HEALTH and the 18th Amendment

Dr. Sania Nishtar

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Need for a national structure

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Heartfile

Contents

Preamble

Pakistan is a federation, with power shared between the federal government and four major federating units—the provinces. Up until the recently promulgated 18th Amendment to the Constitution of Pakistan, the federal government enjoyed a legislative, and stemming from it, an executive role in several sectors of state governance, which were concomitantly provincial responsibilities as well. Scale back of that role is one of the major changes introduced by the 18th Amendment, with provincial autonomy and devolution of legislative and executive authority in many sectors, including health, as a result.

The devolution of several responsibilities in health is a step in the right direction as it has the potential to improve health governance. However, this does not mean that there is no federal/national role in health[1]. One of the complicating effects of the 18th Amendment is the decision to scrap the Ministry of Health by June 2011. Unfortunately, this decision comes at a time when there is a dire need to step up the country's health systems capacity in view of certain ominous indications. One of the two illustrative examples is polio, where the country now runs the risk of becoming the last remaining reservoir of poliovirus transmission in the world. The other is Pakistan's failure to comply with International Health Regulations (IHR) 2005, evident in the underreporting of H1N1 last year.

Within this context, this paper is focused on outlining modalities of the game change in health introduced by the 18th Amendment and their implications at the health systems level. The paper draws on qualitative insights. Its specific objective is to present the technical and constitutional rationale for retaining a national role in health and discuss options that currently exist for a way forward.

1 Use of the terms 'national' and 'federal' has a connotation in this paper. Federal refers to prerogatives and functions that are taken at the federal, as opposed to the provincial level. In these areas, provincial concurrence and oversight in policy formulation and implementation is not necessary. National, on the other hand, refers to functions where provincial concurrence and policy interplay is mandatory. The appropriate policy forum for national subjects is the Council of Common Interests, as described later in this paper.

Health and the Constitution of Pakistan

Unlike 115 countries of the world, the Constitution of Pakistan does not explicitly recognize the right to health. The preamble to the Constitution and its Principles of Policy refer to socioeconomic rights but courts cannot enforce these.[2] However, courts in Pakistan have previously handed down progressive decisions in public interest through the application of an expansive definition of 'right to life.'[3,4] Under the 18th Amendment, the right to education has now been included as a fundamental human right; however, the amendment has not accorded attention to the right to health.

The Constitution did not at any time—before or after the 18th Amendment—include health *per se*, as a specific legislative subject. However, reference was made to several subjects related to health in the Constitution's legislative lists. Since the mandate of the federal and provincial governments and their executive authority is linked to legislative authority, understanding the latter is important, especially in relation to the 18th Amendment, which has made fundamental changes to federal-provincial mandates through changes in the legislative lists.

Prior to the 18th Amendment, the Constitution contained two legislative lists—the Federal Legislative List (FLL) and the Concurrent Legislative List (CLL).[5] These lists laid out the distribution of legislative powers between the Parliament and the four provincial assemblies.[6] The Parliament was given exclusive power to make laws with respect to any matter listed in the FLL and both the Parliament as well as the provincial assemblies were conferred with the power to make laws with respect to any matter contained in the CLL. Any matter not enumerated in either of the lists fell under the jurisdiction of the provincial assemblies.[7]

The FLL comprises two parts—Part I and Part II. Subjects in Part I are exclusively within the jurisdiction of the federation whereas those in Part II are subject to the overall direction of the Council of Common Interests (CCI), an important institutional framework guaranteed by the Constitution, relevant to the distribution of powers between the Parliament and the provinces. The CCI is chaired by the Prime Minister and its other members are the Chief Ministers of the provinces and three members from the federal government, to be nominated by the Prime Minister. The CCI is responsible to the Parliament. Its mandate under the Constitution is to *formulate* and *regulate policies* in relation to matters in Part II of the FLL and to exercise *supervision* and *control* over related institutions—as such, it acts

2. Under the Constitution of the Islamic Republic of Pakistan 1973, most of the fundamental rights fall within the domain of civil and political rights. Socio-economic 'rights' feature in two areas. The Objectives Resolution makes an explicit reference to social justice as one of the five principles guiding the democratic state. Secondly, Article 25 and 38-d of chapter 2, Part II—Principles of Policy—refers to 'Equality of citizens' and 'Promotion of social and economic well being of the people.' Other articles of relevance to health include Article 9 on 'Security of a person' and Article 14 on 'Inviolability of the dignity of man.' By convention, these covenants are referred to as being the basis of the 'rights-based approach to health in Pakistan,' with Article 8 and 9 read with Article 199 providing the basis of enforcement of fundamental rights. (*Nishtar S, Choked Pipes: Reforming Pakistan's Mixed Health System. Oxford University Press, 2010)*
3. Miss Shehla Zia and others vs. WAPDA [PLD 1994 Supreme Court 693]
4. Syed Mansoor Ali Shah vs. Government of Punjab [2007 C. L. D.533]
5. Fourth schedule of the Constitution of the Islamic Republic of Pakistan
6. Chapter 1 of Part V of the Constitution of the Islamic Republic of Pakistan
7. Article 142(a), 142 (b) and 142 (c) of the Constitution of the Islamic Republic of Pakistan

like a super cabinet. The role of the CCI assumes importance in the post-18th Amendment scenario as is described below.

