has a family health strategy covering around 70 per cent of the population, but its referral system is inefficient, and patients have difficulties in accessing secondary and tertiary care.

South Africa is moving away from its hospital-centred approach to one that emphasises primary care and ensures availability of funding at different levels of service delivery. India has adopted a pyramidal health system⁷ based on primary care but is struggling to improve the base of the pyramid (i.e. rural health service delivery and the referral system). Each country has severe inter-regional disparities, not only in health indicators but also in the availability of resources and governance; there are shortages and regional imbalances among categories of health professionals as well as inadequate regulation of the private sector.

The imbalanced distribution of resources between the public and private health sectors severely impacts the poorest and most vulnerable segments of society, thus accentuating the problems of access and inequity. In addition to difficulties in accessing general health services, particular groups such as elderly people, people with disabilities, women and

children face other types of neglect in these countries.

Addressing the challenge of equity and access

Moving beyond principles of fairness, the growing recognition that access to good health services produces direct positive impacts on poverty and inclusiveness has stimulated the creation of policies geared towards the expansion of the provision of health interventions and services. Over the last decade, indicators related to infant mortality, infectious diseases, malnutrition, vaccination and longevity have improved in all three countries; however, their public systems continue to display deficiencies in capacity and resources. Each country is striving to address the challenges of equity and access.

The Brazilian public health system is currently facing many such challenges, among which imbalances in health financing—due to fiscal constraints—and system coordination—due to excess decentralisation. Another challenge relates to human resource shortages in a context of growing demand for public services. In the case of medical doctors, the shortage is exacerbated due their high mobility across different private markets (selling their services to the public sector, participating in private health plans, having their own private practice etc.), which can decrease the attractiveness of working with the public sector. Concerning private health plans, the challenges are mostly regulatory.

India is addressing inequities in rural health services through the National Rural Health Mission (NRHM), a sub-mission of its National Health Mission initiative, with additional funding, contracting of human resources, private-sector collaboration and insurance schemes. However, the poor regulation of the private sector continues to be a major cause for concern.

South Africa's health policy agenda is centred on revitalising the organisation of health services through human resource training, financing and insurance, and the strengthening of the district health system.

Central to any health system, human resources comprise the single largest expenditure in public health. Therefore, the efficiency of any health system is directly influenced by human resource management policies and practices. All three countries face shortages across different categories of health personnel and imbalances in their distribution over geographical regions as well as between the public and private sectors. The public sector often competes rather unsuccessfully with the private sector for health professionals: work conditions and comparatively low wages not only make public health services less attractive but can also cause absenteeism and moonlighting among doctors in the public sector. All of these factors aggravate the problem of deficient access to health services in public health facilities. The rapid expansion of private medical schools and the high cost of medical education often create a set of circumstances and incentives that can lead to doctors being unwilling to work in the public sector due to archaic service rules and lower pay.

The role of the private sector in a country's health system can be assessed not only by the proportion of services it provides but also by comparing private health

TABLE 1: Brazil, India and South Africa – selected indicators			
Demographic and human development indicators		Brazil	India S. Africa
Population (millions) in 2012 (*)		199	1236 52.3
GDP per capita (PPP in USD) (*)		12,526	5,777 12,722
Percentage of the population living on below USD1.25 per day, 2002–2012 (**)		6.14	32.68 13.77
Income inequality (GINI Index 2003–2012) (*)		0.55	0.34 0.63
Gender inequality, index rank (*)		85	127 94
Health financing and resources (input indicators)			
Health expenditure, 2012 (percentage of GDP) (*)		9.3	4 8.8
Per capita health expenditure, 2012 USD (*)		1056	61 645
Public health expenditure (as a percentage of total health expenditure 2012) (*)		46.4	33.1 47.9
Private health expenditure (as a percentage total health expenditure 2011) (***)		54.3	69.5 52
Out-of-pocket health expenditure (as a percentage of total health expenditure 2012) (*)		31	57.6 7.2
Private prepaid plans (as a percentage of private expenditure on health 2012) (***)		40.4	4.6 81.1
Physicians per 10,000 population, 2007–2012 (*)		18	7 8
Hospital beds per 1000 population, 2007–2012 (**)		2.3	0.7 2.4
Health outcome indicators			
Life expectancy at birth (years) 2013 (**)		73.9	66.4 56.9
Crude birth rate (per 1000 people) 2012 (*)		15	21 21
Crude death rate (per 1000 people) 2012 (*)		6	8 13
Maternal mortality rate (per 100,000 births) 2010 (**)		56	200 300
Infant mortality rate (per 1000 births) 2013 (*)		12	41 33
Under-five mortality rate (per 1000 births) 2013 (*)		14	53 44

Source: * World Bank 2014; ** UNDP 2014; *** WHO 2014.

expenditure to total health expenditure. The private health sector in all three countries is a complex amalgamation of non-state service providers that range from unqualified practitioners to polyclinics, nursing homes and hospitals of varied sizes, diagnostic centres, pharmacies, blood banks etc. They differ in size, ownership and purpose, sources of

funding, market segments, resources and technology deployed, tariffs and regulatory control. Private health expenditure in proportion to out-of-pocket expenditure is significantly higher in India than in Brazil and South Africa. In countries where the private sector dominates service delivery and where out-of-pocket expenditure is high, governments have sought to

collaborate with the private sector (through public–private partnerships); however, these arrangements have their own set of associated complexities.

In Brazil, the upper and middle classes, as well as portions of the working class, pay for private health insurance and private service providers, which deliver services through public contracts. Municipalities manage and regulate service delivery according to such contracts, but the high cost and low quality of monitoring mechanisms remain a major weakness.

India's private sector is responsible for the treatment of around 80 per cent of outpatients and more than 60 per cent of inpatients, but almost 80 per cent of costs for services are paid out of pocket, with significant inter-state and urban–rural variations. Estimates suggest that out-of-pocket medical costs drive nearly 6 per cent of India's population (63 million people) below the poverty line each year (World Bank 2014). In addition to pro-market policies, low expenditures on public health and poor regulatory systems have stimulated the rapid growth of India's private sector.

In South Africa, a small proportion of people use private medical insurance schemes, even though the private sector controls more than a quarter of total hospital beds. Private health expenditure accounts for around half of all health expenditures, but less than one fifth of the population uses the private sector for health services. Private insurance schemes constitute 44 per cent of total health funds but cater to only 16 per cent of the population. Around 16 per cent of the uninsured population consult with private general practitioners. There is also a large disparity among different racial groups in accessing private health care services: nearly 71 per cent of white South Africans, 47 per cent of Indians and only 10 per cent of black South Africans use the private sector.⁸ Despite the low coverage of the private sector, it employs significantly more doctors, nurses, dentists and pharmacists.

The need for policy research
Socio-economic, demographic and health indicators concerning India, Brazil and South Africa are already

well known. New studies, based on primary data and in-depth analyses, are crucial tools for understanding local features, problems and arriving at potential solutions. They should review the achievements and flaws of each health system and explore possible innovative solutions from each other's experiences. Comparative analyses and documentation of best practices can then identify policy alternatives and options for reform.

Of course, 'one size does not fit all', and a number of responses may be feasible to address similar issues. Different schemes, programmes or policies might facilitate increased access to universal health services, and lessons may be learned on how service delivery systems help to address inequities in different contexts of gender, social group, income, age and geographical areas. ●

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2. University of the Free State, South Africa.
3. National School of Public Health and Centre for Strategic Studies – Oswaldo Cruz Foundation, Brazil.
4. Fluminense Federal University, Brazil.
5. National School of Public Health and Centre for Strategic Studies – Oswaldo Cruz Foundation, Brazil.
6. Institute of Social Studies, The Netherlands.
7. A system whereby primary health centres (state-owned rural health care facilities at the base) are connected to secondary care facilities, such as district hospitals, and tertiary care units, such as state medical college hospitals.
8. Whites, Blacks, Coloured and Indians were the main population groups defined under the Apartheid regime and still count as the major population groups for the purpose of social policymaking today.

“ Given their large and diverse populations, all three countries experience the challenge of guaranteeing equitable access to health care.



Photo: Stephan Bachenheimer/Word Bank. Mother of low-income family takes care of her children, Brazil, 2015 <<https://goo.gl/cefU8>>.

Improving health and access to health care in South Africa and India¹

by Charl Swart,² Kieke Okma³
and Radhika Arora⁴

Countries have addressed the challenge of safeguarding access to health care and improving their population's health in different ways, ranging from social insurance to tax-financed health services or targeted schemes for different population groups. However, those policies have not always been successful at reaching minority populations. In several cases, the health of ethnic, cultural and other minority groups has remained much worse than the majority of the population (Liao, Buy et al. 2009).

This article discusses the efforts of South Africa and India to achieve universal access to health care. It describes major social and economic inequities, and explores whether new health policies—both fiscal policy including health insurance, and the targeted delivery of health care services—have enhanced access to health services and improved the population's health in these two nations.

Social differences and inequities—the problem

South Africa and India share the legacy of colonialism, heterogeneous populations and widening inequalities. In India, this heterogeneity extends to a bewildering spectrum of social, cultural and geographical diversity. Apart from the major racial groups defined under the apartheid regime,⁵ South Africa has many other racial and ethnic minorities. Both countries have witnessed economic growth over the last few decades, which, while ushering in multiple benefits, has also widened social and economic inequities. South Africa, with a Gini coefficient of 0.634 in 2011 (World Bank 2010), is one of the most unequal societies in the world.

South Africa's colonial and apartheid legacies of racial discrimination and segmentation are reflected in disparities in the overall health of the population and unequal access to health services

(Coovadia et al. 2009). In 2012, life expectancy at birth among different groups of the population ranged from an average of 47.2 years for Black to 59.7 for Coloured (mixed-race), 65.8 for Indian/Asian and 71 for White South Africans (van Rensburg 2012: 192).

The wealthier white minority accesses health care largely in the private sector—characterised by out-of-pocket payments or coverage by private health insurance (Ataguba and McIntyr 2012; Harris et al. 2011). The private health sector offers better services than the public sector, with a disproportionate share of resources—over 40 per cent of total health expenditure for only 16 per cent of the population. Private health insurance covers over 70 per cent of the white population, but only 10 per cent of black South Africans, 22 per cent of the mixed-race (coloured) population and 47 per cent of Indian/Asian South Africans (Mayosi et al. 2012). Black South Africans have an unemployment rate five times higher than whites; they are far more likely to be uneducated, and to lack access to safe drinking water and adequate housing (ibid.). Socio-economic status, race, insurance status and urban/rural location are generally associated with access barriers to health care in South Africa (Harris et al. 2011).

The impact of India's caste system on access to health care is reflected in divergent immunisation rates and access to safe child delivery, among other aspects. For example, only a third of the women living in urban slums have delivered their babies in clinics or hospitals, versus 93 per cent of women living outside those slums in the same region (Sanneving et al. 2013). Discrimination results in poor quality of care. Moreover, health workers may refuse to enter homes of people of a certain caste. Social health insurance schemes are sometimes simply not implemented in areas where people belong to a certain caste or religious group. Minority and disadvantaged groups are often ill

informed of their rights and have little to no access to legal recourse (ibid.).

Access to health services

South Africa and India have extensive formal legal, political and constitutional safeguards to provide access to health care to all their people. South Africa's Constitution of 1996 states that health care is a fundamental right for all South Africans. It lays the foundation for a “liberal and egalitarian healthcare system” (van Rensburg 2012: 127). Furthermore, improving health and access to health care are important goals of the African National Congress (ANC), the dominant political party since the country's first democratic election in 1994.

The ANC government sought to actively address inequalities in different ways. It presented no fewer than 40 health policies, plans and programmes aimed at improving the population's health and the health system (ibid.). Those policies consider primary health care (local clinics, community health centres and regional hospitals) crucial to ensure universal access to health. The National Development Plan (NDP) served as its long-term “socio-economic development roadmap” (SAPA 2013). The NDP chapter on health reform includes specific targets—for example, raising the average life expectancy from 52 to 70 years and reducing infant mortality to 20 deaths per 1,000 live births.

The ANC announced National Health Insurance (NHI) as a means to reach its targets and reduce inequities in access to health (National Planning Commission 2011). The NHI is to become a population-wide health insurance, financed by contributions from all citizens and long-term residents. All patients can contract a public or private insurance plan for basic medical care (Longman 2015). However, the plan's actual implementation has been slow. By 2016, pilot schemes had started in only 11 of the 52 districts, and concerns were raised about costs, administrative complexity, and the monopoly position



Photo: JPippa Ranger/Innovation Advisor/DFID. Community health worker gives a vaccination in Odisha state, India, 2011 <<https://goo.gl/OOAAQfn>>.

of the existing (private) medical insurance schemes (WHO 2010; Surender 2016).

There has been fierce opposition against the NHI from political opposition parties and different stakeholders—including the private medical sector. When the state Competition Commission appointed the private auditing firm KPMG to investigate funding of the private health sector, Netcare, a major private medical company took the Competition Commission and KPMG to court, citing a conflict of interest (Hodgson and Heywood 2014). The High Court ruled in favour of the Competition Commission and decided the investigation could continue (Rugege 2014). Other health plans and the majority of the physicians continued their opposition against the NHI, fearing excessive government control (Business Tech 2016; Surender 2016). Such opposition is not new or unique to South Africa; when the UK introduced its National Health Service in 1948, there was fierce opposition from the British Medical Association; likewise, the Australian Medical Association opposed Australia's national health insurance in 1985 (Mooney 2011).

The Indian Constitution promises universal access to health care and other social services. The notion of ‘health for all’ has figured in the Indian social policy agenda for decades, reappearing in the health debate over the last decade. The first post-colonial Indian government adopted a blueprint for a universal public health system, outlined by the 1946 *Bhore*

Committee Report. This focused on the needs of vulnerable groups, especially women and children across all social strata. In the following decades, successive national health and development policies and government programmes, such as the Reproductive and Child Health Programme and the Integrated Child Development Service, emphasised the needs of disadvantaged groups such as Scheduled Castes (Dalits) and Scheduled Tribes (Adivasis).

India has undertaken major health-sector reforms since 2005, starting with the National Rural Health Mission (NRHM), now the National Health Mission (NHM). The NRHM aimed to improve maternal and child health and the quality of and access to primary care, and to strengthen outreach services in rural and remote areas; it also included health insurance through the 2008 National Health Insurance Programme (*Rashtriya Swasthya Bima Yojna*—RSBY) for people living in poverty. The Maternal Security Scheme (*Janani Suraksha Yojana*—JSY) covers the costs of institutional delivery of up to two live births for INR500 for poor people, while RSBY covers inpatient care for up to INR30,000 annually per family (currently undergoing changes) (Mandal, Prabhdeep, and Murhekar 2012; Powell-Jackson, Mazumdar, and Mills 2015; Thakur 2016). The NHM is undertaking further initiatives towards strengthening the health system and urban health. Even so, public health expenditure remained near 1 per cent of GDP, a very low level given the high

ambitions for universal insurance coverage (World Bank 2010).

The result of interventions

Despite lofty ambitions, policy implementation in South Africa over the last decade has been modest (Gray, Vawda, and Jack 2013). The introduction of the NHI has been slow, eliciting speculation about its future (Archer 2014; Kardas-Nelson 2014), and the private medical sector has not relented in its resistance against it (Hodgson and Heywood 2014). Despite these challenges, there are no signs that the government has abandoned plans for the further development of the NHI, maintaining that it will help address inequalities in access to health care (Motsoledi 2014).

In India, multiple schemes run in parallel, targeting different social and economic population groups, yet they have not managed to solve the challenges of a crumbling health system. India has been taking significant steps in framing formal health policies to address the urgent needs of its health system, achieve universal health coverage and improve access to health for its most vulnerable populations, but there is a large gap between ambition and reality. Efforts are fragmented, however—often conceptualised and implemented with short-term political goals in mind. Moreover, solving major health issues requires not only public health care but also investment in education, sanitation and the reduction of poverty, in addition to increasing awareness, education and knowledge and empowering vulnerable and marginalised sections of society (Thakur 2015).

Conclusion

South Africa and India have expressed high ambitions to realise universal access to health care as a strategy to improve overall population health. Both are aware of the need to pay special attention to the position of disadvantaged ethnic and cultural minorities. However, declaring intentions to implement universal insurance or even passing legislation to that effect does not automatically mean that everybody has equal access to health services. Abstract discussions about financial protection and funding mechanisms tend to dominate the current global health policy agenda. For example,

the current debate about ‘universal health insurance’ or ‘universal coverage’ seems to pay little attention to how this principle actually translates into effective policies and programmes in the countries that struggle with their day-to-day fiscal and political realities.

South Africa and India have made progress in their health care systems and in the overall health of their populations. They have failed to deliver on the sweeping promises of improved health, better quality and universal access to health care, however. In India, the very low level of public health funding signals that health has remained a ‘soft sector’ in the eyes of policymakers, and that does not seem likely to change soon. This means that in the foreseeable future, despite political promises of universal coverage, most Indians will continue to depend on private resources for health care. In South Africa, governments have committed far more financial resources, yet the legacy of apartheid and racial division remains a massive obstacle to equal access to health care. The focus on the main racial groups as a legacy of apartheid policies has also been a barrier to more targeted policies for other ethnic minority groups.

Moreover, reforms that seek to improve the health of the population require a much wider policy scope than simply access to health services. Such policies need to include education, sanitation, housing and access to clean water if they are to deliver on the promises of improving health and effective health care for the entire population.

Given the current dominance of the private health care and health insurance sectors in both countries, governments must involve the private sector—be it health insurance or health care providers—in its policymaking process. Shifting resources from one destination to another always entails political struggle. Raising taxes or introducing contributory universal social health insurance are measures bound to face strong resistance from private business interests.

In both South Africa and India, the rhetoric around health care leans towards universal access to health care based loosely on social welfare ideologies.

Both countries are struggling to float the proverbial ‘socialist boat in a capitalist ocean’; both consider universal access to health care an important element of policy development, and both are dedicated to improving the health of their populations. For both nations, the major challenge is how to align their social policy rhetoric to their day-to-day political, social and fiscal realities. ●

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1. The authors would like to express their appreciation for Prof. James Bjorkman’s comments and inputs on an earlier draft.
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5. ‘Black’, ‘White’, ‘Coloured’ and ‘Indian’ racial groups still count as the major population groups for the purpose of social policymaking today. This means that there is less explicit attention to the position of other specific minority groups.

Innovations in the financing and delivery of oral health care in Brazil

by Edvaldo Batista de Sá¹

Following the re-democratisation process that culminated in the enactment of a new Constitution in 1988, Brazil went through a series of policy changes to strengthen the public financing and delivery of health care. The country’s public health care system (*Sistema Único de Saúde*—SUS) aims to provide universal and comprehensive health care to all Brazilian citizens. Although still far from achieving its goals,² SUS has helped to improve access to health care, particularly to primary and emergency services; it has ensured universal coverage of vaccination and prenatal care and free HIV/AIDS antiretroviral therapy (ART), among others. It also provides most high-cost medical services and complex procedures, such as transplants.