Health: changes introduced by the 18th Amendment

A series of changes relevant to health have been introduced in the Constitution through the 18th Amendment. These can be enumerated as follows:

1. Changes in the Concurrent Legislative List:

The CLL has been omitted in its entirety. Subjects related to health over which both the Parliament as well as provincial assemblies were competent to legislate in the pre-18th Amendment situation and which now stand omitted, are listed in Panel 1. In some areas, deletion of certain entries has given rise to issues in relation to the federal mandate where, for policy and other reasons discussed in this paper, the deleted subjects ought to have been retained. This is particularly so in the case of drug regulation—Entry 20—as has been described later. In other areas, although an entry has been omitted, there are other mechanisms through which the federal mandate can be retained. Entry 22 is illustrative in this regard. Through this Entry, health information and disease security previously fell within the national/federal purview. This is a critical area where national coordination and conformity needs to be ensured and abolition of this entry would have posed a problem, had it not been for the introduction of another Entry in Part I of the FLL: *"International treaties, conventions and agreements and international arbitration*," which restores a national/federal mandate in this area. Health information and disease security are now international obligations assumed under the WHO-negotiated International Health Regulations 2005, to which Pakistan is a signatory.

In other areas related to health, abolition of a subject auger to the advantage of the health sector. The population-health disconnect in Pakistan is a case in point. Previously, Pakistan was the only country in the world where health and population existed under two separate ministries. This institutional separation created problems due to marginalization of family planning and reproductive health as core health issues.[8] Several attempts were made by the government of Pakistan at the highest level in the past to merge both the institutional hierarchal arrangements—with none coming to fruition. Therefore, abolition of the Ministry of Population, which has already taken effect and devolution of the population planning mandate to provinces, may enable restructuring service delivery arrangements, where family planning and reproductive health can be grouped alongside and together with essential health services at the provincial level. Every effort should be made to maximize synergy at this level.

8. Nishtar S. Amjad S. Synergizing health and population in Pakistan. J Pak Med Asoc 2009;Suppl3:S3-20.

Panel 1: Subjects relevant to health in the Pre-18th Amendment Concurrent Legislative List

Entry 20	Drugs and medicines
Entry 21	Poisons and dangerous drugs
Entry 22	Prevention of the extension from one province to another, of infectious or contagious diseases or pests affecting men, animals or plants
Entry 23	Mental illness and mental retardation, including places for the reception or treatment of the mentally ill and mentally retarded
Entry 24	Environmental pollution and ecology
Entry 25	Population planning
Entry 26	Welfare of labour, conditions of labour, provident funds, employer's liability and workmen's compensation, health insurance including validity of pensions, old age pensions
Entry 43	Legal, medical and other professions
Entry 45	Inquiries and statistics for the purpose of any of the matters in this List

2. Changes in the Federal Legislative List:

Three changes have been made in the FLL. One, the Entry: "*Legal, medical and other professions"* has been shifted from the CLL to Part II of the FLL. This enables human resource regulation and related professional issues of health workforce to be dealt with federally, albeit now subject to formulation and regulation of policies in this respect by the CCI as well as supervision and control of related institutions (such as, for instance, Pakistan Medical and Dental Council) by the CCI.

Secondly, a new Entry has been inserted in Part I of the FLL: "*International treaties, conventions and agreements and international arbitration."* This augments an existing Entry: *"External affairs; the implementing of treaties and agreements, including educational and cultural pacts and agreements with other countries; extradition, including the surrender of criminals and accused persons to Governments outside Pakistan."* Thirdly, the Entry: "*National planning and economic coordination, including planning and coordination of scientific and technological research"* has been shifted from Part I to Part II of the FLL. Through this, the provinces have been empowered to play a role in an area/subject, which was previously not their mandate.

Panel 2 presents a health systems domains-relevant listing of Entries in the post-18th Amendment FLL. Through this listing, areas now within the legislative and executive jurisdiction of the federal government become apparent. Since superior courts have previously held that entries in legislative lists are to be construed broadly, the areas allow the federal government to retain many critical functions which need to be dealt with at the national level. As elaborated in subsequent sections in detail, these include health information, disease security, trade in health, human resource regulation, compliance with international agreements, and research. Through the forum of the CCI, coordination can also be enabled in the post-18th Amendment situation. However, the explicit exclusion of Entry 20 from the CLL and lack of inclusion thereof in the FLL, has given rise to issues and anomalies described in the sections below.

Panel 2: Post-18th Amendment health systems domains-relevant entries in the Federal Legislative List

Governance (regulatory aspects)	All regulatory authorities established under a federal law (P II, E 6)
Health Financing	The law of insurance, except as respects insurance undertaken by a province and the regulation of the conduct of the insurance business, except as respects business undertaken by a province; government insurance, except so far as undertaken by a province by virtue of any matter within the legislative competence of the Provincial Assembly. P1, E 29)
Service Delivery	-
Human Resource	Legal, medical and other professions (P II, E 11)
	Federal agencies and institutes for the following purposes, that is to say, for research, for professional or technical training, or for the promotion of special studies (P I, E 16)
	Federal Public Services and Federal Public Service Commission (P 1, E 11)
	Education as respects Pakistani students in foreign countries and foreign students in Pakistan (P1, E 17).
Medicines	Opium so far as regards sale for exports (P1, E 26)
	Copyrights, inventions, designs, trade-marks and merchandise marks (Part I, E 25)
Health Information, disease security	Inquiries and statistics for the purposes of any of the matters in this Part (P II, E 7)
	International treaties, conventions and agreements and international arbitration (P 1, E 32)
	Port quarantine, seamen's and marine hospitals and hospitals connected with port quarantine (P I, E 19)
	Carriages of passengers and goods by sea and or air (P 1, E 24)
Trade in health	International treaties, conventions and agreements and international arbitration (P 1, E 32)
Research	Federal agencies and institutes for the following purposes, that is to say, for research, for professional or technical training, or for the promotion of special studies (P I, E 16)

3. Changes/amendments in Article 144

Article 144 of the Constitution enables any one provincial assembly by resolution to empower the Parliament to enact legislation *to regulate* matters not contained in the FLL in respect of such province. Previously, resolutions by two of the four provincial assemblies were needed to enable that. However, after the 18th Amendment, any one provincial assembly can confer such power in respect of its province through a resolution. This is an important prerogative conferred upon provinces—a flexibility to enable the federation to assume a role in an area/subject, which is not its mandate. This represents one constitutional mechanism for overcoming some of the issues that have arisen as a consequence of the massive devolution of legislative and executive authority of the federation to the provinces through omission of the CLL as part of the 18th Amendment.

4. Changes/amendments in Article 270

Article 270AA deals with impact of the 18th Amendment and the transitional provisions arising out of the abolition of the CLL. Article 270AA(6), saves all laws (including ordinances, orders, rules, bye-laws, regulations, notifications and other legal instruments having the force of law) with respect to any matter contained in the omitted CLL, which were enacted prior to the 18th Amendment. These laws continue to remain in force until altered, repealed or amended by what is referred to as the 'competent authority.' This, in turn, is defined in the *Explanation* to Article 270AA(2) in respect of orders, ordinances and all other laws as the 'appropriate legislature.'. The expression 'appropriate legislature' is not defined but would, on a reasonable and purposive interpretation, be taken to refer to the legislature to which the legislative authority now stands devolved (where the subject was in the CLL and has not been transferred to the FLL) rather than the Parliament. Existing health-related laws will, therefore, continue to be in force—an important consideration. However, it is relevant to underscore that the Constitution overrides sub-constitutional statutes in case of any conflict and that while the 18th Amendment 'saved' laws, it may have transferred (or devolved) the power to alter, repeal or amend laws in favor of the provinces, which may now be 'competent authority' as referred to in Article 270AA(6).

In sum, therefore, although the CLL has been omitted (including many entries related to health), there is still constitutional and legal space for the federal government to assume responsibility for many critical functions in the health sector. The subsequent sections of this paper outline the technical and legal rationale for doing so, using a health systems lens. The description of envisaged federal roles in health has been outlined in the seven conventional health systems domains, namely: health governance, service delivery, health financing, health information systems, human resources for health, medicines and related products and technology for health.

Federal role in health governance

Institutional arrangements—Ministry of Health

In the pre-18th Amendment scenario, the Ministry of Health (MoH) functioned according to the 1973 Rules of Business of the government of Pakistan and the Concurrent and Federal Legislative Lists of the Constitution. Its mandate and functions, as deciphered from several documents of the Ministry of Health and grey literature, are summarized in Panel 3.

There were a number of problems in the pre-18th Amendment Ministry of Health. First, although the ministry was theoretically tasked with many important roles, it lacked capacity to do full justice to them. Its functionaries were overwhelmed by administrative and logistic tasks, which related to day-to-day administrative control and micromanagement of the national public health programs and attached and subordinate institutions. Its oversight functions related to autonomous institutions affiliated with it, morphed into administrative control by expanding further on a reporting relationship inherent to oversight. This was particularly so in case of autonomous institutions, which were not granted autonomy through acts of Parliament, but through executive orders. As a result, the space for

stewardship tasks, inclusive of policy formulation, collecting and using evidence, planning, and regulation got crowded out. Related institutional arrangements remained under-resourced and lacked capacity.

With respect to *evidence and health information,* there was limited capacity both for collating as well as analyzing information and using locally relevant information and evidence for policy, as explained in the section on health information. The evidence-policy disconnect was, therefore, pervasive and policies continued to be donor-driven. The most illustrative example of this is lack of attention accorded to non-communicable diseases, while data from the Pakistan Demographic Surveys continued to report staggeringly high burden over the last 10 years.