Primary care is organised around two co-existing models: the traditional model and the Family Health Strategy (*Estratégia Saúde da Família*—ESF). In the traditional model, a team of health care professionals comprising doctors (e.g. general practitioners, gynaecologists and paediatricians), nurses and assistant nurses provide health care according to individual demand. The ESF is an attempt to integrate medical care with health promotion and public health through family health teams comprising a doctor (a general practitioner or a family doctor), a nurse, assistant nurses and community health workers caring for a registered population. Since the start of its roll-out at the national level in 1994, the number of ESF teams has been steadily increasing, and now more than 40,000 teams care for about 124 million people (almost 64 per cent of the total population) in more than 98 per cent of municipalities (5,463 out of 5,570).

Oral health care has evolved at a slower pace. In 2001, however, the federal government defined a new set of financial incentives to make dental care available through oral health teams (OHTs) in the ESF. As a result, the number of OHTs reached almost 7,000, distributed across about 2,800 municipalities in 2003.

Nevertheless, an oral health survey conducted by the Ministry of Health (Ministério da Saúde) from May 2002 to October 2003 involving almost 109,000 individuals of various ages revealed alarming levels of prevalence of dental caries among children and adolescents; an astounding increase in the number of decayed, missing or filled teeth (DMFT) with age; high levels of periodontal disease among adolescents, adults and elderly people; and high levels of use of or need for dental prosthetics. The survey also found significant barriers to access and major disparities in oral health and access to dental care between different population groups, particularly between individuals living in the different regions of the country (Ministério da Saúde, 2004).³

To tackle these problems, the Brazilian government enacted a new programme, named *Brasil Sorridente* (BS), in 2004. The programme aims to improve access to public dental care through the expansion of OHTs, the provision of specialised dental care through public service providers (specialised dental centres or *Centros de Especialidades Odontológicas*—CEOs) and the expansion of fluoridated water supplies.

Each OHT comprises at least one dentist and a dental assistant or a dental hygienist. They work on the promotion of oral health and the prevention of oral diseases, including oral cancer, and perform less complex dental procedures. They are also responsible for referring patients to CEOs and hospitals, if necessary, where they can receive more specialised dental care. The services provided by the OHTs are financed by the federal and municipal governments.

CEOs must provide at least the following procedures:

- i. the diagnosis of oral diseases, including the detection of oral cancer;
- ii. specialised periodontics;
- iii. minor soft and hard tissue surgeries; and
- iv. endodontics.

Additionally, they might provide orthodontic appliances and dental implants. Another component of specialised dental care within the BS programme are the laboratories of dental prosthetics (LRPD), which are public or private providers contracted to produce dental prosthetics. Similarly to primary dental care, the services provided by the CEOs and LRPDs are financed by the federal and municipal governments. The federal government also allocates funds to help build public facilities and to acquire the equipment and materials required for the provision of these services.

The fluoridation of water supplies started in Brazil in 1953. Currently, the federal government is promoting it through the BS programme by allocating financial resources for projects proposed by sub-national governments. Priority is given to jurisdictions most in need; however, only to those communities with developed water supply systems and that are able to ensure the quality of water actually manage to access these resources.

The BS programme is a health policy priority, and available data show improvements in access to dental care since its inception. Data from the National Household Sample Survey (PNAD) conducted by the Brazilian Institute of Geography and Statistics (IBGE) estimate that 38.8 per cent of the population visited a dentist in the 12 months prior to the survey in 2003 (IBGE 2005). For 2013, this figure was estimated to be 44.4 per cent (IBGE 2015). These estimates are consistent with the most recent surveys carried out by the *Ministério da Saúde*.

Table 1 shows that access to dental care, as measured by at least one visit to a dentist in the last 12 months prior to the survey, has improved for all age groups for which data are available and in all geographic regions of the country—except for adolescents in the Southeast region, where a minor decrease in the variable during the period under analysis was observed. It is worth noting that the North and

Northeast regions had the highest increase in the percentage of the population visiting a dentist, contributing to reducing inequalities in access to oral health services among the different regions. The data also show improvements in oral health outcomes, as measured by the Decayed, Missing or Filled Teeth (DMFT) index.

CEOs are central to the specialised dental care provided by SUS. Some studies show that financial resources have been allocated to more deprived areas (Baldani, Almeida and Antunes 2009; Junqueira et al. 2006) and that, in some localities, specialised dental care was not provided before the CEOs were made available (Deitos 2009). However, the targets for the implementation of new centres are not being met on schedule, and barriers to access remain even in localities favoured by the programme. Currently, there are more than 1,030 CEOs providing specialised dental care, but the National Health Plan 2012–2015 set a target of more than 1,900 by the end of 2015.

A case study for the state of Rio de Janeiro highlights some of the difficulties faced by SUS managers to implement the policy: a shortage of specialised dental care professionals, unreasonable requirements—such as the provision of a minimum number of procedures even when they are not required—and administrative discontinuity (Guerra 2009).

In any case, the main barrier seems to be the lack of financial resources. Federal resources are uncertain: even when resources are allocated to help build facilities and purchase equipment, there is no guarantee that the resources required to pay for ongoing expenses will still be available. The state level has rarely taken part in the funding of dental care, not even at the primary care level. Municipalities, in turn, lack financial resources or do not prioritise the CEOs in their budgets. As for access, a sample of patients interviewed for a case study undertaken in the city of Recife found that more than 50 per cent of respondents claimed it was either difficult or very difficult to arrange a first visit to dentists in the CEOs (Souza and Chaves 2010).

The data presented suggest that the BS programme has had a positive impact on dental care access and oral health

TABLE 1: Brazil and regions – oral health and access to dental care by age, 2003 and 2010								
Variable	Survey year							
	2003				2010			
	Age group				Age group			
	12 y/o	15-19y/o	35-44y/o	65-74y/o	12 y/o	15-19y/o	35-44y/o	65-74y/o
Visited the dentist in the last 12 months (% of group population)								
Brazil	48.55	37.84	16.83	56.60	53.90	49.10	30.40	
North	42.77	31.49	13.61	52.10	54.70	44.20	22.00	
Northeast	40.62	31.91	12.35	61.90	57.70	51.00	32.20	
Southeast	51.02	41.55	17.81	53.40	50.00	46.50	31.00	
South	60.80	46.59	23.52	67.80	63.80	59.20	30.40	
Middle-West	46.50	37.38	14.90	61.00	56.40	46.40	26.40	
DMFT Index								
Brazil	2.78	6.17	20.13	27.79	2.07	4.25	16.75	27.53
North	3.13	6.14	19.88	28.34	3.16	5.64	17.51	28.26
Northeast	3.19	6.34	19.62	27.27	2.63	4.53	16.62	27.20
Southeast	2.30	5.94	20.30	28.61	1.72	3.83	16.36	27.65
South	2.31	5.77	20.61	27.33	2.06	4.01	17.56	27.10
Middle-West	3.16	6.97	20.32	27.93	2.63	5.94	17.66	27.49

Source: Author's elaboration based on data from the Ministério da Saúde (2003, 2010).

outcomes. However, significant disparities remain, and further improvements are required. In the short term, priority should be given to increase and improve the allocation of available financial resources and promote a greater role for state governments. In the long term, the programme might benefit from improvements in the availability of specialised dental care professionals and adequate water supplies—allowing not only fluoridated water to reach poorer communities but also providing an important input into the promotion of health in general. ●

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2. For instance, more than 55 per cent of health care in Brazil is privately financed, and around 25 per cent of the population has duplicate or parallel private health insurance. In the field of health economics, duplicate or parallel private health insurance refers to contexts in which individuals have private insurance covering aspects also covered by the public health system.
3. For instance, in the Northeast region almost 22 per cent of individuals aged 15 to 19 years have never visited a dentist, whereas in the South region this proportion is less than 6 per cent.

The role of the Brazilian Unified Health System (SUS) and the contributions from the Oswaldo Cruz Foundation in response to the outbreak of the zika virus

by Paulo Gadelha, Nísia Trindade Lima, Valcler Rangel and Rodrigo Stabeliⁱ

In November 2015, as a result of the dramatic increase in the number of cases of microcephaly in the northeast of the country, the Brazilian Ministry of Health declared the existence of a Public Health Emergency of National Importance (*Emergência em Saúde Pública de Importância Nacional*—ESPIN) through Decree No. 7.616, of 17 November 2011. This decree demands the urgent use of preventive measures, risk control and containment to limit damage and harm to public health. The strong correlation between zika virus infection and the rapid rise in the number of microcephaly cases has led to increased priority on the intensification of control measures regarding the *Aedes aegypti* mosquito, the vector of what has been conventionally termed the 'triple epidemic': dengue, zika and chikungunya.

Two months later, in January 2016, the World Health Organization (WHO) officially recognised the global significance of the zika outbreak and its potential link to microcephaly, declaring a Public Health Emergency of International Concern. In February, during her visit to the country, Dr. Margaret Chan, Director-General of the organisation, reaffirmed Brazil's central role in solving the problems resulting from the zika epidemic. This was not mere rhetoric, as, despite the recent economic and political crises and the gravity of the public health scenario, Brazil has become the most effective protagonist in confronting the epidemic. This was made possible by the vigorous scientific production in the country and the configuration and capillarity of the Unified Health System (*Sistema Único de Saúde*—SUS), established by the 1988 Constitution, which was promulgated after the

re-democratisation of the country and as a result of an intense social movement for health reforms.

The health emergency currently taking place is connected with an urgent challenge to inform the global health community about the characteristics that are common to other arboviruses, in particular regarding vector control. It is a complex enigma for science and technology, given the lack of insight into biological interactions, etiopathogens, immune response, clinical-pathological manifestations, and the lack of diagnostic instruments and of preventive therapies for what is referred to as congenital malformations and the Guillain-Barré syndrome, both of which are related by the zika virus infection.

That does not mean the absence of registers in scientific literature about the zika virus. According to a brief record, the virus was isolated in rhesus monkeys (sentinels) in the Zika forest in Uganda in 1947. After its discovery, there were only a few reports of infection in humans in South Africa and Asia. Until the 2007 epidemic in the Yap Islands, only 14 cases were documented in the existing literature (Duffy, Chen, and Hancock 2009). During the 2007 epidemic, there were approximately 60 cases that presented cutaneous rash and light symptoms with the presence of IgM and IgG immunoglobulins against the virus (ibid.).

In October 2013, the presence of the zika virus was detected in a small epidemic in French Polynesia, in Micronesia. It was the first reported occurrence of the virus outside the Asian and African continents. At the time, around 8,700 cases were reported—certainly the biggest epidemic recorded before the inception of the virus in Brazil, which exhibits far superior numbers to the epidemic shown in the literature (Roth et al. 2014; Musso 2015). Effectively,

the Brazilian outbreak is unprecedented, reaching a great number of people in a parcel of the population that is not immune to the virus. Undoubtedly, Brazil could be considered a great 'laboratory' for the study of this disease, which has brought so much uncertainty worldwide.

It is important to point out that the dramatic increase in microcephaly cases in Brazil and their possible correlation to the zika virus infection were identified through the care of pregnant women at a hospital in the northeast of the country. From the facts surrounding these initial cases, it was possible to activate an integrated system of surveillance, science and technology. By integrating treatment, diagnosis, inspection, research, development and technological innovation, SUS has been able to gauge the magnitude of the crisis, establish research protocols and design innovation chains to enable a better understanding of the disease, and thus formulate strategies to protect the population.

The existence of a national body that encompasses all these dimensions and that has advanced significantly over the last few decades through the strengthening of basic health care and family health strategies is noteworthy. On the other hand, however, it is also a fact that a failure in vector control has caused Brazil to suffer from extensive dengue epidemics since 1981. The relationship between these epidemics and social and environmental factors can be verified mainly in the urbanisation model adopted by the nation, which has led to the creation of large population centres. These great concentrations of people have led to a lack of proper access for many to public services such as potable water and sewer systems, which are serious issues for the public policy agenda in the country. To rise to this set of challenges, the Oswaldo Cruz Foundation

(Fiocruz), as a strategic institution of the Ministry of Health, comes into play by organising institutional responses to the current emergency as well as contributing to short- and long-term solutions.

The contribution of Fiocruz to national actions related to the response to the zika virus outbreak

To help respond to the current crisis, Fiocruz has created an Emergency Sanitary Council. Since its inception, it has coordinated the employment of research, technological development, teaching, scientific dissemination and care. It is thus seeking ways to integrate initiatives, contribute to public policy, achieve social results and generate scientific knowledge. It has established, in collaboration with other national and international research institutions such as the National Institutes of Health (NIH), the Pasteur Institute and the French Institute of Health and Medical Research (Inserm), a scientific agenda that emphasises the necessity to gather multi- and inter-disciplinary forces around six axes: the improvement of infection evidence databases; the development of rapid diagnostic tests; vector control improvements; the definition of protocols for the treatment of pregnant women and children born with malformations; vaccine development; the reorganisation of health services to confront the epidemic and congenital malformations resulting from it; and popular mobilisation (Barreto 2016).

This is in line with Fiocruz's institutional history, given that it has, since its inception, been oriented towards solving public health challenges based on research and technological development with the end goal of meeting the demands of Brazilian society. The institution was born in response to a public health emergency at the beginning of the 1900s, brought about by epidemics of yellow fever, bubonic plague and smallpox. Over time, some structural characteristics have been recreated and adapted to each historic moment. As part of the Ministry of Health, the institution's mandate is to meet demands and optimise its research to deal with problems.

Another important characteristic is that it deals with a great variety of activities, incorporating the capacity for vertical innovation but also generating synergy,

as in the current case of the zika virus infection. Fiocruz has always demonstrated its excellence in the fields of research, innovation and public health actions. These qualities can be observed in areas such as: vector control; surveillance laboratories; research on congenital malformations; epidemiology; clinical studies; and the development of diagnostics and vaccines, among others. It also brings together groups of excellence in the area of public health with an interdisciplinary focus.

In facing the challenges presented by the zika virus outbreak, a special research programme is being developed, encompassing many areas of knowledge—from biomedical research to the humanities and social sciences. The resulting studies will be capable of dealing with the multiple challenges, including the analysis of social and environmental conditions; the production, technological development and dissemination of scientific understanding of the impacts of the epidemic; the perception of risk and vulnerability; ethical questions such as gender behaviour and reproductive strategies; and the potential impacts of the organisation on public health care networks. To this end, Fiocruz has established clinical management courses for basic health services related to the outbreak, already comprising over 50,000 students, in addition to intense information and social communication programmes.

In the brief period since the outbreak of the zika epidemic, Fiocruz has been directly involved with: the first genetic sequencing of the zika virus linked to microcephaly (Calvet et al. 2016); proving placental transmission and pathological effects on the placenta (Adibi et al. 2016; De Noronha et al. 2016; Oliveira Melo et al. 2016); proving that effects on the foetus can take place during the entire gestational period (Brasil et al. 2016); the detection of the active virus in saliva and urine (Bonaldo et al. 2016); the development of a tri-viral diagnostic kit that is able to detect zika, dengue and chikungunya infections during their acute phase; the development of bio-larvicides; new methods of vector control, such as infecting mosquitoes with the *Wolbachia* bacteria (Caragata, Dutra, and Moreira 2015); and the technique of dispersing

larvicides by the mosquito itself (Abad-Franch et al. 2015).

While these contributions augment a group of actions by the national and international communities to reduce the perplexity at the beginning of the epidemic, at the same time they reveal new questions. We now have no doubts that the zika virus causes congenital malformations and the Guillain-Barré syndrome, and that the *Aedes aegypti* mosquito is its main transmission vector. However, we cannot assume the inexistence of other co-factors, other vectors, or the possibility of other alternative sources of infection. The nature of the interactions with other arboviruses and the immunological response are still largely unknown, and there is some evidence of subacute manifestations.

The answers to many of these questions require installed scientific capacity and regular policies for science, technology and innovation, as well as proper conditions in what is referred to as research material. It is well known that Brazil has a significant number of zika cases and, thus, the genetic material capable of generating references for the construction of serology panels, for test validation, and for the development of vaccines. The country also possesses a structure for organising multi-centric clinical research across various regions. To this end, Fiocruz, as well as various other Brazilian institutions, can provide very significant responses.

In addition to providing research, Fiocruz also works in helping construct a national productive base that enables the country to respond to the demands of the population and of SUS. The zika virus public health emergency could be an exemplary case for the promotion of access to diagnostic tools, vector control technologies or a vaccine that would be feasible for the entire population, if a system of innovation and a production base were in place, capable of making these technologies and products available at a cost-effective level relative to the capacity of the SUS budget.

Some points of great relevance that usually only receive secondary attention in emergency situations are the social and environmental conditions that can decisively interfere in the genesis of vector-transmitted



Photo: Sumaia Villela/Agência Brasil. Baby with microcephaly during a physical therapy session, 2016 <<http://goo.gl/gkR95y>>.

diseases. A considerable problem is that, due to not dealing adequately with structural problems, the search for focal solutions ends up being much more costly. The effects of dengue could be significantly reduced through practical environmental initiatives. This process could not only help control the zika infection but also a series of other problems and threats.

Often a short-term response is employed without the realisation that it is much more expensive, especially when rapid responses are necessary to reduce the incidence of the vector and develop a vaccine. Fiocruz is acting on these fronts, developing new technologies that are exemplified by the introduction of the *Wolbachia* bacteria, the use of bio-larvicides, as well as new techniques for the dissemination of larvicides. These solutions offer the possibility of strong short- and medium-term impacts. The great challenge is how to move from such questions into necessary actions according to social and environmental determinants.

Certainly, the outbreak of the zika virus and its consequences are only the tip of the iceberg. We need to face the broader questions that are central to Brazil's health system in general, from its financing to the creation of its administrative models and the debates about technological models. It is also important to discuss how to model the development of the country, involving broader issues that take into account the loss of quality of life and public health issues. In the context of

global health, the most relevant themes are related to the capacity of governance and the response of multilateral organisations, especially the WHO. It is important to consider the diplomacy of research, with its commitment to the immediate dissemination of results to be shared with the scientific community, the administrators of public health systems and the general population, thus ensuring the capacity of the production system to supply the needs of the population, as well as a commitment to share biological material, based on the norms established by the different countries for the development of research and products.

The project of a society and a nation, the role of the State, a sustainable development model, together with social demands in the field of public health and the new international solidarity ethos will be the great determinants of Fiocruz's capacity to respond to the threats presented by this outbreak of the zika virus. ●

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Photo: Mateus Pereira/Government of Bahia. Fiocruz researcher, Brazil, 2013 <<https://goo.gl/lrxVf4>>.

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Brazil’s triple epidemic: dengue, chikungunya and zika; challenges to society and opportunities for science, technology and innovation

by Rivaldo Venâncio¹

At the end of 1985, Rio de Janeiro was surprised by a disease characterised by acute-onset fever and generalised pain. Months later, researchers from the Oswaldo Cruz Foundation (Fiocruz) identified the causing agent: the dengue virus, transmitted by the *Aedes aegypti* mosquito (Schatzmayr et al. 1986). Since then, dengue has become a common disease in the country, reported in all Brazilian states as well as in the Federal District. There has been an uninterrupted, 30-year-long period of dengue epidemics, during which 15 million cases of the disease have been reported nationwide.

Since October 2013, countries in Central America and the Caribbean have had to deal with chikungunya epidemics—another virus borne by the *Aedes aegypti* mosquito. Between then and January 2016, approximately 2 million cases of the disease were notified, spreading to over 40 countries/territories in the Americas (PAHO 2016). In Brazil, the circulation of chikungunya was verified in September 2014 (Nunes et al. 2016), with thousands of people affected across the 17 states where it was identified.²

Since the end of 2014, the country has had to deal with yet another disease, caused by the zika virus, of the same family and genus as the dengue virus, also borne by the *Aedes aegypti* mosquito (Dick, Kitchen and Haddock 1952). The clinical manifestations of zika were considered ‘benign’, featuring a low fever (not always present), a rash all over the body, itching and joint pains (more prevalent in the hands, fists and ankles), sometimes accompanied by swelling, in addition to irritation in the eyes (Campos, Bandeira and Sardi 2015; Zanluca et al. 2015). In parallel, beginning in September 2015, health surveillance services in some states of the Northeast region of the country started being notified of an abnormal

increase in the number of microcephaly cases in babies born during that period. In Brazil, the Information System on Liveborn Infants (*Sistema de Informações sobre Nascidos Vivos*—SINASC) is responsible for recording epidemiological information related to pregnancy, childbirth and congenital malformations, in addition to the socio-demographic characteristics of mothers. It recorded over 170 cases of microcephaly each year between 2000 and 2014 (Ministry of Health 2015).

Surprisingly, epidemiological investigations suggested the temporary association of these congenital alterations in newborn infants whose mothers were infected by the zika virus during the first few months of pregnancy. Subsequently, the viral genome was detected in the amniotic liquid of two pregnant women whose foetuses were diagnosed with microcephaly. The presence of the virus was also detected in blood and tissue samples of a newborn infant with these and other congenital malformations who passed away soon after birth (Costa et al. 2016). The confirmation of the zika virus as a possible cause of these alterations in newborns represents an unprecedented find in global scientific research.

Both climatic as well as social conditions in Brazil are conducive to the proliferation of the vector mosquito for these viruses. The country features high temperatures and frequent rains, in addition to suffering from severe deficiencies in the collection of solid urban waste and irregular supply of water for domestic use; this intermittent supply fosters inadequate storage and can lead to new *Aedes aegypti* breeding grounds, favouring the occurrence of dengue, zika and chikungunya. In addition, historical urban violence, especially on the outskirts of medium-sized and large cities, hinders the access of agents who work to control these mosquitoes.

The current situation is extremely concerning. The congenital zika epidemic might turn into a real health tragedy (Brito 2015), causing suffering on the level of the HIV/AIDS pandemic. The epidemic that is occurring in the Northeast region, concentrating over 80 per cent of the suspected microcephaly cases (COES 2016), is possibly already starting to affect other states in the country, and, due to the infection affecting pregnant women, an increase in the number of infants with congenital malformations is expected. From September 2015 to the end of March 2016 there had been 907 recorded cases of microcephaly, with 4,293 others being investigated throughout the country.

The recent zika epidemic has spawned a new agenda for overcoming barriers to science, technology and innovation in the country (Barreto et al. 2016). Brazil urgently needs to invest in projects that help understand the dynamics of the transmission of this virus, as well as the mechanisms through which congenital alterations happen, in addition to evaluating the real dimensions of the problem. The answers to this and other challenges demand a multidisciplinary, cross-cutting approach across several professional fields. New solutions to old problems are necessary, such as those related to the control of the *Aedes aegypti* mosquito. Similarly, solutions must be sought to answer the new demands caused by the emergence of diseases that were until very recently inexistent in the country, such as chikungunya and zika.

Overcoming problems of such magnitude demands innovation in the strategies of vector control and the organisation of the entire health care network, including diagnostics, pre-natal care, and support to those who are sick and their families. Over the last 30 years, countless campaigns to

“Both climatic as well as social conditions in Brazil are conducive to the proliferation of the vector mosquito for these viruses.

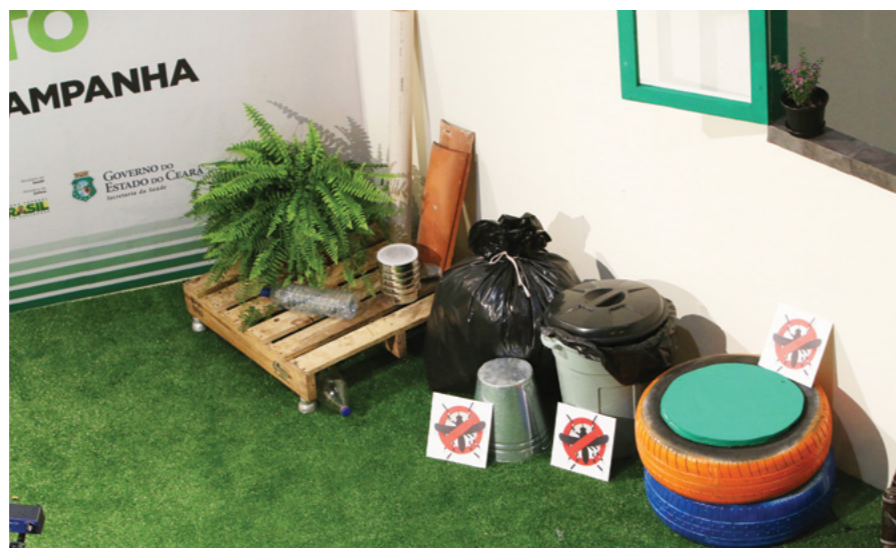


Photo: Brazilian Ministry of Health. Action to combat the *Aedes aegypti* mosquito, Ceará, Brazil, 2016 <<https://goo.gl/DCmBdh>>.

control the spread of the *Aedes aegypti* were enacted (Braga and San Martin 2015), most of the time alluding to ‘battles’ of a purported ‘war against the mosquito’ as a means to engage society. These mobilisations certainly helped to reduce the impact and magnitude of the epidemics; however, they proved insufficient to stop the virus from spreading (da Silva et al. 2016).

Some underwhelming results have been attributed to the mosquito control model adopted over the last three decades in Brazil. One of them relates to the activities aiming to reduce the number of potential *Aedes aegypti* breeding grounds, having been performed without the active participation

of society. After the 1986 epidemic in Rio de Janeiro, a real ‘army’ of vector control agents was established. With each new epidemic, this ‘army’ gains greater visibility in the media, and, as a consequence, the hopes for solving the problem are placed squarely on its shoulders.

Media campaigns are generally geared towards fighting an ‘enemy’, the *Aedes aegypti* mosquito. In practice, this fight was restricted to the use of two tools: chemical products against larvae and also for the elimination of adult mosquitoes; and removal and mechanical destruction of objects that might collect water and, therefore, become potential breeding grounds for the *Aedes aegypti*. The use of insecticides for the

elimination of adult mosquitoes is performed through the dispersion of ultra-low volume (ULV) products.

This idea, spread during national mobilisation campaigns, contributed to reinforcing the belief that once the mosquito had been eliminated, the problem would be completely solved. Furthermore, and even worse, this led to the population believing that the use of these chemical products was the only viable way to eliminate the mosquitoes. Questions related to basic sanitation conditions, including the collection of urban waste and the regular supply of drinking water for domestic use, have not been dealt with. Likewise, this approach also encouraged the passivity

of a significant portion of the population. Often they wait for mosquito control agents to visit their homes and remove objects that might inadequately collect water. This model of social mobilisation has not stimulated reflection about how Brazilian citizens have been taking care of their environment.

It is not possible to control the *Aedes aegypti* mosquito only with the currently available tools, unless some significant, innovative technological development emerges. A good example of innovative technology is the possibility of using the *Wolbachia pipientis* bacteria; once inoculated in a female *Aedes aegypti* mosquito, it renders it unable to transmit viruses. Research on this technology being developed by Fiocruz in partnership with colleagues from Monash University is part of the “Eliminating Dengue: Our Challenge” programme. The incorporation of this new technological innovation must be understood as a complementary tool to *Aedes aegypti* control activities, and does not exclude the need for the implementation of the aforementioned structural measures, such as the improvement of environmental sanitation.

Among the demands that arose from this new epidemiological scenario due to the Zika virus, one requires absolute priority: the development of good-quality diagnosis kits, which are easily performed and accessible to the majority of the Brazilian population. All other actions geared towards attending to those who are sick, especially mothers and babies exposed to the viruses, depend on the existence and availability of trustworthy laboratorial diagnoses. Brazil urgently needs to improve its performance in this area. The Ministry of Health and the institutions related to it, such as Fiocruz, are actively seeking national and international partnerships to overcome the lack of such products in the country.

Another demand resulting from this health emergency is to develop a vaccine against the Zika virus. Naturally, obtaining a vaccine is not sufficient; it must be safe, easily deployed, long lasting, efficacious and accessible for use on a sufficiently large scale. The Zika virus was ‘forgotten’ for the five decades between 1947, when it was first isolated in Uganda, and 2007, when it caused an epidemic in Yap, Micronesia. This ‘dormant’ period of the virus means that it was not thoroughly studied—a fact that is

easily verified by the scarcity of scientific articles published in indexed journals between 1947 and December 2015: a little over 200 articles in almost 70 years.

The reluctance to admit the magnitude of the current triple epidemic—dengue, Zika and chikungunya—might delay the debate about the reorganisation of the current health care model in Brazil even further. It is necessary to establish an outpatient care network for pregnant women suspected of being infected with the Zika virus and, afterwards, for the full-time care of the mother–infant dyad. This outpatient network would be responsible for patient care by doctors of various specialties, such as neonatology, neuropaediatrics, ophthalmology and otolaryngology; likewise, other equally indispensable professionals for the health care of infants and their mothers, such as psychologists, physiotherapists, phono audiologists and occupational therapists, among others, would be guaranteed a role to play. Another equally important aspect of effective care for children exposed to the Zika virus, and which can be performed through this outpatient network, is the performance of the majority of laboratory examinations and imaging; all of this without requiring hospitalisation.

Currently, this kind of patient care is provided mainly by the hospital network, which has less flexibility to adapt to the new demands imposed by epidemics, because it requires the admittance of patients. An outpatient network would allow administrators to create, for example, a third service shift, something that would be impossible in the traditional hospital network.

The aforementioned challenges represent only part of a complex chain of requirements imposed by this international health crisis. Now is the time for action; any omission from this point onwards might be directly responsible for permanently compromising the cognitive capacities of an entire cohort of children. ●

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“Some underwhelming results have been attributed to the mosquito control model One of them relates to the activities aiming to reduce the number of potential *Aedes aegypti* breeding grounds, having been performed without the active participation of society.



Photo: Rondon Vellozo/MS. Fighting the *Aedes aegypti* larvae during awareness campaign, Bahia, Brazil, 2016 <<https://goo.gl/DCmBdh>>.

The history of HIV-focused policy in Peru:

A complex interaction between public health practice, sexual orientation, community empowerment and international mobilisation

by Carlos Fernando Caceres¹

Substantial medical progress during the 20th century allowed the opportunity to significantly reduce maternal and child mortality and improve the quality and expectancy of life in most of the world. Despite such crucial improvements, the HIV pandemic that emerged towards the end of that century generated not only a strong response from health providers and scientists but also an unprecedented mobilisation of affected communities globally. This has helped generate international mechanisms that, over time, led to innovative collaborations, which may have irreversibly altered the dynamics of symbolic power between scientific institutions, medical practitioners, ‘patients’ and affected communities in general.

The HIV epidemic had characteristics that made it transcend the medical realm: it remained lethal until the discovery of combination antiretroviral treatment in 1996 (WHO 2016); moreover, it disproportionately affected people who were socially excluded: non-heterosexuals, sex workers, people who use drugs, poor people and migrants. Despite many governments’ initial resistance to address the HIV issue, community mobilisation led to a strong, participatory global response that has radically transformed the profile of HIV infection over the past three decades.

This is the context underlining the policy response to HIV in Peru. There, HIV has also exhibited the same regional (Latin American) pattern of a mostly urban epidemic concentrated on men and transgender women who have sex with men (MSM/TGW), with HIV prevalence over 10 per cent among MSM and 20 per cent among TGW in large cities (while below 0.5 per cent in the general population) (Bastos et al. 2008). Since its inception, the epidemic has been the target of

multi-layered stigma, based on the fear of a lethal disease associated with sexual non-conformity and poverty, resulting from sensationalist misinformation. Arguably, the evolving HIV response has been both a factor and a reflection of important cultural changes concerning sexuality and human rights; likewise, increasing community participation is both a determinant and a consequence of new spaces for inter-sectoral articulation promoted internationally and facilitated by actors in the health sector (Caceres, Cueto and Palomino 2008). Local recognition of the need for such spaces echoes an international consensus supported by Joint United Nations Programme on HIV/AIDS (UNAIDS) co-sponsors and key funders (e.g. the Global Fund), regionally adopted by peer HIV programmes in the Horizontal Technical Cooperation Group (Grupo de Cooperación Técnica Horizontal—GCTH), a long-standing regional mechanism that also includes regional community networks.

Key phases of the HIV response in Peru
The HIV epidemic in Peru has demonstrated significant changes over time concerning prevalence, incidence, morbidity and mortality. Some of them—particularly in the early stages—may reflect unchecked dissemination of the virus through sexual networks and changes in the pool of susceptibles. Many others, however, reflect changes in HIV-related policy, which was influenced by:

- i. an evolving understanding of HIV in the health sector;
- ii. the international context, including the changing policy frameworks, evolving technologies, and funding opportunities; and
- iii. the formation of a relatively well-positioned civil society constituency that demanded that the State take

concrete responsibility (Caceres and Mendoza 2009).

Table 1 identifies key phases in the Peruvian HIV response, including conditioning factors, the main characteristics and the resulting epidemiological profile. These phases are based on the perception of the global HIV epidemic as of 2016.

As shown in Table 1, the national response to HIV may be generally described in five phases, conditioned, for the most part, by international events that have favoured its evolution towards more complex or comprehensive structures:

- Phase I is, in fact, a non-response phase, through which international consensus was still being reached regarding the appropriate ways to respond.
- Phase II was an early response
- phase, which allowed for some initial strategies regarding blood safety, HIV testing guidelines and initial steps in prevention, mostly at the level of the Ministry of Health.
- Phase III was a first phase of strong, yet sectoral, legal and country-level programmatic development. It focused on prevention, with an emphasis on ‘core groups’ (a term used at that time, following modelling work on epidemics of sexually transmitted infections—STIs), and defining prevention as focused on (individual) risk, meaning STI control (a tendency observed in the 1990s), condom promotion and the development of new guidelines for HIV testing and counselling (Cueto 2001).
- Phase IV adopted the United Nations General Assembly Special

TABLE 1: Phases in the Peruvian response to the HIV epidemic

Phases (chronology)	Conditioning factors	Main characteristics	Epidemiological profile
Inception (late 1970s–1985)	World initially unaware of HIV transmission; first cases described in 1981 (USA); Peruvians were part of international sexual networks	Lack of official awareness (very early discussions; identification of the first cases)	Intense, silent transmission, with only a few cases of advanced disease identified in/after 1983
Early official response (1986–1995)	International promotion of national responses (creation of Global Programme on AIDS by the WHO; funding for HIV-related policies)	Creation of the first national structures to define policies and standards; mandatory testing of blood for transfusion; initial HIV education and condom promotion	Highest visibility of the first wave of HIV cases, mainly among MSM and TGW; high morbidity and mortality among people living with HIV; the promotion of condoms as the leading prevention method began.
Technocratic growth (1996–2003)	A cohort of graduates of US HIV training programmes strengthened the national HIV programme and linked it with the broader STI field; establishment of UNAIDS	New legislation outlawing HIV discrimination; establishment of a larger, stronger programme (at country level) featuring activities with pregnant women and ‘core groups’ (MSM and sex workers); focus on risk	HIV acquires its present-day male: female ratio (3:1) and expands nationally; HIV screening among pregnant women and medical check-ups for ‘core groups’ as well as condom distribution are implemented nationally
Post-UNGASS, Global Fund-led (2004–2012)	UNGASS agreements, creation of the Global Fund against AIDS, TB and Malaria; increasing community leadership at the global level	Establishment of a country coordination mechanism (CCM—multisector + civil society); three projects funded by the Global Fund, implemented with NGO participation; HIV legislation is reformed to include free antiretroviral therapy (ART) for all who need it; increasing focus on vulnerability and human rights	Rapid implementation of the HIV ART programme, leading to drastic reduction in HIV morbidity and mortality; preventive activities lose momentum, and there are no reductions in incidence; HIV testing, and to some extent linkage to care, remains low
Present: Towards the 90-90-90 Goals (2013–)	Decrease in funding available for Peru; UNAIDS promotes the 90-90-90 goals; new prevention technology available; consolidation of ‘combination prevention’; analytical use of the continuum of care	Establishment of a mainly locally funded HIV response with ‘combination prevention’ and a focus on increased impact and control; efforts to implement combination prevention and measure the continuum of care	Current development of policies that respond to the perceived need of ‘combination prevention’ with new strategies, and of increasing HIV testing and improving linkage to care.

Source: Author’s elaboration.

Session (UNGASS)-promoted multisectoralisation of HIV responses, often materialised through the Country Coordination Mechanisms (CCMs) required by the Global Fund to submit funding applications; locally it brought about a revolution—the provision (mandated by law) of antiretroviral therapy (ART) to all those in need (as defined by clinical/laboratory criteria that have changed over time). Not surprisingly, this has led to significantly reduced morbidity and mortality rates, with no major improvement in prevention. (Social) vulnerability and human rights were part of the focus.

- Finally, the ongoing phase V reflects changes resulting from a decline in global HIV funding that has especially affected Latin America; but also a growing consensus about the need to accelerate the control of HIV by increasing the proportion of people diagnosed, treated and virally suppressed by 2020; to this end, the State is taking on a higher proportion of programmatic costs, and international guidelines concerning

when to treat, and what strategies to use for prevention, are in the process of being adopted locally.

A country balance

An attempt to indicate a balance of the national response to the epidemic, including policies and programmes at the government level, as well as community mobilisation and participation, suggests that the country has managed to incorporate increasing levels of complexity into policies and programmes, and to reach national coverage (although several concerns regarding access among rural populations have been raised). It has also focused on key populations (with more inclusive approaches over time), although the levels of stigma against MSM and TGW were so high in some cases that insufficient linkage to care among some newly HIV-positives is explained by self-exclusion, based on negative experiences in the past. Indeed, discrimination based on sexual non-conformity has been traditionally pervasive in all realms of life in Peru. It may be argued that as much as in other countries, the establishment of HIV care programmes has forced health systems and societies at large

to face sexuality and sexual/gender diversity in previously unseen ways.

Despite the progress that has been achieved, improvements need to go beyond HIV-related services and include policies for the comprehensive care of communities. The approval of government-funded HIV treatment in 2004 was an extraordinary policy change and showed that the country, with consistently positive economic indicators, was able to increase its health investment (Caceres et al. 2010) and should continue to do the same with prevention activities.

The multisectoral governance of the HIV response (through CONAMUSA, a Global Fund-mandated CCM) (Collins 2006) deserves further analysis, beyond the scope of this article. Such an analysis might begin by tackling at least two dimensions:

- **The way the CCM defined itself—and how it was further delimited by the Ministry of Health:** Given its mandate for inclusiveness and its role in the development and approval of proposals, as well as

“Despite the progress that has been achieved, improvements need to go beyond HIV-related services and include policies for the comprehensive care of communities.



Photo: Peruvian Ministry of Defence. Central Hospital of the Peruvian Air force, Peru, 2012 <<https://goo.gl/msSWL8>>.

project oversight, the CCM faced considerable governance challenges in defining an adequate structure for its decision-making mechanisms, the election of civil society representatives and resolution of conflicts of interest. Its experience and the way such challenges were, and continue to be, confronted should be a topic of study regarding public–private coordination mechanisms for national policy.