Panel 3: Pre-18th Amendment functions of the Ministry of Health

National policy planning and coordination
International health and donor coordination
Human resource development and medical/allied education
Standardization of manufacture of drugs and biologicals/legislation/licensing of drugs and medicines
Prevention of infectious and contagious diseases
Vital health statistics
Service provision National Program of Primary Health Care and Family Planning (LHWs Program); Expanded Program on Immunization; National TB Control Program; National Rollback Malaria Program; National Nutrition Program; National Hepatitis Control Program; National Blindness Control Program; Maternal Neonatal and Child Health Programme; National Health Information Resource Centre; National Health Policy Unit ; Tobacco Control Programme; National Programme for Control of Avian Influenza
Administrative control of attached departments and subordinate institutions *Attached Departments* Pakistan Institute of Medical Sciences (PIMS), Islamabad; Jinnah Postgraduate Medical Centre (JPMC), Karachi; Federal Government Services Hospital (FGSH), Islamabad; National Institute of Child Health (NICH), Karachi; Federal TB Centre, Rawalpindi; Directorate of Central Health Establishment (CHE), Karachi; Directorate of Malaria Control, Islamabad *Sub-ordinate Offices* Central Drugs Laboratory (CDL), Karachi; National Control Laboratory (Bio), Islamabad; National Institute for Rehabilitation Medicines (NIRM), Islamabad; Drugs Control Administration, Lahore/Peshawar/Quetta/Karachi/Hyderabad
Oversight of Autonomous Bodies National Institute of Cardiovascular Diseases (NICVD), Karachi; National Institute of Health (NIH), Islamabad; Health Services Academy (HSA), Islamabad; Pakistan Medical Research Council (PMRC), Islamabad; Pakistan Medical and Dental Council (PMDC), Islamabad; Pharmacy Council of Pakistan (PCP), Islamabad; Pakistan Nursing Council (PNC), Islamabad; National Council for Homoeopathy (NCH); College of Physicians and Surgeons of Pakistan (CPSP), Karachi

In relation to *health policy,* the only institutional arrangement ever created was the donor-supported National Health Policy Unit (NHPU), which existed for 10 years without explicit indigenous support. This was recently folded in an existing institution, a services academy, where it is not part of the mainstream agenda. The capacity of the Ministry of Health in the area of norms and standards, therefore, remained weak. There can be many examples of the lack of attention to norms and standards. The most illustrative is lack of quality

standards in the country for private sector to comply with. The private sector is pervasive in Pakistan; more than 70% of the healthcare encounters are with entities, which provide services in the non-state sector; yet its potential has not been harnessed.

In terms of *planning*, there were no notable attempts to augment capacity of the Planning and Development Division within the Ministry of Health in ways that could have made it more effective. In view of all these institutional weaknesses, it has become imperative to recast the ministry so that it can divest itself from administrative tasks and focus on building its own capacity for normative and oversight functions.

Fragmentation of various policy agendas was also evident across the scope of operations of the Ministry of Health. The case of institutional arrangements to interface with international development partners and across the global health landscape in general, can be illustrated as an example (Panel 4). For example, despite the existence of the office of international health and planning department of the Ministry of Health, a separate office was created to handle operations of the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). Parallel arrangements are duplicative and do not enable capacity to be built and consolidated in one institutional arrangement.

Panel 4: Pakistan's institutional arrangements to engage with international agencies and partners in global health

Government of Pakistan's responsible institution	International agency/agreement/initiative
Office of International Health, Ministry of Health	-WHO's Joint Program Review Missions -Agreements in the field of health with countries that do not have aid missions in Pakistan (e.g., China, Tajikistan, UAE, Cuba, Oman, Kuwait, Libya)
Planning and Development Division, Ministry of Health	Agreements with major bilateral donors such as USAID, DFID, CIDA
Individual programs of the Ministry of Health (e.g., Expanded Program for Immunization)	Agreements with corresponding Units—in this case, the Global Alliance for Vaccines and Immunization
Country Coordination Mechanism, Ministry of Health	Global Fund to Fight AIDS, Tuberculosis and Malaria
Foreign Office	-Health projects linked to Friends of Democratic Pakistan (FoDP) grants -Resources committed bilaterally under Kerry Lugar Legislation by the USA -Country negotiations in international agreements/treaties -Assistance in disasters
Economic Affairs Division	Agreements with multilateral development agencies, e.g., World Bank, Asian Development Bank and some major bilateral donors

The institutional malaise, which the Ministry of Health suffers from and which is inherent to the overall system of governance, is another cause for concern. Over the years, political and external interference in decisions, particularly in relation to recruitments, transfers and disciplinary actions, has become deeply ingrained. Erosion of mechanisms to compel

accountability and politicization of governance are an impediment for efficiency and a demoralizing factor within the public sector. As a result of all these weaknesses, the Ministry of Health has continued to perform sub-optimally. Institutional reform of the Ministry had, therefore, become an imperative. These weaknesses will have to be addressed in any new federal institutional arrangement for health, thedetails of which are discussed below.