- **The way the government, and particularly the Ministry of Health, incorporated the CCM within its organisational chart for HIV (and to a lesser extent, tuberculosis):** It may be argued that, particularly during the early years of phase IV, the CCM became a ministry within the Ministry of Health, and responsibilities for policymaking concerning HIV and tuberculosis became confusing, as the CCM became a new space where certain decisions could be challenged, and sectoral positions could be negotiated. The extent to which opportunities for real integration of other sectors—and civil society stakeholders in particular—to spaces of policymaking and programmatic design were lost due to excessive focus on implementation is also unclear to us.

These aspects are all the more important when we assess the sustainability of certain components of the response that were undertaken by civil society organisations. If it is implied that countries

‘graduate’ from Global Fund support as they continue to fund previous projects with national resources, CCMs should be used to develop the social capital (Sprungli 2003) needed for the establishment of mechanisms through which valuable community-implemented activities can continue through state funds.

Over three and a half decades, the history of the Peruvian response to the HIV epidemic may be understood as encompassing five phases, partly resulting from changes in international circumstances. Such analysis reveals active efforts to reflect the complex, evolving international discourse and practice concerning HIV. Each phase reveals accomplishments and drawbacks. The most meaningful accomplishment of HIV-related policy in Peru has been the inclusion of government-funded ART, as it has led to drastically reduced morbidity and mortality, turning HIV infection into a chronic disease. Prevention, with less effective tools available, and relying more on civil society implementers, has not progressed as significantly over time. It must be bolstered through the emerging perspective of combination HIV prevention, and its funding through state sources—yet still counting on community implementers—should be ensured. More generally, lessons learned from the HIV field concerning civil society involvement and public–private partnerships should be more thoroughly assessed, as they might significantly contribute to developments regarding community participation in comprehensive health care. ●

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National nursing and midwifery legislation in countries of Southeast Asia with high HIV burdens¹

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The need for a legislative review

HIV/AIDS remains a serious global health issue, as evidenced by its contribution to the global burden of disease and by global commitments to expand access to prevention and treatment services. The World Health Organization (WHO) South-East Asia Region⁵ is second only to the African Region in the number of people living with HIV and the number of AIDS-related deaths (WHO 2016). However, the Member States of the Region have committed to expand access to antiretroviral treatment (ART) and eradicate new HIV infections.

To provide universal access to prevention, care and treatment of HIV/AIDS, health care systems need sufficient competent human resources. In this context, competence means that health workers, particularly nurses, who comprise the majority of professional health workers in the countries reviewed, have and use the requisite knowledge and skills to fulfil their defined roles.

In all five countries included in this review (India, Indonesia, Myanmar, Nepal and Thailand), there are more nurses than physicians, suggesting that nurses are probably providing a larger proportion of health care services—especially in Indonesia and Thailand, which have the highest densities of nurses and lowest densities of physicians in the Region. The importance of nurse-initiated and -managed ART education, policy, regulation and practice for scaling up HIV treatment in east, central and southern Africa has already been discussed in the literature (Zuber et al. 2014). Additional research suggests that, to provide ART to 1,000 patients, between one and two physicians and between two and seven nurses are required (Hirschhorn et al. 2006). However, in the WHO South-East Asia Region, there is a severe shortage of physicians and nurses (the latter averaging

fewer than 2 per 1,000 patients); the distribution of these professionals within countries is skewed towards urban areas, and many nurses and midwives lack the clinical skills to adequately respond to health care demands.

Legislation can establish mandates, authorise the issue of regulations and allocate resources to address deficiencies in the numbers of health workers, their distribution and clinical capacity. In many low- and middle-income countries, nurses are in greater supply than physicians, and a growing body of evidence suggests that the quality of nurse-led ART initiation and management services is not inferior to that provided by physicians (Sanne et al. 2010). These studies have noted the importance of high-quality training and supervision to ensure quality of care, and professional regulation can facilitate both.

Traditionally, the purpose of professional regulation has been to set standards (such as pre-service and continuing education requirements, and scopes of practice) that ensure the competence of practising health workers, such as nurses and midwives. In countries around the world, health professionals are regulated through national or sub-national legislation (such as a nursing act) that establishes a regulatory body or council and authorises it to issue regulations pertaining to education and practice. Common regulatory functions of nursing and midwifery councils include accreditation of training institutions, registration and licensing of qualified nurses and midwives, implementation of continuing education requirements, delineation of scopes of practice, and enforcement of professional codes of conduct. Thus, nursing and midwifery acts aim to ensure the quality of nursing and midwifery services to protect the public from harm and to advance these professions.

While legislation on health professionals varies from country to country,

international non-governmental organisations such as the International Council of Nurses (ICN) and the International Confederation of Midwives (ICM) have issued global standards for nursing and midwifery legislation and regulation. The ICN Model Nursing Act outlines 21 standard elements (seven structural and 14 functional) that are encouraged for inclusion in national nursing acts (Wallace 2007). Thus, international guidelines can be used as a benchmark to evaluate the content of national nursing acts. Furthermore, the WHO urges countries to regularly review and strengthen their legislation governing health professionals and to ensure that nurses and midwives make an optimum contribution to the community, which need not be limited to delivering health services. For example, to promote community outreach, they may be called on to supervise other nurses, midwives and community health workers.

The purpose of this article is to analyse nursing acts in countries of the WHO South East Asia Region with a high HIV burden, with respect to global standards and to suggest areas that could be further examined to strengthen the nursing profession and its critical role in addressing HIV specifically, and primary health care more broadly. Countries were selected for inclusion in this review according to a 2010 global report on HIV-related disability-adjusted life years (DALYs), a common measure used to quantify disease burden (Ortblad et al. 2013). Five countries in the Region account for more than 99 per cent of its HIV burden: India, Indonesia, Myanmar, Nepal and Thailand. The most recent nursing and midwifery legislation from these five countries was obtained by searching the online legislative archives of the ICN, the International Labour Organization (ILO) and national regulatory bodies and governments, from May to October 2013.

The overview of the current legislation and recommendations

National pieces of legislation or acts in India, Thailand, Myanmar and Nepal each incorporated over 70 per cent of the 21 elements recommended by the ICN; Indonesia was the only country in the review without a national nursing and midwifery act. Since their enactment, all acts have been amended, albeit not recently (between 14 and 20 years ago). This suggests that countries may benefit from reviewing their national nursing acts to take into consideration current health care needs and global guidelines. Revisions to nursing and midwifery acts, or permissive interpretation of existing legal and regulatory scopes of practice, could expand the workforce for health services such as ART. This is particularly relevant, as nurses greatly outnumber physicians in the countries profiled, as well as globally.

While functional regulatory elements relating to registration and pre-service education were well represented in all the acts reviewed, none of the acts required continuing education after initial registration. Continuing education or continuing professional development ensures that nurses and midwives update their knowledge and skills to keep up with the rapid evolution of medical research, science and technology. Continuing education also helps to ensure that health workers sustainably provide high-quality health care services.

“Revisions to nursing and midwifery acts, or permissive interpretation of existing legal and regulatory scopes of practice, could expand the workforce for health services such as ART.



Photo: ILO. Youth being tested for HIV in Jakarta, Indonesia, 2013 <<https://goo.gl/c efU8>>.

Only two acts (those of Thailand and Myanmar) included a general scope of practice, which elaborated on the brief definitions provided. However, none of the acts included a detailed, task-oriented scope of practice for nurses or midwives, making it difficult to interpret how the terms in the general scope of practice, such as ‘diagnosis’, ‘care’ and ‘treatment’, might relate to HIV-specific tasks, such as diagnosing HIV and initiating ART.

How general or how specific a scope of practice should be is not a question this article seeks to answer, as strong arguments could be made for both approaches. General scopes of practice can provide greater flexibility for health professionals to respond to changing

needs with new technologies and skills, whereas specific scopes of practice can provide greater protection for, and direction to, health professionals, as authorised tasks are explicitly delineated in writing. In the absence of specific scopes of practice, the ways in which Thailand’s and Myanmar’s general scopes of practice are interpreted and implemented may well make a significant difference to the involvement of nurses and midwives in HIV service delivery. General scopes of practice could be made more specific, to provide further guidance to providers and their employers about what tasks nurses and midwives are authorised to undertake. Specific scopes of practice could include HIV-related tasks, such as nurse-initiated and -managed ART, as recommended by



Photo: Trin Suwannapha/World Bank. AIDS prevention kit, Bangkok, Thailand, 2011 <<https://goo.gl/c efU8>>.

the WHO to include prescriptive authority for nurses. Scopes of practice could be reformed through legislative amendment or by issuing rules or regulations.

Comparing nursing acts in countries of the WHO South- East Asia Region with the ICN Model Nursing Act can assist national governments and regulatory bodies to identify areas of regulation in need of review and strengthening to improve the nursing profession and its contribution to national health systems. Though the connection between national law and local health care practice is not a direct one, it is certainly plausible that national legislation may have a major impact on both the quantity and quality of nursing and midwifery services for HIV prevention, care and treatment, and for primary health care in general.

The intent of nursing and midwifery acts is to set standards for these professions, thereby facilitating quality of care. Furthermore, as noted earlier, evidence suggests that health workers undergoing continuing education are able to provide higher-quality health care services. For example, strengthening health policies for continuing education on HIV care and treatment may lead to improvement in the quality of HIV service delivery. Additionally, better delineation of scopes of practice to align with WHO guidance (for example, ART initiation including prescribing authority for nurses) may facilitate sustainable scale-up of health services, including ART coverage.

The role of nurses and midwives in HIV/ AIDS care is paramount in South-East Asia and elsewhere. This is due to the greater density of nurses and midwives compared with physicians, and to their placement at the front lines of health care, often in facilities lacking physicians. In short, nurses and midwives are critical to HIV/AIDS care. Therefore, those interested in improving the sustainability of the scale-up for HIV services may benefit from a greater understanding of the manner in which nursing and midwifery are regulated, be it through continuing education, scopes of practice or other relevant requirements for training, registration and licensing.

In conclusion, the national nursing acts of India, Thailand, Myanmar and Nepal were all fairly comprehensive, containing 15–20

elements of the 21 elements in the ICN Model Nursing Act. Continuing education was the only element not included in any act. Given the importance of continuing education to the quality of practice in HIV care and other areas, this is a problematic finding; however, our research did not assess whether continuing education is required through means other than the acts (such as regulations). Requirements for continuing education can help health workers to maintain and improve on training received prior to entry in service, thus facilitating high-quality patient care.

Furthermore, none of the acts included a scope of practice specifically listing HIV-related tasks. Without explicit and specific directions concerning which tasks a nurse or midwife may undertake within their scope of practice, some of them may hesitate to practise to their full scope, for fear of exceeding it. However, general language in scopes of practice may potentially be interpreted by domestic authorities to include such tasks, without necessarily listing each one. Thus, the lack of specific scopes of practice is not necessarily a barrier to task-sharing of HIV services. Countries considering reform to their existing nursing and midwifery acts may benefit from comparing their legislation with those of other similarly situated countries and with global standards. Such a review may assist countries in the WHO South-East Asia Region and beyond to evaluate and improve their nursing and midwifery legislation and regulations as part of efforts to strengthen their national health systems, and increase coverage of HIV and other primary health care services. ●

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2. Health and Education Foundation of Indonesia.

3. CDC.

4. National Council of State Boards of Nursing.

5. The WHO South-East Asia Region comprises the following countries: Bangladesh, Bhutan, the Democratic People’s Republic of Korea, India, Indonesia, the Maldives, Myanmar, Nepal, Sri Lanka, Thailand and Timor-Leste.

Eradication of the hepatitis C virus in low- and middle-income countries: between treatment advances and structural bottlenecks¹

by Francisco I. Bastos,² Lydia Boudarène,³ Roberta Pereira Niquini⁴ and Peter Vickerman⁵

With the advent of a new generation of highly efficacious, short-duration direct acting antivirals (DAAs) for the hepatitis C virus (HCV), relevant stakeholders and policymakers, including the World Health Organization (WHO), have started discussing the medium- to long-term prospects of curbing and possibly eradicating HCV. Although exciting, the challenge remains considerable, given the huge number of people infected by HCV worldwide, estimated at 130–150 million people (WHO 2015a).

Approximately one quarter of HCV infection cases undergo spontaneous viral clearance after the first six months. The remaining cases may progress to chronic HCV disease (Hajarizadeh et al. 2013). In the absence of appropriate treatment, over three decades, 41 per cent of these patients might develop progressive liver fibrosis and cirrhosis (Thein et al. 2008), and 1–3 per cent might progress to liver cancer (Hajarizadeh et al. 2013) and ultimately death, when the possibility of a liver transplant is not available. Hepatitis C claimed about 500,000 lives in 2010: 16,000 resulting from acute hepatitis, 195,700 due to liver cancer, and 287,400 resulting from cirrhosis secondary to the hepatitis C infection (Lozano et al. 2012).

HCV is a single-stranded ribonucleic acid (RNA) blood-borne virus, transmitted predominantly through unsterile medical equipment and supplies, transfusion of unscreened blood/blood products and unsafe injection practices (WHO 2015a). HCV is highly mutable, and 11 different strains with different sub-types have been described so far, making the design of an efficient vaccine a great challenge. Genotype⁶ 1 is responsible for 46 per cent of all infections worldwide, prevalent in

North and Latin America, Europe and Australasia (Gower et al. 2014). Genotype 3 distribution corresponds to 22 per cent of total global infections, predominantly in Asia. Genotype 2 accounts for 13 per cent, and Genotype 4 for 13 per cent, predominantly in North Africa and the Middle East (ibid.). Unlike interferon⁷ treatments, which present a different prognosis depending on genotype, the new DAAs are effective for a wide range of genotypes, with fewer side effects.

In the context of low- and middle-income countries, several bottlenecks may pose formidable challenges for scaling up treatment to eradicate HCV. For the sake of conciseness, we have divided these bottlenecks into three broad categories:

- difficulties associated with transforming the findings from clinical trials into real-life condition outcomes;
- high treatment and screening costs (and tight/shrinking budgets); and
- pockets of very high prevalence of the disease, usually among disenfranchised and vulnerable populations.

Such categories may overlap, since disenfranchised populations are usually uninsured, unemployed and/or homeless, therefore lacking any assistance outside inclusive government programmes.

The difficulties facing the translation of findings from randomised clinical trials (RCTs) into concrete outcomes in real-life conditions have been discussed by several authors (e.g. Victora et al. 2004). Such difficulties are universal, since RCTs are—by their very nature—‘artificial’, in the sense that their ‘controllability’ is secondary to strict rules imposed to eligibility and follow-up. The overall health conditions of potential recruits tend to be better

than those prevailing in the general population, especially among those from deprived segments. Purposeful biases are an essential component of such protocols, such as those relative to age (usually to the detriment of children, youth and seniors) and gender—for example, women of reproductive age tend to be excluded from protocols or must be thoroughly screened for the consistent use of contraception). Strict follow-up rules tend to function as a disincentive for people with complicated working schedules, unstable housing and/or a lack of family/social support.

Difficulties are context-specific and tend to be more pronounced and difficult to mitigate in settings where health systems and/or services are affected by structural deficits such as: scarcity or demotivation of the workforce; scarcity of clean water and/or electric power; less than optimal enforcement of biosecurity procedures and proper disposal of hazardous materials; and, in a broader sense, less than optimal health coverage, mandatory consultation fees, long waiting times and inefficient transportation.

Countries of all income levels (respecting obvious differences) have been challenged by the high cost of such new medicines, which may cost as much as an additional USD65 billion over the next five years in the USA (Chhatwal et al. 2015). Even the best-funded health systems, such as the UK National Health System (NHS), have been struggling to fully incorporate a comprehensive portfolio of DAAs (NHS 2014). The innovative concept of ‘minimum target prices’ (MTP) has been explored by the international literature, and a recent analysis published by van de Ven et al. (2015) has estimated costs at USD171–360 per person without genotyping or USD261–450 per person with genotyping.

These costs preclude the adoption of such therapeutic regimens by very low-income



Photo: Gustavo Nardon/Trensurb. Fighting hepatitis C, Porto Alegre, Brazil, 2015 <<https://goo.gl/sZ7V7x>>.

countries. Some of them have a per capita health budget far below both global market prices and MTPs. In the absence of substantial help from international donors, it is very unlikely that such treatments could be offered. International donors have paved the way for the current increased access to antiretroviral medicines for HIV/AIDS. A similar commitment will be required to curb HCV.

A second dimension is to translate the concept of MTP into a practical and affordable alternative in different contexts—i.e. making these theoretical lowest prices a benchmark for actual procurement prices. This requires the sustained commitment of national governments with the full adoption of large-scale treatment programmes, which cannot operate in a vacuum but must necessarily incorporate large-scale programmes on detection, testing and counselling, and agile referral between outreach programmes, teams and health services. It also calls for the provision of decentralised treatment, not involving doctors (especially costly specialists) but, rather, nurses and harm reduction staff, and simplified testing regimens (Lobo et al. 2015). Finally, the concrete adoption of MTP calls for a comprehensive partnership between governments, international institutions, organisations and private companies. Available alternatives comprise a whole gamut of policies and initiatives that are not mutually exclusive, such as negotiating substantial discounts, the implementation of revolving funds—such

as those adopted by institutions such as the Pan American Health Organization (PAHO), the Revolving Fund on Vaccines Procurement (PAHO 2016)—and/or the domestic production of generic medicines.

The third and final category comprises the need to reach and enrol hard-to-reach populations and to implement culturally sensitive programmes targeting key populations. These populations vary to some extent in different contexts but usually include people who inject drugs—an umbrella category that requires interventions tailored to the needs of people who inject different substances (Tavitián-Exley et al. 2015). These groups drive the HCV epidemic in many developed settings and are a crucial transmission group with high prevalence in all settings (De Angelis 2009; Nelson et al. 2011). Although treatment compliance and re-infection are a common concern among people who inject drugs (Aspinall et al. 2013), it is likely that the treatment of this group could be a highly cost-effective prevention strategy (Martin et al. 2013). Other key populations are those among whom increased vulnerability is associated with the failings of the health services themselves and/or community contamination—for example, tattooing personnel, barbers or dentists who do not comply with the consensus guidelines regarding the sterilisation of tools and materials.

Inefficient and poorly supervised services may impose additional harm and burdens

“The simple structure of several services and health systems could be boosted by carefully designed policies, which benefit from their simplicity to scale-up testing, counselling and access to treatment with simpler diagnostic tools and less specialist monitoring.

on people who are already struggling with debilitating medical conditions, such as patients with renal failure undergoing haemodialysis (Su et al. 2013) and haemophiliacs (Canaro et al. 2015), as well as others who receive frequent blood transfusions or are intermittently exposed to contaminated blood or blood products.

Ironically, the full implementation of some of the most advanced and costly therapies might be hampered by the failings and basic deficiencies of health systems and services. Conversely, the simple structure of several services and health systems could be boosted by carefully designed policies, which benefit from their simplicity to scale-up testing, counselling and access to treatment with simpler diagnostic tools and less specialist monitoring.

Despite these bottlenecks, more or less relevant depending on individual country contexts, rising global awareness regarding the hepatitis C epidemic and access to DAAs is encouraging. Multiple global initiatives and coalitions play a synergistic role to work towards the end of the epidemic. The WHO has recently included DAAs in its Model Lists of Essential Medicines (WHO 2015b). The World Health Assembly has reaffirmed the importance of the improvement of prevention, diagnosis and treatment of hepatitis, as well as access to quality and affordable medicines, while considering the international intellectual property legislation for the production of generic drugs. Global hepatitis C coalition groups play an important advocacy role,

“Political will and drug negotiation agreements are key factors towards eradicating the HCV epidemic.



Photo: Albert González Farran/UNAMID. Patient receiving a blood transfusion at the El Fasher Hospital, Sudan, 2012 <<https://goo.gl/kSXIMd>>.

and the *Glasgow Declaration on Viral Hepatitis*, which emerged from the first World Hepatitis Assembly summit (World Hepatitis Alliance, WHO and The Scottish Government 2015) called on governments to work towards the goal of eradicating hepatitis by 2030.

Therefore, political will and drug negotiation agreements are key factors towards eradicating the HCV epidemic. Different programmes at national levels are slowly emerging in different parts of the world. High-income countries, such as Australia and Portugal (despite the fiscal crisis affecting the latter), have recently designed and are implementing HCV eradication programmes. Portugal, with 130,000 estimated cases (Anjo et al. 2014), is initiating its eradication programme by treating 13,000 patients over three years, through an agreement with Gilead Sciences, Inc. Australia, with 230,000 estimated cases (The Kirby Institute 2015), recently decided to invest AUD1 billion over five years to make treatment available to all its population.

In low- and middle-income countries, fielding such a large budget is challenging, but experience in disease-elimination programmes is crucial to better inform similar efforts in other countries.

The purchase of generic drugs, as recently carried out by Argentina, or the drastic price negotiation with international corporations, as carried out by Egypt (El-Zanaty and Way 2009) and Brazil

(Ministério da Saúde 2015) can also contribute towards tackling the epidemic. The Brazilian health system ensures access to medical treatment for all patients diagnosed with chronic hepatitis C. New drugs (Daclatasvir, Simeprevir and Sofosbuvir) have been delivered to patients since the end of 2015, starting with those who have not benefited from previous treatment. Warning campaigns have helped to expand diagnosis, especially among people who underwent surgeries, blood transfusions or transplants before 1993 (ibid.).

In Eastern Europe, Georgia also launched its HCV elimination programme in 2015. To support the programme activities, it enlisted the help of the US Centres for

Disease Control (CDC) to assess the epidemiology of the disease, evaluate health care capacity and conduct programme monitoring. In this context, the following key priorities were determined: a national HCV seroprevalence⁸ survey and improved access to new HCV treatments (preferential treatment for patients who have severe liver disease, providing discounted diagnostic services to all persons, and, as a subsequent step, improving the capacity to treat all infected people) (Mitruka et al. 2015).

Economies of scale have been sought through joint procurement. At the XI Union of South American Nations (UNASUR) Summit, in Montevideo in 2015,

a group of countries from the Southern Common Market (Mercosur) signed an agreement on the joint purchase of medicines for the treatment of hepatitis C, through PAHO, in partnership with local governments. As a benchmark, they used prices paid by Brazil in 2015 for a 12-week course of Sofosbuvir and Simeprevir (USD9,474.56) or Sofosbuvir and Daclastavir (USD9,425.64), corresponding to 10–20 per cent of the standard European prices for equivalent courses. The two main goals were to accommodate tight budgets and to foster sustainability over time (Ministério da Saúde 2015).

Perhaps, in the near future, the failure to curb the spread of hepatitis C will be viewed as a sentinel event used for the diagnosis and eventual improvement of failing health systems worldwide. ●

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6. “Genotype can be defined as the complete genetic constitution of an organism or group, as determined by the specific combination and location of the genes on the chromosomes” (*Mosby’s Medical Dictionary* 2009. <<http://medical-dictionary.thefreedictionary.com/genotype>>). Accessed March 24, 2016. In the context of our sentence, it means a given strain (e.g. Genotype 1) of the hepatitis C virus, as fully characterised by its specific RNA sequence.

7. “A small class of glycoproteins capable of exerting antiviral activity in homologous cells through metabolic processes involving synthesis of RNA” (*Mosby’s Dental Dictionary* 2008. <<http://medical-dictionary.thefreedictionary.com/interferon>>). Accessed March 24, 2016. The sentence highlights its use as a bio-pharmacological drug classically used in the management and treatment of hepatitis C.

8. “The proportion of a population that is seropositive—ie, has been exposed to a particular pathogen or immunogen; the seropositivity of a population is calculated as the number of individuals who produce a particular antibody divided by the total population” (*McGraw-Hill Concise Dictionary of Modern Medicine* 2002. <<http://medical-dictionary.thefreedictionary.com/seroprevalence>>). Accessed March 24, 2016.

Challenges facing access to medicines under the expansion of international trade

by Maria Auxiliadora Oliveira
and Gabriela Costa Chaves¹

The year 2015 was marked by a series of events that characterise an ambitious agenda for the health sector. On the one hand, in September 2015, the United Nations (UN) General Assembly established an action plan for 2030 featuring 17 Sustainable Development Goals (SDGs), among which is Goal 3: “Ensure healthy lives and promote well-being for all at all ages”. New high-cost medicines for the treatment of cancer and hepatitis are now part of the World Health Organization (WHO) model list for essential medicines (Experts in Chronic Myeloid Leukemia 2013). Ban-Ki-moon, UN Secretary-General, has convened a High-Level Panel on Access to Medicines. On the other hand, 2015 marked the 20-year anniversary of the World Trade Organization (WTO) and multilateral agreements such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Ending the AIDS, tuberculosis, malaria and tropical disease epidemics, as well as fighting viral hepatitis and other communicable diseases by 2030, is one of the objectives of SDG 3. Adequate control of these and other epidemics depends on access to medicines, many of which are launched at prohibitive prices. Another goal of SDG 3 is to reduce premature mortality due to non-communicable chronic diseases by a third, through prevention and treatment.

In this context, the objective of the aforementioned UN Panel is to identify proposals that minimise the “incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies” (UN Secretary-General’s High-Level Panel on Access to Medicines. 2016).

All of these events occur at a time when life-saving medicines are being marketed at prices that can surpass USD100,000 per treatment, threatening the sustainability of the health systems of developing and even

developed countries (Experts in Chronic Myeloid Leukemia 2013; Londeix 2014; PAHO 2015; Boseley 2015).

This article presents an overview of the trajectory of medicines in the international health agenda and their linkages with the agenda of intellectual property rights and international trade over the past 20 years, focusing on the challenges of meeting the ambitious health-related SDGs.

Access to medicines—international commitments

Since the 1970s, when the theme entered the WHO agenda (WHA28.66), the regular provision of medicines to people in need has been considered one of the key components of health systems and services, occupying a crucial space in international health, commerce, development, human rights and diplomacy agendas. Essential medicines are one of the primary pillars of health care established in 1978 by the Declaration of Alma-Ata (PAHO 2015).

Regular access to medicines is one of the essential conditions for the realisation of the basic human right to health. The worsening of acute or chronic diseases, the appearance or dissemination of infectious illnesses, the avoidable suffering of great masses of the population, the loss of quality of life, the increase in mortality and health system expenditures, as well as the deepening of social inequities are some of the consequences of the lack of regular access to medicines.

At the health service level, access to medicines depends on certain factors such as availability, geographic accessibility, affordability, acceptability and quality (Boseley 2015). From a political perspective, it is necessary that government representatives and leaders have the political will to bring about related international commitments. This goes beyond the technical availability of medicines, and it is necessary to invest in strengthening health systems and achieving affordability to ensure the sustainable financing of medicines policy.

Trade agreements and access to medicines

In the 1990s, the expansion of the HIV epidemic across developing countries coincided with the implementation of the WTO TRIPS agreement. At that time, a variety of effective medicines to treat the infection and control the epidemic already existed. However, over 90 per cent of people living with HIV in those countries did not receive treatment, leading to thousands of early deaths. This reality drove the emergence of a broad international movement to improve access to medicines, which questioned the prevalence of intellectual property rights established by the TRIPS agreement over the human right to life of people affected by diseases for which effective treatments already existed.

Significant efforts over the last two decades, involving governments, big donors, civil society organisations and the UN, made a rapid response to the epidemic possible, leading to—in early 2014—13.6 million people living with HIV having access to antiretroviral therapy (ARV) and 7.6 million deaths being avoided due to access to such medication (Bigdeli et al. 2013).

Despite these advances, Millennium Development Goal (MDG) target 6.B—to achieve, by 2010, universal access to treatment for HIV/AIDS for all those who need it—was only partially met (United Nations 2016). One of the persisting problems is the high price of ARV medicines, often under a monopoly due to patent protection.

The TRIPS agreement was enacted in January 1995 and led to concerns due to its implications for local production and access to medicines (Velasquez and Boulet 1999). This is because, unlike the previous international system established by the Paris Convention of 1884, the TRIPS agreement determines that all WTO member countries must grant patents for products and processes across all technological areas, including the pharmaceutical sector.



Photo: Arne Hoel/World Bank. Malaria medication, Nigeria, 2008 <<https://goo.gl/cefU8>>.

At the time, the vast majority of developing countries did not grant patents for pharmaceutical products, as they had the right to choose technological areas to be excluded from patentability. The TRIPS agreement created a new international system of intellectual property, globalising the patent rules—considered a flaw by those who defended a stricter protectionist system. Patents provide the holder exclusive rights in the commercialisation of the invention for the duration of the patent’s term, which in the case of medicines allows patent holding companies to charge high prices (’t Hoen 2009).

In the context of initial efforts to ensure access to ARV therapy, the negative effects of TRIPS were felt as early as the end of the 1990s, representing one of the first high-cost products to be adopted by health systems in developing countries, raising questions related to their sustainability. Patent protection for a period of at least 20 years confers to the patent holder the power of monopoly, allowing it to set high prices and temporarily excluding third parties from commercialising generic alternatives to these medications.

One possible way for governments and civil society to deal with the high prices of medicines under a monopoly is the adoption of the TRIPS agreement safeguards for the protection of public health (Chaves and Oliveira 2007). Such safeguards ensure the availability of generic medicines, which can be cheaper and prevent the abuse of patent rights and the granting of secondary

patents, while promoting scientific and technological advancement.

Among the main safeguards are the transition period for adopting the granting of patents in the pharmaceutical sector, parallel importing (based on the international exhaustion of rights), compulsory licensing,² experimental use and the Bolar exception,³ restrictive interpretation of patentability requirements, and patent opposition.

Despite the defence and incorporation of these safeguards, their use has been quite limited. Over the last decade, developing countries have adopted compulsory licensing in specific cases such as AIDS and cancer medicines, but pressures against its use have crippled more widespread and systematic adoption.

“The TRIPS agreement was never enough”: free trade agreements and the mega trade deal

Susan Sell (2010) argues that the TRIPS agreement met up to 95 per cent of the demands of those who advocated for a stricter patent system. However, in parallel and after the TRIPS agreement negotiation process, they sought to reach the remaining 5 per cent through the inclusion of so-called TRIPS-plus provisions in regional and bilateral free trade agreements signed between the USA or European Union countries with developing countries. These provisions include mechanisms that restrict or even make unavailable the use of safeguards

“Regular access to medicines is one of the essential conditions for the realisation of the basic human right to health.”

related to the protection of health. Studies have estimated the impact of TRIPS-plus provisions in the pharmaceutical market and in expenditures with medicines in Latin American countries (Colombia, Ecuador, Peru, Costa Rica and the Dominican Republic) (Gamba, Buenaventura, and Bernate 2010; Gamba 2006; Gamba, Cornejo, and Bernate 2009).

In October 2015, negotiations came to a close on the so-called Trans-Pacific Partnership (TPP), comprising 12 countries (USA, Japan, Australia, Brunei, Canada, Chile, Malaysia, New Zealand, Peru, Singapore and Vietnam), which represent 40 per cent of the global economy (Baker 2016). Defined by specialists as a “mega trade deal” (Drahoš 2015), this trade agreement is seen as a deepening and an increase of the monopoly related to patents for medicines. In addition to the provision of the so-called TRIPS-plus measures, which might nullify TRIPS flexibility and restrict the space for the adoption of policies for the protection of public health, the agreement also features a chapter (Chapter 9) on investor–State disputes, under which companies can challenge government decisions that affect their intellectual property investments in private supranational courts that override national courts (Baker 2016). The threat or use of these measures can restrict the policy space for countries to promote medicine price reduction through competition.

Ensuring access to new medicines compromises the sustainability of

“Ensuring access to new medicines compromises the sustainability of health systems in developing as well as developed countries.



Photo: Pranjal Mahna. Pills, California, USA, 2010 <<https://goo.gl/cefU8>>.

health systems in developing as well as developed countries. Not by chance, the UN Secretary-General convened a High-Level Panel on Access to Medicines to address the goals related to the expansion of access to health technologies. The hardening of international trade rules in the post-TRIPS period contributes to the reduction of space for the regulation of monopoly and of the price of essential health technologies. Without properly and systematically facing this problem, countries will have great difficulty in reaching the goals set for 2030. ●

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1. ENSP/Oswaldo Cruz Foundation (Fiocruz), Department of Medicines Policy and Pharmaceutical Services.

2. Compulsory licensing allows for the exploitation of a patented object without the consent of the patent holder, through government authorisation.

3. The Bolar provision allows companies to complete all the procedures and tests necessary to obtain market approval before patent expiration.

Colombian policies on generic and biotherapeutic medicines¹

by Claudia Vaca²

Colombia is moving faster than other Latin-American countries towards universal health care coverage. Nearly 97 per cent of its citizens have access to health insurance. Furthermore, income does not determine the health benefits package (HBP) whatsoever, and out-of-pocket expenses are the lowest in the region (Knaul, Wong and Arreola-Ornelas 2013). The country has the widest-reaching immunisation plan in the Americas, including all the latest recombinant vaccines. Over the past four years, the HBP has grown more than those in other countries, and coverage goes beyond the recommendations of the latest update of the World Health Organization (WHO) Essential Medicines List, including biotherapeutics (BTs) for cancer, diabetes and rheumatoid arthritis (MINSALUD 2011; ‘t Hoen 2016).

BTs are drugs that harness living cells to make or modify protein products to create therapies. They are often expensive medicines used for non-communicable diseases and some infectious diseases. Many patents for BTs have begun to expire. Promoting generic versions of those products, known in some countries as ‘biosimilars’, is an efficient way to guard the sustainability of health care systems and protect them from the technological and financial pressure produced by BTs.

Expanding the Essential Medicines List, including BTs, however, poses a huge financial challenge for the Colombian government, because new medicines represent a significant proportion of overall public expenditure on health care. To manage this burden, in 2012, the Ministry of Health (MINSALUD) issued a pharmaceutical policy based on three components: strengthening of health technology assessment processes, price control of medicines and the promotion of competition in the pharmaceutical market.

Decree 1782, of 2014, is part of the promotion of competition in the

pharmaceutical market. It was publicly discussed for three years, having produced intense global debate, especially around an ‘abbreviated pathway’ (to having drugs approved) introduced as a possibility for bio-competitors.

This article presents the core of the Colombian regulation, comparing it with similar regulations in Europe and Latin America. It also lays out the Colombian strategy to discuss and negotiate the contents of the decree. Finally, the article explains the approach taken by the Colombian regulatory body regarding access to BTs, which is based on: i) coherence with its previous generics policies; ii) alignment with the current Colombian pharmaceutical policy; and iii) global regulatory tendencies that incorporate scientific and technical developments for the characterisation of proteins.

Context

In 2013, the global BTs market was worth around USD170 billion (18 per cent of the total pharmaceutical market). According to several forecasts, in 2020 it will reach USD250 billion (Rickwood 2011). For that same year, it was projected that 55 of the 100 best-selling medicines would be BTs (Lindgren 2014).

Between 2014 and 2020, the patents for most of the best-selling BTs in the USA will expire. This means that competition will grow (Rickwood 2011). According to a forecast by Express Scripts (Miller 2013), the market entry of biosimilars (known also as ‘biocompetitors’, ‘biogenerics’, ‘biocomparables’ or follow-on biologics) in the USA will lead to projected savings of around USD250 billion over the next 10 years.

Data from MINSALUD (2014) and FOSYGA (2016) indicate that in Colombia in 2013 almost 36 per cent of the pharmaceutical market (worth around USD1.25 billion) appertained to BTs. In 2012, eight of the top ten reimbursed³ medicines were BTs (Zapata, Bernal, Castillo, and Garzón 2012).

Since 2010, Colombia has been implementing price control mechanisms for medicines, using national and international price references. This has led to reduced public health care expenditures but has not been sufficient to rise to the challenge of universal coverage, mainly due to the absence of competition in many segments of the pharmaceutical market. It is clear that increased competition results in greatly increased savings and more sustainable access.

For example, a ‘biocomparable’ of rituximab—a drug used in the treatment of a type of leukaemia—has been sold in Mexico since 2013 at a price 35 per cent less than the current Colombian regulated price for MabThera®, F. Hoffmann-La Roche AG’s patented rituximab compound, which is the only option for the medication in Colombia. Norway was able to secure a 72 per cent price discount on the biosimilar infliximab, trademarked in Colombia as Remicade® (IMS Consulting Group 2015).

An even better example would be trastuzumab, used in the treatment of breast cancer—one of the leading causes of women’s mortality in Latin American. Pichón-Rivière et al. (2015) analysed the price of F. Hoffmann-La Roche AG’s patented trastuzumab compound Herceptin®, in Bolivia, Colombia and other countries, to determine its cost-effectiveness. They found that under such conditions, the price in Colombia should be around 80 per cent lower than the current regulated price (which would be reflected in a decrease from USD2000 to USD340 per unit), for the medicine to be cost-effective. The situation in Bolivia is even worse: for Herceptin® to be considered cost-effective there, the price should be only USD95 per unit.

Only through widespread competition will such price levels be attained. Price controls by the State are insufficient, as demonstrated by the Colombian price regulation experience. Fortunately, competition is imminent. There are at least 11 biosimilars of trastuzumab

“Promoting generic versions of those products, known in some countries as ‘biosimilars’, is an efficient way to guard the sustainability of health care systems and protect them from the technological and financial pressure produced by BTs.



Photo: Junta de Andalucía/García Cordero. Medicines, 2013 <<https://goo.gl/OOQfn>>.

from India, South Korea and Europe in the pipeline, getting ready to enter the market (IMS Consulting Group 2015; Pichon-Riviere et al. 2015). These competitors have to obtain authorisation to enter the market, and governments should have the political will to establish a deliberate strategy to facilitate market entry of those drugs, ensuring that registration requirements are not unnecessary barriers to competition, while still demanding compliance with high quality standards. This is precisely what the Colombian government has managed to achieve.

The core of Colombian regulation

Decree 1782 establishes three pathways to present information regarding the quality,

safety and efficacy of any given BTs—namely: the full dossier for new biologics, and two pathways for known biologics: a comparability pathway and an abbreviated comparability pathway (ACP). For these three routes the Drug Regulatory Authority requires the presentation of results of immunogenicity studies conducted with each specific BT. This was the solution found for the main safety concerns posed by BTs.

The ACP was at the centre of the controversy that arose during the public discussions of the regulation. The multinational pharmaceutical industry and the governments of the countries where those companies are headquartered (through their embassies in Colombia) strongly opposed the procedure.