Technical rationale for retaining an institutional arrangement at the federal level:

Despite its weaknesses, the Ministry of Health plays an important role in many areas, which need to be served nationally at the federal level in Pakistan's federating system. Most federating countries have similar functions retained at the national level. In light of the arguments presented in this paper, a re-cast federal structure for health must be mandated to serve the following national functions:

1. Evidence, health information and disease security
2. In the regulatory stream, regulation of medicines and related products and certain aspects of human resource regulation
3. International agreements, partnerships and conventions, including trade in health
4. In the normative and policy sphere, i) overarching norms to establish standards related to the state's commitment to health, ii) establishing standards where inter-provincial conformity is needed, iii) areas where national policy coordination can obviate unnecessary duplication, and iv) support to provinces with weak capacity
5. Service delivery where a specific advantage is to be gained through a national/federal role

The rationale for retaining these national roles federally has been alluded to in various sections of this paper. In relation to roles in the normative and policy sphere—this has not been discussed elsewhere in this paper—it is critical to appreciate that there is already a capacity and institutional void, and therefore, a dire need to step up capacity. There is need for deep-rooted reform to overcome distortions in Pakistan's Mixed Health System.[9] This entails complex reorganization and reform of existing institutions of service delivery and those that regulate them and provide oversight. This cannot be possible unless there is astute analytical and normative capacity within the system to oversee and guide the process of reform and ensure policy consistency.

Proponents of the idea of scraping the Ministry of Health argue that these capacities can be built at the provincial level. These notions are mistaken for three reasons. One, the costs of doing so would be exorbitant; in fact, fiscal managers' argument centered on using the ministry's abolition as a way of curtailing expenses would be self-defeating if the costs of creating parallel provincial structures is borne to bear. Second, capacity constraints, which

9. Nishtar S. Mixed Health Systems Syndrome. *Bull World Health Organ* 2010;88:74-75. doi: 10.2471/BLT.09.067868 http://www.who.int/bulletin/volumes/88/1/09-067868/en/

currently prevail in the country, would make it almost impossible to do so. The federal government's Ministry of Health struggled unsuccessfully with institutionalizing a National Health Policy Unit over a 10-year period with massive donor support; trying to do that in each of the four provinces would be an institutional nightmare and fiscally, out-of-the-question. There are many other areas where central coordination by the Ministry of Health on behalf of the provinces, even in the scenario of enhanced provincial autonomy, can spare provinces from unnecessary duplicative work for which they neither have human resource capacity nor the institutional arrangements in place. This consideration is of particular relevance to provinces with weak capacity. Federal oversight—its weaknesses notwithstanding—ensured the delivery of some services which will be risked in the event of loss of that role. Thirdly, lessons from other countries with federating structures are instructive. Most have ministries of health and MoH-equivalent institutions, e.g., departments of state, which have clear and meaningful missions whilst corresponding institutions at the sub-national level technically have the 'health service delivery mandate' (Panel 5).

In view of these considerations, it is hoped that the decision to scrap the Ministry of Health and abolish a federal/national role in health, as a consequence of giving effect to the sweeping changes by the 18th Amendment, will be reconsidered by the Implementation Commission. It is imperative to retain a high-level federal institutional structure to develop a national vision for health and serve national health-related objectives. Currently mooted views with reference to replacements for the Ministry of Health are fundamentally flawed.

One view promotes 'housing' various institutional entities charged with national functions under different federal institutional arrangements. This has already been done with the Ministry of Population Welfare, where the affiliated institutions which could not be devolved, have been placed under the oversight of the Planning Commission. It is being mooted that different national/federal organizations in health be placed under various other federal ministries/divisions—international agreements under Economic Affairs Division of the Ministry of Finance, normative and training agencies (e.g., Pakistan Medical and Dental Council, Health Services Academy) under the supervision of the Planning Commission and the drug regulatory arrangement under the Ministry of Industries. Such course of action would be extremely deleterious since it would augment existing fragmentation of the health sector. Additionally, placing drug regulation under the Ministry of Industries is fundamentally flawed as a policy move. The primary objective of a medicines policy is to make quality essential medicines affordable and accessible for all, as a priority. Any objective relevant to the business side of pharmaceuticals must be subservient to this core objective.

Other options for housing federal health institutions, such as the Cabinet Division, are also being suggested. There is already a precedent with the Peoples/Presidents Primary Healthcare Initiative (PPHI) and Sheikh Zaiyed Hospital, a federal hospital reporting to the Cabinet Division. Such a course of action will also further augment existing fragmentation. In addition, there would be capacity constraints—the Cabinet Division has no explicit expertise in health. Fragmenting health's institutional structures will absolve a particular institutional entity, normally a ministry of health, from overall responsibility in health.

The idea to create a 'Health Commission' is also being floated as an alternative to the Ministry of Health. The rationale for this probably stems from the realization that for the Implementation Commission, ministerial abolition has now become symbolic of the entire process of devolution. In the event of their realizing that a federal health structure is needed but absolute recalcitrance on their part to restore the ministry, the Health Commission may become a viable alternative for them to accept. Theoretically, such an institution can enable structuring broader governance oversight and can also draw constituencies relevant to the inter-sectoral scope of health, an important dimension in health planning. In this case, however, a commission is not an appropriate option. Commissions are created for defined objectives and do not have a policymaking mandate. The construct of a commission and the needed institutional parameters are quite different from an ongoing policymaking and oversight role, which a ministry of health has to play to protect and promote the health and wellbeing of the country's population. It is also being mooted that if the Commission's mandate is defined by the CCI, it may have legitimacy. This may be so, theoretically. However, lessons from past experiences with commissions in policymaking roles should be instructive.

Ideally, the Ministry of Health should not be abolished as it is also symbolic of the significance of health at the national level. However, since ministerial abolition has become symbolic of provincial autonomy, there is need to explore the next best alternative, which can enable retaining national functions in health at the federal level.

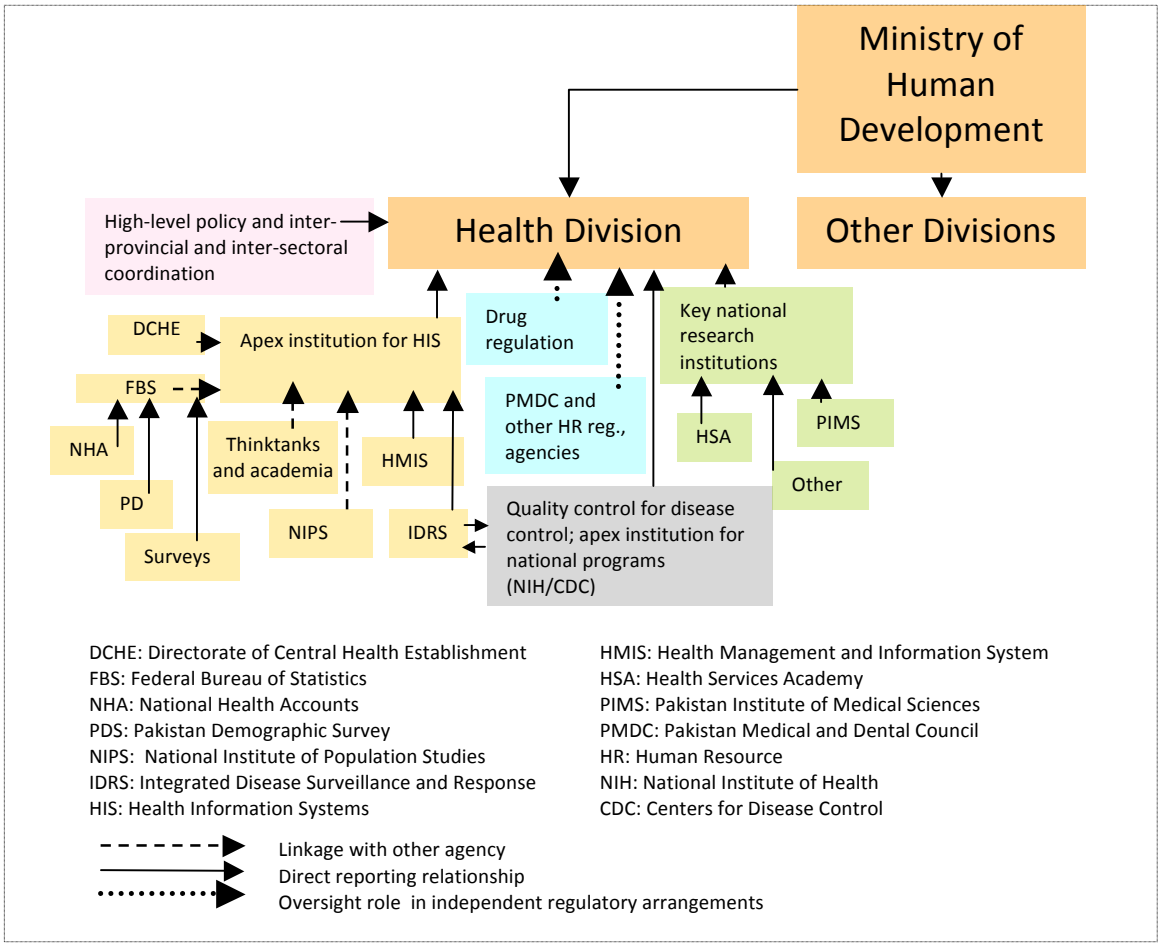
In deciding the fate of the federal institutional arrangement for health, the government of Pakistan's Rules of Business must be brought to bear, as elaborated in Article 99 of the Constitution. According to these rules, the conduct of business of the federal government has to be carried out in a 'distinct and specified sphere.' It has been clearly stipulated in Rule 1 (vi) of the Rules of Business that a 'Division,' which is a self-contained administrative unit of the government, has to be responsible for the conduct of business of the federal government. In view of this, the only apparent option is to recast the Ministry of Health as a Division.

This conclusion can be supported by a number of arguments. First, in addition to being an option with a constitutional color, it is also in keeping with the spirit of times vis-à-vis provincial empowerment and devolution of powers. Converting a 'Ministry' into a 'Division' would mean stepping down hierarchically in the federal government's organgram and therefore, indicative of its intent to relinquish powers. However, at the same time, it will enable retaining a coherent institutional structure at the federal level to serve national functions in health in a consolidated manner, without the kind of fragmentation feared in the currently envisaged options. Secondly, and importantly, health is not a legislative subject *per se,* in the Constitution, and therefore, the creation of a 'Division' will not be regarded as unconstitutional. With some other options, such as the Health Commission, 'giving another name' could be construed to be suggesting that somehow the effect of the amendment is sought to be circumvented.