The use of the term ‘abbreviated pathway’ does not mean a reduction in quality standards, nor a less strict or faster evaluation by the sanitary authority (Instituto Nacional de Vigilancia de Medicamentos y Alimentos—INVIMA). The ACP allows for the submission of readily available information regarding the safety and efficacy of a particular therapeutic protein to the relevant authority, to demonstrate as a corollary the safety and efficacy of a highly similar protein (in analytical terms). As a consequence, there will be less human and animal exposure to unnecessary experiments when there is no reasonable scientific uncertainty that would justify such experiments. From a public health policy perspective, the ACP also reduces unnecessary barriers to market access.

“Price controls by the State are insufficient, as demonstrated by the Colombian price regulation experience.



Photo: Pan American Health Organization. Man works at biomedical research in infectious diseases, Colombia, 2010 <<https://goo.gl/VAhsB>>.



Photo: EC/ECHO/Andrea Lamount. Colombian girl takes medicine, Colombia, 2011 <<https://goo.gl/cefU8>>.

Colombia’s proposal was coherent with its previous decisions on generic medicines. It has promoted generic medicines since 1963 (Pichon-Riviere et al. 2015), and in 1990 introduced a fast track for market authorisation of generic medicines through Decree 709, which was aligned with the Hatch-Waxman Act, established some years before in the USA.

Nevertheless, the ACP is not the same pathway used for traditional generic medicines. It requires its own essential tests, which are more extensive and specific than those required for a classical generic medicine. The ACP only applies to known BTs, characterised well enough and possessing a widely available breadth of information and global evidence about its use, quality and efficacy. The global regulation tendencies of BTs do not stray too far from the Colombian approach.

Colombian strategy to take the regulatory proposal forward

While at local and global levels BT patent holders promoted controversy, the Colombian government established a strategy to discuss and successfully negotiate the contents of Decree 1782. This strategy was based on widespread transparency (to publish all comments sent from every stakeholder)⁴ and on a diplomatic agenda with the strong support of the Union of South American Nations (UNASUR). In addition, the media, Congress, various experts and physicians were involved in the communication plan.

The diplomatic agenda included an internal paper that identified international regulatory tendencies that supported the Colombian stance. The paper was used across all government levels and ministries (Trade, Presidency, Health and Foreign Affairs) in all negotiation scenarios. Moreover, the diplomatic agenda also included a presentation at the World Health Assembly (WHA), detailing a Resolution (WHA67.21)⁵ related to access to BTs, led by Argentina and Colombia and supported by all UNASUR countries.

Some of the principal elements of the position paper and elements of Resolution WHA67.21 are as follows:

1. Regarding the relationship between the Colombian Decree and WHO and European regulations: In 2013, the European Medicines Agency (EMA) released a document⁶ which modifies the 2006 guideline of biosimilars. This document came into force in April 2015 and allows for the reduction of clinical trials through a simplified approach: “In specific circumstances, a confirmatory clinical trial may not be necessary. This requires that similar efficacy and safety can clearly be deduced from the similarity of physicochemical characteristics, biological activity/potency, and pharmacokinetic (PK) and/or pharmacodynamic (PD) profiles of the biosimilar and the reference product. In addition, it requires that the impurity profile and the nature

of excipients of the biosimilar itself do not give rise to concern.”

This document illustrates how after ten years of experience with biosimilars in Europe, researchers and experts have come to realise the challenges related to clinical comparability exercises required of biosimilars by the EMA. Schellekens and Moors (2010) analysed the biosimilars dossiers approved by the EMA and concluded that only one—Fligrastim—had fulfilled all the required clinical comparability conditions. They concluded that all biosimilars in Europe have produced similarly positive outcomes compared with the reference.

As the simplified approach proposed by the EMA agrees to waive clinical confirmatory testing, the Colombian ACP also allows a waiver for confirmatory clinical testing if physicochemical characteristics, biological activity and potency are similar between the reference product and its biocompetitor.

2. Regarding the relationship between the Colombian Decree and 2009 WHO guidelines:

These guidelines are based on the 2006 EMA comparability paradigm, which is in turn perhaps based on the precautionary principle.⁷ These guidelines represented the abbreviated pathway for competitors but until now did not establish the scientific, methodological or ethical circumstances in which confirmatory clinical tests are not necessary. Pharmaceutical companies have exploited this weakness to pressure countries into an exaggerated interpretation of the WHO guidelines. In any case, it is understood that the WHO technical documents are a general guide and not compulsory.

3. Regarding the relationship between the Colombian Decree and USA regulations:

The US Affordable Care Act mandates the design of an abbreviated pathway for biotech competitors to reduce the financial burden placed on the health care system. This pathway was included in section 351 (K) of the Public Health Service Act, which adopted the comparability standard and left the decision whether to reduce or waive any requirements to

the discretion of the Food and Drug Administration (FDA), a federal agency of the US Federal Government.

Since February 2012, the FDA has released two guidelines regarding marketing authorisation of biosimilars to public consultation, including, similar to the Colombian decree, the option to waive clinical and preclinical tests in some circumstances.

Grabowski et al. (2014) present the cases of Omnitrope and Enoxaparine, where the FDA had approved two BTs through the Abbreviated New Drug Application, using the classic generic application.

4. Regarding the relationship between the Colombian regulation and WHA Resolution WHA67.21:

Acknowledging the delicate context in which to issue pro-competitive BT regulations, Colombia, Argentina and other UNASUR countries presented a resolution to the WHA that was sponsored by many countries. In May 2014 Resolution WHA67.21 was released, regarding “Access to biotherapeutic products including similar biotherapeutic products and ensuring their quality, safety and efficacy”. The resolution included language similar to the Colombian regulation and a written letter that requested the WHO Director-General: “to convene the WHO Expert Committee on Biological Standardization to update the 2009 guidelines, taking into account the technological advances for the characterization of biotherapeutic products and considering national regulatory needs and capacities and to report on the update to the Executive Board”. This resolution was key for the final stage of the negotiation process regarding Decree 1782 in Colombia.

5. Regarding the relationship between the Colombian regulation and tendencies in Latin America: Over the last five years, Latin-American countries—in particular the so-called emerging economies, such as Brazil, Colombia, Ecuador, Chile, Mexico, Peru and Argentina—have established their own abbreviated regulatory schemes. In general, they follow the EMA and WHO guidelines, adapted to local political, economic and historic contexts.

These regulations allow for clinical tests to be reduced or waived, with some restrictions and specific requirements, in the same vein as discussions about generic medicines 20 years ago.

Conclusion

Ongoing scientific advances and the deepening knowledge of therapeutic proteins can support regulators to overcome the clinical comparability test paradigms and to introduce public health objectives to sanitary regulations. The goal of universal coverage, without compromising the quality of BTs, requires the promotion of competences.

The Colombian ACP has adopted and adapted a global tendency to take advantage of technical and scientific advances to assure the quality of BTs, while at the same time reducing the costs related to unnecessary clinical testing.

Colombian Decree 1782 applies the same set of considerations and circumstances as European and US regulations for waiving clinical experiments of some well-known therapeutic proteins to fast-track their market entry; however, it is innovative in that it presents the ACP explicitly to send a clear public health message. ●

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A strategic roadmap for telehealth in the community of Portuguese-speaking countries

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The health agenda within the Community of Portuguese-Speaking Countries (*Comunidade dos Países de Língua Portuguesa*—CPLP) was strengthened in 2008 with the creation of the Strategic Plan for Cooperation in Health (PECS/CPLP) that was signed in May 2009 by all CPLP Ministers of Health. This plan outlined seven strategic areas and 21 development projects with an emphasis on the training of human resources and institutional development for strengthening health systems.

Following up on the Third Meeting of Ministers of Health of the CPLP in Maputo, Mozambique, in February 2014, during which Ministers of Health affirmed their commitment to promote the use of new technologies to ensure universal health coverage to guarantee access to quality health care at a sustainable cost, the authors propose an analysis of the potential use of telehealth, an assessment of existing capacities and a set of recommendations for the nine Portuguese-speaking countries (Portugal, Brazil, Mozambique, Angola, Cape Verde, Guinea-Bissau, Equatorial Guinea, East Timor, and São Tomé and Príncipe). These recommendations serve as a medium- and long-term strategic roadmap for CPLP countries to develop their own national strategies for the appropriate use of information and communication technologies (ICTs)—more specifically, the use of telehealth—and collaboration among CPLP member countries.

Most CPLP members already have extensive experience in the use of ICTs for telemedicine, telehealth, e-health and digital health, especially in distance learning (or e-learning). In addition, a well-recognised and important tool is the use of video and web conferencing in case discussions, seminars and scientific events

related to research and collaborative discussion. However, this potential is far from fully realised, and many opportunities for cooperation may still be leveraged. Distant rural areas can benefit enormously from these services.

The development of a strategic roadmap focusing on the use of new technologies to promote distance education and collaborative research and to ensure universal access to health care is in line with the priorities of the PECS/CPLP. The proposal was presented, discussed and approved at the Technical Meeting of PECS/CPLP 2009–2016 at the CPLP Executive Secretariat in Lisbon on 2 March 2016. All the topics approved in the meeting, including telehealth, will make up a Resolution to be signed by all nine CPLP member countries’ Ministers of Health, sealing the main topics to receive attention and investment to advance universal health coverage.

Goals

Regarding the CPLP telehealth strategic roadmap, the initial goals are to:

- take a quick inventory of existing physical, human and technical resources in the context of telehealth in CPLP countries;
- establish network cooperation mechanisms among CPLP member countries;
- propose recommendations related to the potential of telehealth to CPLP member countries;
- consider important aspects of telehealth in public health, health surveillance, distance education in the fields of health promotion and prevention, health emergencies, multicentric trials etc.; and
- strengthen the means of networking among members of CPLP-Health and its various networks, particularly the

Network of National Health Institutes (Rede de Institutos Nacionais de Saúde Pública—RINSP) and the International Network for the Education of Health Technicians (Rede Internacional de Educação de Técnicos em Saúde—RETS).

The more developed experiences of Brazil and Portugal, and the more recent experiences of Angola, Cape Verde, Mozambique, and São Tomé and Príncipe, serve as the basis to promote the use of telehealth in the Portuguese language, which can transform and consolidate the mechanisms for cooperative and collaborative networking, effectively improving the health systems of these countries from a global health perspective.

Summary of experiences of telehealth in CPLP member countries

In 2013 the Ministry of Health of Angola started a project to take the first steps into telehealth via a collaboration with international partners (the Geneva University Hospitals (HUG), Switzerland, and the Institute of Tropical Hygiene and Medicine, Universidade Nova de Lisboa (HMI/UNL), Portugal).

The first telehealth steps in Cape Verde started in 1999, after the signing of an agreement between the Agostinho Neto Hospital in Cidade da Praia, Cabo Verde, and the University Hospital of Coimbra, Portugal; telehealth covered gynaecology and obstetrics. The Cardiology Department followed in 2009. In 2012, Cape Verde implemented a crucial strategic shift by connecting central hospitals to regional and health districts, across all islands. Research on the impacts on the referral network and evacuations demonstrates its relevance to the more distant populations, increasing overall health system efficiency (Lapão and Correia 2015). More recently, in 2014 Cape Verde started its national telemedicine programme (Azevedo 2014), having inaugurated the National Telemedicine Centre in the Agostinho Neto Hospital on 23 July 2015. This new

programme fully extends the telemedicine service to all islands and works on a daily basis, whenever necessary (to deal with clinical evacuations).

The Pan-African e-Network is present in Guinea-Bissau, São Tomé and Príncipe, Cape Verde and Mozambique, among 42 other countries of the African continent. Through this project, the Indian government and the African Union carry out the training of African health professionals and provide telehealth services for specialty consultations (Wamala and Augustine 2013; Yusif and Jeffrey 2014). Language barriers must be pointed out; most professionals in the region find content in English difficult to understand. This problem presents an opportunity for Portuguese-language training programmes.

Mozambique is currently developing its strategy for information and telehealth systems. The Brazilian National Research and Education Network (Rede Nacional de Ensino e Pesquisa—RNP) has a cooperation agreement with the Mozambique Research and Education Network (MoRENNet) under the Ministry of Science & Technology, that seeks to promote advanced networks and telehealth. At the moment MoRENNet is still focusing on capacity-building of personnel for advanced network infrastructure.

The Health for All programme is a specialised care and telehealth project from São Tomé and Príncipe, which since 2012 has been effectively improving health indicators through the use of a telehealth platform, to enable missions of medical specialties such as radiology, psychiatry, paediatrics, pathology, general surgery, cardiology, imaging and ophthalmology. This project is supported by the Camões Mission, Institute for Cooperation and Language, and the Calouste Gulbenkian Foundation, with the direct collaboration of the Prof. Doctor Fernando Fonseca Hospital (Freitas 2013).

East Timor has been developing diagnostic tests using Android™ technology, in cooperation with the World Health Organization and the Public Health Foundation of India. Other data concerning advances in telehealth in East Timor and the Guineas are still missing.

Brazil has invested specifically in telehealth extensively since 2006, so much so that today the area has been turned into a strategic framework, especially considering investments from the Ministry of Education, the Ministry of Science, Technology and Innovation, the Ministry of Health and, recently, the Ministry of Defence. The national public policy model, based on scientific evidence, features the following structure and numbers:

- The National Telehealth Programme, an initiative of the Ministry of Health, focuses on telecare, tele-education and remote diagnostics in collaboration with 14 of the 27 Brazilian states and 2,367 out of its 5,570 municipalities.
- The Open University of the Unified Health System (UNASUS), in collaboration with other universities, teaching hospitals and health research institutes, has provided training in services to 200,000 health professionals.
- The Telemedicine University Network (Rede Universitaria de Telemedicina—RUTE),⁴ which is integrated into the National Telehealth Programme, connects and integrates 120 university and teaching hospitals across all 27 states through the RNP, via dedicated high-speed internet of 1–10Gbps.

The nine initial states (Amazonas, Ceará, Pernambuco, Minas Gerais, Goiás, Rio de Janeiro, São Paulo, Santa Catarina and Rio Grande do Sul) which started the National Telehealth Programme have all developed their networks to provide tele-assistance and tele-education to at least 100 municipalities each. Two of them—Santa Catarina and Minas Gerais—have their projects sustained by the state health department (Alkmim et al. 2010), assisting, respectively, 290 and 880 municipalities, with 2,000 attendance units and over 100,000 tele-consultations. Santa Catarina counts over 4.5 million second opinions on image examinations. Minas Gerais supports 2,000 second opinions on electrocardiograms (ECGs) every day (over 2 million ECGs since the programme started in 2005), with a budget of USD1 million for the first 100 municipalities.

RUTE is a programme coordinated by the RNP and up to now has received direct

investments for last-mile connection and equipment for telehealth units from the Ministry of Science, Technology and Innovation for a total of around USD10 million (Messina et al. 2014; 2015). Investments for maintaining the network infrastructure over these 10 years have come from the Ministry of Education. There are 57 Special Interest Groups across various medical and health specialties in full operation, with 600 video and web conferences recorded annually and made readily available. This represents a daily average of two to three scientific sessions with the active and collaborative participation of more than 150 institutions, including those from all over Latin America and African Portuguese-Speaking Countries (PALOP) in the areas of family health, cardiology, radiology, oncology, nursing, ophthalmology, dermatology, child and adolescent health, rehabilitation, orthopaedics and trauma, tropical diseases and indigenous health, among others.

In Portugal, telehealth initiatives started in the mid-1990s, with the support of European Union programmes that had previously invested significantly in telehealth technology. Portugal defined its national telehealth strategy in 2000, and enacted specific legislations which clarify issues of liability and payment. In 2012, with Directive No. 2445/2012, the ‘Telehealth Contracts Methodology for 2013’ was approved, representing an important measure for increased user accessibility. It stipulated an increase of 10 per cent in tele-consultation procedures, which must be performed in real time. More recently, Directive No. 3571/2013 was enacted, which promotes the widespread use of telehealth in the national health system as well as its introduction into routine (i.e. primary) health care. This introduces mechanisms and strategies to operationalise concrete steps towards the existence of a telehealth network within the national health system. Now most primary care physicians can ask a hospital specialist for a second opinion using telemedicine. Ophthalmology, cardiology and dermatology services are among those used most.

Following the same trend, the Azores archipelago has also been enhancing telehealth for the benefit of the populations of the islands that do not have hospital

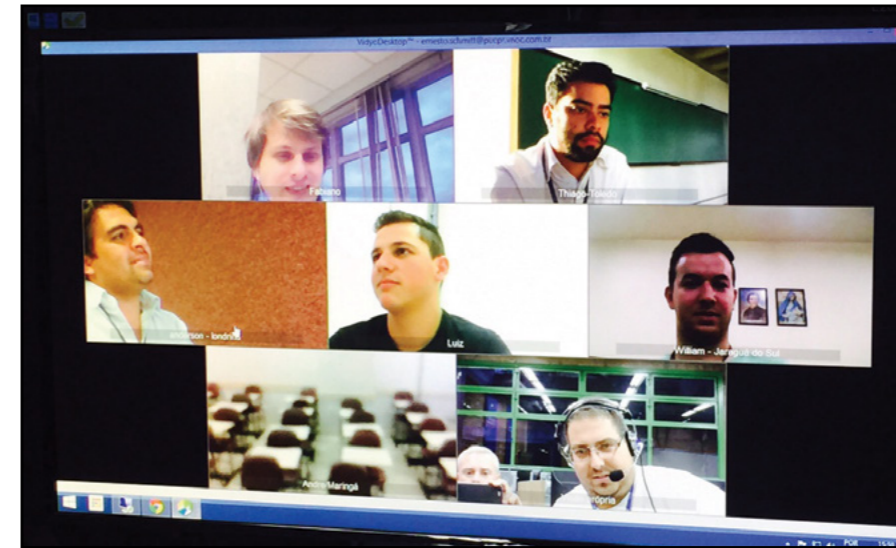


Photo: PUCPR. Telehealth conference in progress, Brazil, 2015.

installations and have to travel to other islands’ hospitals. For evacuations and follow-ups it is possible to use telemedicine to connect to the hospitals on the main islands. The most advanced service is paediatric telecardiology, developed by the Cardiology Service within the Paediatric University Hospital of Coimbra; it is a living example of what the challenges of global telehealth entail (Lapão and Lopes 2013): time and maturity, technology, a sustainable business plan, organisation and staff training. Results show how telemedicine complements the existing services. The service is open every day and provides about 4,000 e-consultations each year to various regions of the country, as well as to Angola, Cape Verde and São Tomé and Príncipe (Maia, Correia and Lapão 2015).

Conclusions

The predominance of the Portuguese language is an integrating factor that facilitates all telehealth activities among CPLP members. The scientific health community and existing assistential, educational and collaborative research programmes may be directly integrated if there is appropriate ICT infrastructure. This is the fundamental requirement. The advancements in National Research and Education Networks (NRENs) over the last decade are a driving force to integrate science and multi-disciplinary scientists into the construction of the modern health system. They demonstrate how telemedicine can support telediagnosis and allow the reduction of costs associated with transferring patients (nationally or

internationally), especially in countries with the greatest need for medical experts. They also show the possibility of using telemedicine in distance learning and collaborative laboratory research.

The strategic roadmap for telehealth in the CPLP is fundamental and must continue not only through proposals for international funding for projects of common interest to promote telehealth in CPLP, but each country must also be aware of the impact telehealth can have on the whole system of monitoring, evaluating and managing health processes. ●

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“The predominance of the Portuguese language is an integrating factor that facilitates all telehealth activities among CPLP members.