Thirdly, since a Division has to be placed under a 'Ministry,' this would also be an opportunity to develop appropriate inter-sectoral linkages for health, which have been the missing piece in health sector planning and development. Recommendations of the National

Commission for Government Reform (NCGR) 2005 are instructive in this regard. The NCGR was created in 2002 as a high-level statutory body and was tasked with the responsibility of developing recommendations to reform the executive branch of the state. Its broad principles underlying institutional reform fell under three domains—civil services structure, structures of the federal, provincial and district governments, and business process re-engineering. The NCGR recommended the creation of a Ministry of Human Development, which could be given the responsibility for health, education, capacity building, labor and overseas Pakistanis. It appears, therefore, that one option would be to have the Division for Health and other devolved subjects placed under the Ministry of Human Development. There are also other alternatives—such as placing the Health Division under the Ministry of Planning. The latter may have a greater appeal with the Implementation Commission since it would obviate the creation of a new ministry. The option to create a Ministry of Inter-Provincial Coordination and place divisions under that, is also being considered. There are strengths and downsides of each of the options being mooted. Ideally, expert technical consultations should be convened to analyze the best solution for housing the Health Division, given the present situation.

Figure 1. Reporting relationships and linkages of federal health organizations with the proposed Health Division



Lastly, creation of the Division and recasting the institutional arrangements of the Ministry of Health can be an opening for defining new reporting relationships for organizations that have to be retained federally to serve national functions. This can also be the entry point for reform of key national health institutions to bridge their weaknesses, which have been referred to in various sections of this paper, but more comprehensively discussed in a recent reform plan.[10] Figure 1 shows a recast landscape for health under the proposed Health Division.

Five institutional streams are envisaged to report to/link with the Health Division. One of these is the high-level policy unit, which should work in close coordination with an apex institutional arrangement for health. The existing National Health Information Resource Center (NHIRC) has the potential to morph into this role if it is adequately resourced in financial and human resource terms. A number of organizational entities are shown with a reporting relationship with the apex information arrangement (Figure 1). Others do not hierarchically report but form important elements of the health information system. Careful attention needs to be paid to creating these linkages, which are currently are not well-established. For example, the Federal Bureau of Statistics does not have seamless linkages with the Ministry of Health in ways that can assist with policymaking.

The third institutional stream is that of federal entities, which could be retained under the constitutional prerogative of 'research;' these have to be placed under a cell/unit for national research institutes. In the fourth place, there is a category of institutions with a regulatory mandate, which need to be retained federally; these need to be in a true autonomous color so that the role of the Health Division is oversight and not regulation *per se*. Furthermore, the other direct reporting relationship with the Division would be that of the federal arrangement for quality control of biologicals through the National Institute of Health (NIH)/Centers for Disease Control (CDC), under which the coordination arrangement for the national health programs can also be housed.

Key message:

It is imperative to retain a federal institutional arrangement for health to fulfill national health mandates. Constitutional provisions and Rules of Business of the federal government call for creating a Health Division. The latter can either be placed under a Ministry of Human Development, a Ministry of Inter-Provincial Coordination or the Planning Ministry. Organizations that have to be retained federally to serve national functions need to undergo reconfiguration, as relevant, and develop appropriate reporting relationships with the Health Division in a 'recast' arrangement so that national health functions are better served.

10 Nishtar S. Choked Pipes: Reforming Pakistan's Health System. *Oxford University Press*, 2010. ISBN 978-0-19-547969-0

Panel 5: Federal structures for health in countries with federating systems

Federation	Federating Units	Federal Structure for Health
Argentina	23 provinces and 1 autonomous city	Ministry of Health and Social Action
Australia	6 states and 10 territories	Department of Health and Ageing
Austria	9 *Länder* or *Bundesländer*	Ministry of Health and Environmental Protection (However, all functions related to this ministry pertain to environment only)
Belgium	3 communities, 3 regions	Ministry of Health
Brazil	26 states and 1 federal district	Ministry of Health (*Ministério da Saúde*)
Canada	10 provinces and 3 territories	Health Canada (the department of the government of Canada with responsibility for national public health)
Comoros	3 islands	National Directorate of Health Services Department
Ethiopia	9 regions and 2 chartered cities	Ministry of Health
Germany	16 *Länder* or *Bundesländer*	Federal Ministry of Health
India	28 states and 7 union territories, including a National Capital Territory	Ministry of Health and Family Welfare
Iraq	18 governorates, including the autonomous region of Kurdistan	Ministry of Health
Malaysia	13 states and 3 federal territories	Ministry of Health
Mexico	31 states and 1 federal district	Secretariat of Health
Nepal	14 zones and 75 districts	Ministry of Health
Nigeria	36 states and 1 territory	Federal Ministry of Health
Pakistan	4 provinces, 1 federal capital territory and specially administered areas	Federal Ministry of Health (to be abolished in June 2011)
Russian Federation	21 republics, 46 *oblasts*, 9 *krais*, 1 autonomous *oblast*, 4 autonomous *okrugs*, 2 federal-level cities[16]	Ministry of Health and Social Development
Sudan	25 states	Federal Ministry of Health
United States of America	50 states; 1 federal district; 1 incorporated territory, 13 unincorporated territories	United States Department of Health and Human Services; all US states have a state health department. (For details, see end of panel)
Venezuela	23 states	Venezuelan Institute of Social Security