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2. Brazilian National Research and Education Network (RNP), Brazil.
3. Oswaldo Cruz Foundation, Brazil.
4. See: <www.rute.mnp.br>.

Development of telehealth services in Latin America: the current situation

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Luis Ary Messina² and Humberto José Alves¹

Public health systems struggle to provide care to meet the needs of populations (Clark and Goodwin 2010). In this context, telehealth initiatives can play a significant role in reducing barriers to access and improving the quality of diagnosis. The development of telehealth activities in Latin America, despite advances in recent years, still faces many challenges.

The use of telehealth services³ is uneven worldwide. According to the World Health Organization (WHO), in less developed countries where the available structure is limited, it has been lower than what is possible. Activities that have already been implemented feature sub-standard use or frequency of use. Whereas more developed countries have geared services towards diagnosis and control, developing countries face challenges related to connecting basic services to higher levels of the health system (WHO 2013).

The challenge of incorporating telehealth resources is significant. Some Latin American countries feature nationwide telehealth programmes, relying to some degree on open forums to strengthen processes. These forums, in addition to the ones comprising Ministries of Health and universities from different countries, include various entities for cooperation in the region, such as the Economic Commission for Latin America and the Caribbean (ECLAC), the Pan-American Health Organization (PAHO), the Inter-American Development Bank (IDB), and the Latin American and the Caribbean Economic System (SELA). The article presents an overview of telehealth in Latin America and constructs a timeline for its development.

Methodology

Following a literature review conducted regarding telehealth in Latin America, using data since 1985, a data collection instrument was developed, targeted at

telehealth managers of the Ministries of Health of all Latin American countries, covering the National Telehealth Projects (NTPs), their objectives and characteristics. The Telehealth Centre of the Medical School of the Federal University of Minas Gerais developed a distance education course for 407 managers of Ministries of Health and major universities. The participants presented essays validating the data collected in their respective countries. Next, a timeline of telehealth was built, and the data were systemised, allowing for an overview of the development of NTPs in Latin America. For the purposes of this article, countries of South America and Central America (including Cuba, Haiti and the Dominican Republic) and Mexico were considered to belong to Latin America.

Results and discussion

Table 1 displays the main telehealth initiatives in Latin America since 1968, highlighting NTP milestones. Considering their characteristics, it is possible to identify three clear stages in the development of telehealth in Latin America.

The initial stage was based on an exchange of experiences between Latin American countries and the USA. During this period—from the 1970s up to the 2000s—the experiences of Mexico, Panama and Costa Rica stand out.

It has been observed that Mexico was the first country in Latin America to introduce telehealth resources. In 1995 it launched the first NTP in the region, focused on providing distance teleconsultation services. Continuing to innovate, in 2009 it started using standards in the medical information technology (IT) field. The Mexican NTP remains a model for the region as a whole (Gertrudiz 2010).

Since 1986 Argentina has been connecting its hospital units with an important development in medical IT. By the end of the 1990s there were 2,000 interconnected health institutions performing teleconsultations. In 2000 Argentina

launched its NTP; however, it was not possible to fully implement the project (Oliveri 2010; Riccur 2011).⁴

In 1996 Costa Rica launched its telemedicine project in primary care. The project was ambitious from the start; however, it happened to be discontinued over time (Ortega 2011).⁵

In 2002, in a partnership between the Ministry of Health and the University of Arizona, Panama launched an NTP in radiology and pathology which covered rural areas and penitentiaries (Vega 2010).

In the early stages of the development of telehealth in Latin America, the initiatives were isolated and fragmented, mainly influenced by the USA. However, a new stage began in 2003, when local telehealth initiatives became connected to the development of telehealth in European countries, with the aim of using resources for projects to exchange experiences between Europe and Latin America and demonstrate their results. The Alliance for the Information Society (@LIS) and EUROsociAL programmes, established by the European Union and Latin American countries, now have an impact on telehealth in Latin America. Demonstration projects carried out in various Latin American countries contribute towards strengthening capacities in telehealth.

Primary care now plays an important role in telehealth, and there are already some continuous forums—still restricted to few countries—for the exchange of experiences between Latin America and Europe (EUROsociAL 2008).

As a result, many countries took their first steps towards NTPs: Ecuador launched its NTP in 2006 (Lopes et al. 2010), and Brazil and Colombia did the same in 2007 (Galegos 2014). These were important experiences, usually focusing on providing teleconsultation, connecting primary care to distant experts. Colombia also deploys telehealth resources across semi-intensive care.

TABLE 1: Telehealth milestones in Latin America

STAGE 1	1968	Ramiro Iglesias (Mexico) receives electrocardiogram from NASA's Apollo 8 spaceship
	1986	Argentina: National Survey Network—PAHO
	1995	Mexico: National Telehealth Programme
	1996	Costa Rica: NTP—which will later be more slowly developed
	1998	Argentina: The Garrahan Hospital connects with Patagonia to perform teleconsultations
	2000	Argentina: 1 st Congress on Medical Informatics NTP in Argentina: but it does not materialise
STAGE 2	2002	Panamá: NTP Brazil: University of São Paulo—Virtual Man Project
	2003	European Community: Project @LIS—Telehealth Healthcare Network, TELMED, EHAS, RedCLARA Brazil: BHTelessaúde, Belo Horizonte; and Health Net, Pernambuco state Argentina: tele-Ophthalmology
	2004	Europe/Latin America: RedCLARA
	2005	Panamá: telehealth for rural areas and the penitentiary population
	2006	Colombia: remote health care Brazil: Telemedicine University Network (RUTE) Ecuador: NTP
	2007	Brazil: NTP Colombia: NTP EUROsociAL Project. I eLAC 2007: Regional Action Plan on the information society in Latin America and the Caribbean, Rio de Janeiro American Telemedicine Association Latin-American & Caribbean Chapter (ATALACC)
	2008	II eLAC 2010, El Salvador ECLAC committee for e-health.
	2009	Brazil: Regional Policy Protocols for Telehealth in Latin America, financed by the IDB SELA: I seminar on telehealth Latin American Journal of Telehealth
	2010	El Salvador: an NTP is in the process of preparation Quito: creation of the Latin American Telemedicine and Telehealth Iberoamerican Association PAHO and Amazon Cooperation Treaty Organization (ACTO) Pan-Amazonic telehealth structure
STAGE 3	2011	PAHO: eHealth Action Plan
	2012	Mercosul Research Network Guatemala: NTP
	2013	Cuba: transmission of ultrasound image in the Hermanos Ameijeiras Hospital, Cuba, and the provinces and the city of Washington, DC, USA
	2014	III eLAC, Mexico Bolivia: NTP
	2015	Peru: regulation framework

In 2007 the Brazilian telehealth project (Campos et al. 2009) became a milestone of telehealth development in Latin America, comprising many different initiatives: the Laboratory of Excellence and Innovation in Latin America, the Telemedicine University Network (Rede Universitaria de Telemedicina—RUTE), the Latin American Journal of Telehealth and the establishment of the Pan-Amazonian Telehealth Network (Santos et al. 2009).

With these positive Brazilian experiences, the development of telehealth was boosted among Latin American countries, establishing a new period of development for these initiatives and enabling the necessary conditions for actions by multilateral organisms, which began to

incorporate telehealth into their action planning. The issue of primary care, perceived as an important organisational strategy, is now significantly integrated into the development of telehealth.

There has been a steady increase in attempts by cooperation organisations to institutionalise telehealth, starting in 2009 with a committee set up by SELA (SELA 2014). In 2009 the IDB designed the project 'Regional development protocols of public policies for telehealth in Latin America', providing a set of integrated telehealth activities for countries of the region (IDB 2012). ECLAC contributed to reflection and analysis towards the formulation of policies, establishing the 'eSalud' adviser group in 2010—a forum

for the development of the information society in Latin America and the Caribbean. PAHO took an important step in 2011 with the approval of the eHealth Action Plan (PAHO 2011).

Both ECLAC and PAHO reinforce the guideline regarding the focus on the development of telehealth based on primary care. After 2010 many countries in Latin America started developing NTPs or building conditions to enable their eventual development: El Salvador (Marroquín 2013), Peru (Correa 2011), Venezuela (Sanchez 2012) and Bolivia (Ministerio de Salud Bolivia 2014). Peru approved a technical standard for telehealth in 2008, and in 2015 the regulatory framework was established.

TABLE 2: NTPs in Latin American countries

Country	Start year	General objective	Main features
Mexico	1995	To contribute to universal health care through a telehealth national system that favours access, quality and efficiency	Teleconsultation Primary care Distance learning ECG, retinography and ultrasound (in select locations)
Costa Rica	1994	To provide health care coverage to the population, improving access to high-quality, specialist medical care	Teleconsultation Videoconferences
Panama	2002	To increase the coverage and quality of health services, including in remote areas	Telemedicine services in x-ray and telepathology Telemedicine in prisons
Brazil	2007	To integrate family health teams with the reference university centres or services; To improve the quality of primary care	Teleconsultation during primary care Webconferences Distance learning ECG and retinography
Colombia	2007	To improve the health conditions in remote areas and in conditions of social vulnerability	Teleconsultation—primary care units Webconferences Distance learning Telemedicine in semi-intensive care, tele-ECG and tele-x-ray
Ecuador	2009	To strengthen the health care model through a network of reference and counter-reference from primary care	Teleconsultation—primary care Webconferences Distance learning
Peru	2010	To develop, implement and spread a telehealth system to improve health services	Teleconsultation
El Salvador	2011	To implement health training and consulting projects for family health teams	Teleconsultation—primary care teams and specialists Webconferences Distance learning
Venezuela	2012	To increase medical assistance coverage in remote rural areas by implementing a telemedicine system or a medical consultation system assisted by the Simón Bolívar satellite	Telehealth—primary care in rural areas (33 areas in total) Two training and virtual triage rooms
Guatemala	2012	To implement a telehealth project involving teleconsultations in primary care, tele-cardiology and tele-x-ray activities	Telehealth in primary care and hospitals with digital x-ray
Bolivia	2014	To democratise specialist medical care, reducing the incidence of diseases and health costs, training doctors and providing an adequate, fast response to health emergencies	Telehealth centres equipped with: general examination camera, vital signs monitor, electrocardiogram, ultrasound probe, digital otoscope and basic medical mobile cart, among others Primary, secondary and tertiary health care level

In 2013 Bolivia implemented the Bolivia Telehealth Project.

There is currently a more accelerated process of NTP qualification, boosted by PAHO, ECLAC and the IDB, with the participation of the countries that already have telehealth projects in place, such as Brazil, Mexico, Colombia and Ecuador. Publications on telehealth initiatives in Latin America are being produced; discussion forums are being implemented; qualification processes involving governments and Latin American universities are being developed, in addition to the establishment of a Latin American Committee for Best Practices in Telehealth, involving the main countries and organisations in Latin America. However, some countries still do not have

a functioning NTP: Argentina, Uruguay, Paraguay, Dominican Republic, Honduras, Nicaragua, Chile, Cuba and Haiti.

A predominance of teleconsultation and distance courses is observed, linking primary care to other levels of health care. In addition, more complex telehealth activities are being developed: tele-radiology, tele-pathology, tele-cardiology, tele-retinography and semi-intensive care.

In the last stage, it was observed that the theme of telehealth became appropriated by Latin America's own dynamics, particularly after the start of the NTP in Brazil. Several organisations are now converging efforts to help develop telehealth as a tool to improve health:

PAHO, ECLAC, IDB and SELA began to create e-health boards, with telehealth occupying an important part of their agenda. Table 2 details the NTPs within specific country contexts.

Conclusion

Despite the discontinuation of some projects (particularly in Argentina and Costa Rica), there are consolidated telehealth activities taking place in several countries (Mexico, Ecuador, Brazil, Colombia and Panama) and new projects being developed nationally (El Salvador, Peru, Venezuela, Bolivia and Guatemala). Most of these programmes focus on the relationship between primary levels of care and other levels of complexity, by performing teleconsultations and various educational activities. Forums



Photo: Universidad Técnica Particular de Loja. Medical appointment using the telehealth system, Ecuador, 2007 <<https://goo.gl/6lj426>>.

for exchanging experiences, developing policies and identifying best practices are under way, driven by PAHO, ECLAC, the IDB and the countries that already have a significant degree of development in telehealth. Though much has occurred in regards to the development of telehealth services in Latin America, there still remains much more to do. This article, among other studies, can hopefully contribute to the further development of such services in Latin America moving forward. ●

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Photo: PUCPR. Telehealth laboratory at a university in Paraná, Brazil, 2014.

“Telehealth initiatives can play a significant role in reducing barriers to access and improving the quality of diagnosis.

“There has been a steady increase in attempts by cooperation organisations to institutionalise telehealth.



Photo: Malova Gobernador. Centre of operations at the Culiacán General Hospital, Sinaloa, Mexico, 2013
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1. Medical School of the Federal University of Minas Gerais, Minas Gerais, Brazil.

2. Telemedicine University Network (RUTE), Rio de Janeiro, Brazil.

3. Telehealth can be defined as the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health and health administration. Technologies include videoconferencing, the internet, store-and-forward imaging, streaming media, and terrestrial and wireless communications.

4. The project was discontinued for audit-checking of the computer equipment. When the audit was completed, there had been a change of government.

5. The government did not continue in subsequent administrations.

A Brazilian policy for telehealth focused on scientific network support to health care, research and education

by Brazilian National Research and Education Network (Rede Nacional de Ensino e Pesquisa—RNP)¹

National Research and Education Networks (NRENs) worldwide are expanding capacities and bridging federal authorities in the fields of science, technology, innovation, education, assistance and health to discuss, finance and work together and comprise an academic telehealth community. The World Health Organization (WHO) promotes universal health coverage as a goal for equitable access to health services without driving people into poverty. The National Telehealth Programme from the Brazilian Ministry of Health focuses its policy on primary health care but also on the NRENs, using information and communication technology to bring health care to people in remote areas of the country and to those who need health services most. In this article, we present some salient features of the Brazilian NREN that include both training of students and professionals, as well as the remote, online provision of services and diagnosis.

Brazilian national telehealth initiatives

There are three major Brazilian telehealth initiatives: the Brazilian Telehealth Programme, the SUS Open University (UNA-SUS) and the Telemedicine University Network. Up until now, little administrative data on such initiatives have been made publicly available. Nevertheless, for this article, the coordinators and stakeholders of this project have prepared some specific information with the aim of expressing the dimension of the projects, their coverage and the overall funding situation. Requests for further information on these data should be sent directly to the authors through their listed emails.

The Brazilian Telehealth Programme

The Brazilian Telehealth Programme is coordinated by the Secretariat of Work and Health Education Management (SGTES) of the Ministry of Health. It seeks to improve

the quality of the service and basic care of the Unified Health System (*Sistema Único de Saúde*—SUS) and to promote tele-assistance and tele-education along with the SUS Open University (UNA-SUS), facilitating the access of patients to health care services and professionals, as well as encouraging their training. Telehealth and telemedicine centres in faculties and teaching hospitals are equipped with cutting-edge equipment. Over 200,000 participants have already registered for e-courses administered by UNA-SUS, in collaboration with teaching hospitals and faculties.

Currently, telehealth services are provided by the National Telehealth Programme in 14 of Brazil’s 27 states, engaging 30,000 professionals from the Family Health Programme (*Programa Saúde da Família*—PSF), who perform remote diagnostics in the following specialties:

- cardiology (electrocardiogram (ECG), Holter and map);
- ophthalmology (retinography);
- pulmonology (spirometry, polysomnography);
- radiology;
- neurology (electroencephalogram); and
- dermatology.

Data from 2008 to September 2015 indicate that the Brazilian Telehealth Programme counted on 46 reference nuclei in 23 of the 27 states in the country, providing 8,257 assistance points in 4,222 of the 5,570 municipalities. This coverage allowed for 2,567,523 tele-diagnoses to be recorded during the period, as well as 3,326,141 tele-consultations and 2,057,517 tele-education sessions. It is noteworthy that, on average, the professionals who use the programme reported an 80 per cent reduction in patient referrals. They also expressed an average satisfaction level with the service of around 90 per cent.

Telehealth projects initiated under the Brazilian Telehealth Programme are becoming fully institutionalised services,

made available to society as part of the public health service through partnerships with state health departments. This is mostly the case in the nine states where programme activities originally started in 2007: Amazonas, Ceará, Pernambuco, Minas Gerais, Goiás, Rio de Janeiro, São Paulo, Santa Catarina and Rio Grande do Sul.

A flagship case is Minas Gerais. The initiative has expanded to cover 780 municipalities (out of a total of 853) through 1,000 service points. Between 2000 and 2010 this initiative performed around 2.5 million tele-ECGs and around 75,000 teleconsultations (Universidade Federal de Minas Gerais 2016).

A similar situation is exemplified by the health service of Rio Grande do Sul, where telehealth reaches all 497 municipalities of the state. Through a toll-free line, it provides remote support to 35,000 care units across the country. So far, the initiative has provided over 65,000 tele-consultations and over 7,000 spirometry exams. Additionally, it has produced 11 apps for medical decision-making support (Universidade Federal do Rio Grande do Sul 2016).

In the state of Rio de Janeiro the tele-education initiative has provided training for 48,974 health professionals, including upper- and middle-level professionals. Since 2015 its tele-education initiative offers a remote Master’s Degree qualification in telemedicine and telehealth, which includes Portuguese-speaking students from different parts of Brazil and abroad (Universidade do Estado do Rio de Janeiro 2016). Since 2008, Amazonas has seen the initiative grow to provide 24/7 remote ECGs to 61 municipalities in the state.

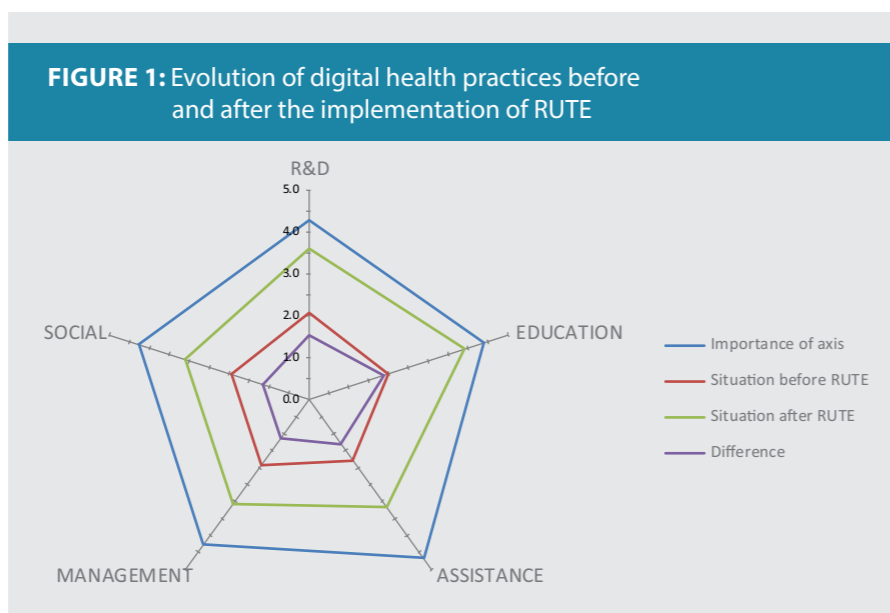
Finally, the programme currently assists 290 of the 294 municipalities in the state of Santa Catarina, with the largest concentration of care units per municipality—1,294, or over four per

“Telehealth projects initiated under the Brazilian Telehealth Programme are becoming fully institutionalised services, made available to society as part of the public health service through partnerships with state health departments.

municipality. Over 9,842 tele-consultations and 4.5 million tele-diagnoses have been provided by this framework, which, in 2015, also started operating a dermatology service. Preliminary analysis indicates that this service has managed to reduce queues by 69 per cent, as well as improve and promote the decentralisation of services and the provision of quick and accurate patient referrals (Sistema de Telemedicina e Telessaúde Catarinense 2016).

The Brazilian National Research and Education Network (Rede Nacional de Ensino e Pesquisa—RNP)

The RNP is the result of an inter-ministerial effort (by the Ministries of Education,



Source: Lopes (2013).

Science and Technology, Culture, Health and Defence), aiming at promoting the innovative use of advanced networks in Brazil as a means of cooperation for health care and other areas, through an advanced national information and communications technology (ICT) infrastructure. In addition to providing connectivity, the RNP allows for the interaction between people and resources far from developed urban centres, enabling the deployment of new network applications and protocols, leading to great benefits for the public in areas such as research, education and health care. Altogether, the RNP brings together around 4 million users. It is one of the top 10 highest-capacity academic

networks in the world, operating through 30 Multi-Gigabit links and connecting 300 campuses (more than 900 institutions and around 27,500 research groups) with speeds of at least 1Gbps (RNP 2016).

The most demanding area of the RNP, after education, is the scientific health community. Since 2006, faculties alongside university and teaching hospitals have been integrated in the Telemedicine University Network (Rede Universitaria de Telemedicina—RUTE), which provides them with an advanced ICT infrastructure that is used in most Brazilian telehealth programmes.



Photo: Luís Oliveira/Ascom-MS. Visit to the Cancer Hospital in Barretos, São Paulo, Brazil, 2016 <<https://goo.gl/lrxVf4>>.

“The RNP is the result of an inter-ministerial effort . . . aiming at promoting the innovative use of advanced networks in Brazil as a means of cooperation for health care and other areas.

Advanced networking for the scientific health community

RUTE was launched in 2006, and by December 2015 its network covered 120 telemedicine units in medical schools and teaching hospitals across all Brazilian states. Its network comprises 57 Special Interest Groups (SIGs) (dedicated to specific health areas), which hold an average of two to three scientific videoconference sessions per day, engaging 380 different health institutions (Messina et al. 2015).

Such results are the outcome of a carefully designed operational routine that starts by developing organisational and technological infrastructure. This is coordinated at national and local levels through advisory committees and SIGs. They are responsible for implementing and certifying telehealth centres as well as overseeing their maintenance and efficient communication. Institutions willing to participate in RUTE have to submit practical examples of the specific projects and proposals they intend to promote to the Network's coordination, and they must provide physical installations and staff to certify the project under RUTE. Once certified, participating institutions are free to propose, create and coordinate SIGs operating under RUTE's infrastructure. Each RUTE member participates in at least three SIGs, in addition to compulsory participation in the Technical Operation SIG.

Lopes (2013) studied the contribution of RUTE to the development of new health care practices. His study assessed five aspects of RUTE:

- education: health care education;
- assistance: remote collaborative assistance and care practices;
- Research and development: multi-centre research, development, innovation, and research on telemedicine itself;
- management: university hospital management; and
- social: social impact.

As illustrated in Figure 1, this study revealed that the operational units were mainly

focused on using RUTE for education, followed by health care provision and then research. The results indicate that the network has instigated and stimulated the development of new digital health practices in university hospitals, especially regarding education and research.

Assessing the impact of collaborative scientific networks using SIGs

Currently, 57 SIGs collaborate in areas such as audiology, nursing, cardiology, psychiatry, ophthalmology, child and adolescent health care, paediatric radiology, neurology, dentistry and others, yielding 625,500 video and 125 web conference sessions per year—all of them recorded and available online for consultation.

To assess the intensity of participation and overall activity of the RUTE units, an online survey conducted between April and July 2014 considered the levels of participation of RUTE units, weighting them according to the nature of the participation—whether they participate in SIGs coordinated by other groups or whether they coordinate SIGs themselves (Brito et al. 2015). The study also allows for the identification of linkages between units, as expressed by participation in SIGs coordinated by other units, and vice versa.

This exercise, combined with the tabulation of similar data from an earlier stage (2007), allows for a comparison that illustrates both the quantitative differences, as represented by the mushrooming of units from 2007 to 2014, and the qualitative differences, as represented by newcomers that managed to be as relevant as institutions that had been participating in the project since the beginning.

Even though a full description of the findings of that study goes beyond the purpose of this article, it is nevertheless worth mentioning that UNIFESP, UERJ, RUTE National Coordination, UFSC, UFPE, UFBA, INCA and ISCMPA are the most collaborative units in the RUTE system.

An interesting initiative that takes place under the scope of the RUTE network is that of providing remote, online synchronous preceptorship for students in multi-professional health areas. This

was coordinated by Brazil's Ministry of Education. Between September and December 2015, students undertook two hours of videoconference activities per week over a period of 12 weeks. An assessment revealed that around 45 videoconference rooms were used during that time, involving 617 participants and comprising 7,282 registered attendances over the course's three-month duration, resulting in cost savings to the order of USD3.5 million. An updated programme is scheduled to start in March 2016.

International collaboration has also evolved as a result of the integration of the Brazilian telehealth initiatives. Eighteen Latin American countries have evaluated their national initiatives (IADB 2016). Moreover, telemedicine was included in the BRICS Moscow Workplan in October 2015 (BRICS 2015) and the technical meeting of the *Comunidade dos Países de Língua Portuguesa* (CPLP) in March 2016 also included telemedicine in its resolution (CPLP 2016).

Conclusions

Telemedicine in Brazil has evolved enormously over the past decade, in both quantitative and qualitative terms. This is probably due to the national initiatives. Pre-existing and newly deployed infrastructure and operational protocols for remote learning and provision of services set by the RNP and the National Telehealth Programme played a crucial enabling role. For a vast and heterogeneous territory such as that of Brazil, remote health initiatives are very likely to gain more and more relevance as facilitators of the constitutional right to universal health care. ●

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“For a vast and heterogeneous territory such as that of Brazil, remote health initiatives are very likely to gain more and more relevance as facilitators of the constitutional right to universal health care.



Photo: Arquivo Telessaúde UERJ. Telehealth conference, Rio de Janeiro, Brazil, 2011.

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The telehealth network of Minas Gerais: a large-scale Brazilian public telehealth service improving access to specialised health care

by Milena Soriano Marcolino,^{1,2} Maria Beatriz Alkmim,¹ Thiago Adriano de Deus Queiroz Santos^{1,2} and Antonio Luiz Ribeiro^{1,2}

Brazil’s Constitution established the public health system (*Sistema Único de Saúde*—SUS) in 1988, ensuring health as a right of all citizens and a government responsibility (Brazil 1988). Primary health care (PHC) provides basic services to the population via multidisciplinary health teams, in a decentralised manner, across all Brazilian cities (Macinko and Harris 2015).

Despite the improvement in health indicators, major problems remain, such as difficulty in accessing health services, poor PHC problem-solving capacity, a shortage of qualified human resources and a high turnover of PHC professionals, especially in remote cities. Brazil’s economic, social and political discrepancies, associated with the concentration of financial, human and health services in large urban centres, have led to precarious access to specialised services in small and remote cities. In Minas Gerais, the fourth largest state in Brazil (586,528 km²), the second most populous and the third largest state economy, access to health care is no different from the rest of the country. There are around 21 million people living in the state, distributed over its 853 towns, 70 per cent of which have fewer than 14,000 inhabitants (IBGE 2016). In Minas Gerais, nearly 50 per cent of all doctors are concentrated in the metropolitan region of the state capital, Belo Horizonte (Conselho Regional de Medicina 2013).

Implementation and expansion of telehealth in Minas Gerais

Given this scenario, telehealth services slowly began to be introduced into the public health service in the early 2000s in an attempt to strengthen PHC and improve the population’s access to good-quality specialised services. The Telehealth Network of Minas Gerais (TNMG) was created in 2005, with the

support of the state government. It is a partnership between seven public universities, with the aim of providing services and conducting research in the field of telehealth. The network operates in accordance with national, state and municipal policies, and is funded by the federal and state governments, as well as research funding agencies (Alkmim, Figueira, Marcolino et al. 2012).

Given the high prevalence of cardiovascular diseases and the limited number of cardiologists in small and remote towns, the first network project was the implementation of telecardiology (*Minas Telecardio*) in 82 towns with less than 10,500 inhabitants, located in the poorest regions of the state. The project proved to be cost-effective (Andrade et al. 2011), increased the satisfaction of health professionals (Maia, de Sousa, Marcolino et al. 2016) and was eventually rolled out as a state-wide programme, with successive expansions (see Figure 1). It currently serves 750 towns in Minas Gerais.

Telediagnosics

The remote diagnostics service is an important part of the TNMG. The tele-electrocardiogram (tele-ECG) is the most important examination (see Figure 2). Prior to the implementation of this service, many patients in small towns had to travel to other cities to have an ECG (Andrade et al. 2011; Ribeiro, Alkmim, Cardoso et al. 2010). Now a health care provider performs the examination at the remote location and sends it via the TNMG website <<http://www.telessaude.hc.ufmg.br>> to the central analysis centre for analysis by experts on duty.

The system used to conduct such diagnoses is simple, easy to navigate, lightweight, capable of working with various Internet connection speeds and thus suitable to local infrastructure conditions. It meets established standards and rules of interoperability, security and confidentiality.

With the success of this service, the TNMG developed the ability to perform remote analyses of other examinations, such as Holter, ambulatory blood pressure monitoring (ABPM), spirometry and retinography, which is an important tool for monitoring diabetic patients. Ensuring diabetic patients’ access to periodic fundus examinations by an ophthalmologist remains a challenge in Minas Gerais. This examination can prevent diabetic retinopathy, a major microvascular complication of diabetes mellitus revealed in 50 per cent of diabetic individuals during their lifetime; it represents a leading cause of irreversible blindness. The TNMG implemented fundus photography in two different remote referral clinics for diabetic patients, which are remotely examined by specialists.

From the start of the service until January 2016, 2.5 million ECGs, 1,024 Holter exams, and 212 ABPM reports were performed, and 744 patients underwent a retinography examination. Currently, the TNMG is developing a tele-echocardiography service.

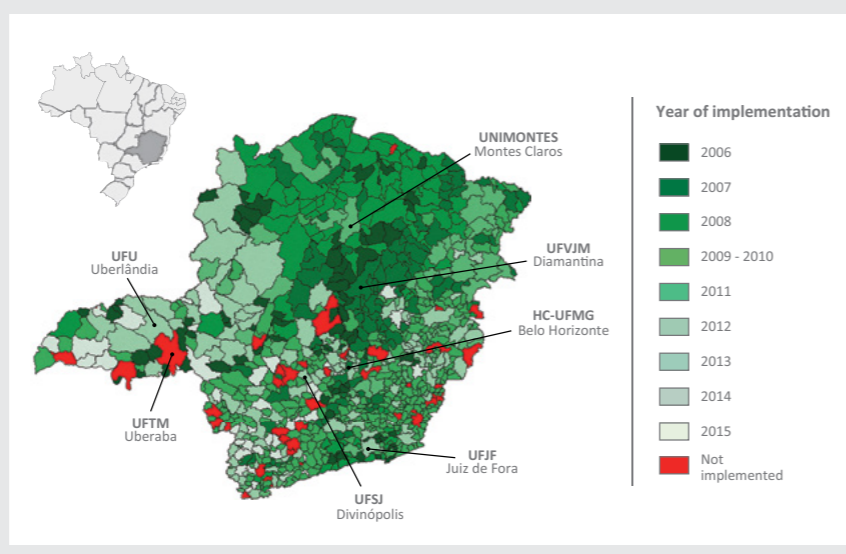
Teleconsultation

Since 2007, a teleconsultation system was incorporated into the service to offer multidisciplinary support to health care practitioners in remote towns in the state. Primary care practitioners can thus perform their clinical activities with the support of TNMG specialists on duty. The specialist who first answers the teleconsultation can seek the help of a subspecialist if he or she deems it necessary. Currently, there are professionals on duty in the areas of internal medicine/family and community medicine, paediatrics, dermatology, gynaecology-obstetrics, nursing, dentistry, physiotherapy, psychology, nutrition, pharmacy and speech therapy. Such professionals respond to teleconsultations in less than 12 hours, while the subspecialists do so in less than 48 hours.

From the very inception of the system until January 2016, 73,698

“Telehealth might become a very powerful tool in supporting health policies that aim to facilitate access to health care, and contributing to the reduction of the inequities of contemporary societies.

FIGURE 1: Year-by-year implementation of the Telehealth Network of Minas Gerais, and the universities that comprise the system



Source: Authors' elaboration.

Notes: HC-UFMG: University Hospital, Universidade Federal de Minas Gerais; UFJF: Universidade Federal de Juiz de Fora; UFSJ: Universidade Federal de São João del-Rey; UFU: Universidade Federal de Uberlândia; UFTM: Universidade Federal do Triângulo Mineiro; UFVJM: Universidade Federal do Vale do Jequitinhonha e Mucuri; Unimontes: Universidade Estadual de Montes Claros.

teleconsultations were performed. Nurses and physicians requested the majority of teleconsultations: 51 per cent and 37 per cent of the total, respectively. The most frequently requested specialty was dermatology (17 per cent), followed by obstetrics/gynaecology (9.2 per cent), nursing (6.3 per cent), internal medicine (5.4 per cent) and cardiology (4.6 per cent). Forty per cent of all teleconsultations were submitted outside working hours, demonstrating the importance of the service to primary care professionals.

At the end of each teleconsultation, the health care professional answers a satisfaction survey. On average, the instrument showed that 80 per cent of the teleconsultations avoided patient referral, and 97 per cent were satisfied with the network.

Aiming at reducing the waiting lists for specialised consultations and at incorporating teleconsultation as a routine activity, a project was implemented in Montes Claros, a town over 400 km from the capital, specifically covering the areas of endocrinology, dermatology and gynaecology. A new workflow was created to attend to the patients on the waiting

lists, based on a new consultation with the family doctor and teleconsultation if necessary. Preliminary results have shown that 79 per cent of patients were removed from the waiting list due to the new, improved workflow. This project will be expanded in 2016 across the entire state, with a large potential impact.

Clinical quality control

To ensure the quality of decentralised clinical services, a quality control centre was established. It implements standard protocols, provides an auditing system for examinations and teleconsultations and promotes clinical research.

Decision support systems

The TNMG has worked on developing innovative solutions to provide remote support to health professionals, to improve the quality of health care and reduce the feeling of professional isolation. Computerised decision support systems (CDSS) were developed for acute coronary syndrome, hypertension, diabetes and stroke. These applications comprise providing reminders, alerts and assistance to the diagnostics and treatment plans. These applications are currently being tested in action to verify the impact on clinical

practice, and other applications are under development (support in caring for elderly patients at risk of falling, patients referred for palliative care and anticoagulation).

Myocardial infarction system of care

The TNMG implemented a myocardial infarction system of care in the north of the state. Using software developed in-house, a tablet-based electrocardiogram apparatus was installed in the ambulances of the region's emergency services, the practice of pre-hospital thrombolysis was implemented, and all health professionals involved in the care of myocardial infarction patients were trained accordingly. Preliminary results have shown that this project increased the access of myocardial infarction patients to early diagnosis and established treatment, with a trend of mortality reduction. This project will be expanded across the entire state in 2016–2018.

Economic indicators

Since 2012, the TNMG has had a contract with the state government of Minas Gerais as a service provider for telehealth, therefore serving as an example of a sustainable service. It has proven to be cost-effective: a recent cost–benefit

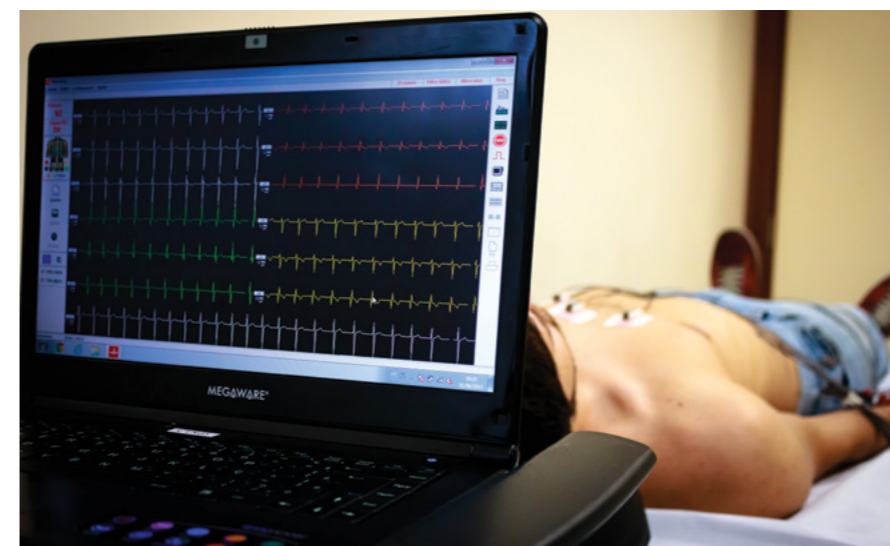


Photo: RUTE. Tele-electrocardiogram.

analysis of the project showed that for each dollar invested, 5.8 are saved as a result of reducing patient referrals (Marcolino, Figueira, Santos et al. 2016).

Concluding remarks

The TNMG provides telehealth services through simple, low-cost and easily-implemented activities performed with a high standard of quality. Its main aim is to support remote health professionals and improve the population's access to specialised care, reducing geographical barriers and qualifying referrals to secondary and tertiary levels of health care. Thus, it contributes towards achieving the basic tenets of Brazil's public health system: universality, equity and integrity.

The experience of the TNMG may be an example of a sustainable and effective service that could be reproduced in other regions of the country, as well as in other middle-income countries. The success of the initiative would depend on several aspects, such as the commitment of policymakers and health professionals from remote locations, the integration of telehealth into the routine of the regular health services and the continuous monitoring of the quality of the service. Another very important issue is the need for adequate reimbursement for activities and to update the technologies in use, to follow the very rapid change in the field of information and communication. Following these principles, telehealth might become a very powerful tool in supporting health policies that aim

to facilitate access to health care, and contributing to the reduction of the inequities of contemporary societies. ●

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“The remote diagnostics service is an important part of the TNMG. The tele-electrocardiogram (tele-ECG) is the most important examination.



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Strengthening the solidarity pillar of social protection systems has been key to providing health care coverage to populations without access to contributory social protection.

Olga Lucía Acosta and Simone Cecchini

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Central to any health system, human resources comprise the single largest expenditure in public health. Therefore, the efficiency of any health system is directly influenced by human resource management policies and practices.

**Venkat Raman, Gert van Zyl, Jeni Vaitsman, Lenaura Lobato,
José Mendes Ribeiro and James W. Björkman**

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Reforms that seek to improve the health of the population require a much wider policy scope than simply access to health services. Such policies need to include education, sanitation, housing and access to clean water if they are to deliver on the promises of improving health and effective health care for the entire population.

Charl Swart, Kieke Okma and Radhika Arora



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