Health Policy

There can be many instruments of policy—a law, office noting, statutory regulatory order, strategic plan, etc. With the responsibility for health completely devolved to the provinces, the policymaking role has automatically been transferred to them. However, a 'health policy' in the traditional context denotes an official statement by the highest level of government, usually the Cabinet, which sets the mission, vision, goals and strategies, and in many cases, operational plans to achieve health and health systems outcomes. Since 1997, Pakistan has had one of the two official health policies (that of 1997 and 2001). In 1990, a draft policy was framed but it could not be presented to the Cabinet for approval. More recently, a draft health policy at the national level went through the technical process in 2009/10. After the 18th Amendment, there are strong views cautioning against its presentation in the Cabinet, on the grounds that health is no more a federal subject.

Proponents of a 'national health policy' argue that it can still be placed before the CCI for endorsement by each of the provinces and that it is important to have a unified vision for implementation in the provinces. Approval by the CCI would certainly strengthen the legal validity of a 'national health policy.' However, some provinces do not concur with the notion and want to exercise their prerogative to pronounce their own policies. The question is—is that prerogative questionable? Clearly not. Provinces now have the mandate to strategize and plan in the health sector. The current draft of the national health policy is too detailed in its stipulations to be framed as a national policy in the post-18th Amendment scenario without provincial buy-in. It lays down specific options for service delivery and financing mechanisms at the health systems level, which are now provincial mandates.

Within this context, a key question emerges: is there a place at all for a federally-driven national health policy after the 18th Amendment? The answer to this is evident in previous sections of this paper. In the normative and policy sphere, first of all, it is important to establish overarching norms related to the state's commitment to health. A set of values and principles needs to be articulated at the national level—the provinces should endorse these as unifying threads in relation to the state's commitment to health. For example, this could be an opportunity to get a consensus on the issue of the right to health. Additionally, setting of norms could also be an opportunity to develop consensus on the extent to which health needs to be part of social protection arrangements. Standards should also be prescribed where inter-provincial conformity is needed and in other areas where national policy coordination can obviate unnecessary duplication. In addition, there are health systems-related functions that have a truly national character, e.g., health information, disease security, compliance with international regulations, and trade in health. For reasons later described in this paper, regulation of medicines and related products and certain aspects of human resource also need to be national mandates, and therefore, within the national policy purview. It is also perfectly legitimate to pronounce a national health policy in areas with federal responsibilities. These areas have been alluded to in the previous section of this paper.

The secretariat for policy, in this case, would be the Health Division and the technical inputs would come from the policy unit assisted by the apex health information institutional

arrangement. However, instead of the Cabinet, the national health policy will have to be in the purview of the CII, which must now be viewed as a super cabinet.

Key message:

It is legitimate to pronounce an overarching national health policy in areas and subjects that should have a national character; some but not all are included in Part II of the FLL. The national health Policy should now be limited to high-level norms and standards, and can be enunciated through the inter-provincial mechanism provided by the CCI. Subjects in Part I of the FLL are national/federal prerogatives and can be dealt with at the level of the Cabinet. All other policy matters stand devolved after the 18th Amendment.

Health regulation

Regulation in the health sector can be relevant to quality, price or numbers in the domain of health services delivery, medical education, human resource and medicines and technologies. There is a degree of ambiguity in terms of how the Constitution can be interpreted with respect to these functions. On the one hand, Entry 6 in Part II of the FLL gives the Parliament the prerogative to legislate in order to create federal regulatory authorities. However, the subject for which a regulatory agency is created may have been devolved by the 18th Amendment, in which case the jurisdiction assumed and exercised by a regulatory authority established under a federal law in respect of a matter which has otherwise been clearly devolved to the provinces (e.g., through omission of subjects in the CLL), may be open to question. This has been elaborated further in the discussion on regulation of drugs.

This notwithstanding, regulation of service delivery and medicines and related products stands devolved after the 18th Amendment. The former is a positive change as it can be used as a tool to improve quality of services in provinces and districts. However, devolution of drugs and medicines, which is a consequence of abolishing the CLL, has given rise to issues since the policy rationale for retaining the federal role in this area is strong, as has been described later in the relevant section. As regards human resource and medical education, several entries in Part I and Part II of the FLL enable the Parliament and the federal government to retain a role in these areas.

Key message:

Post-18th Amendment, the Parliament can enact legislation to create a federal regulatory authority. The problem arises when the subject which the federal regulatory agency is created to 'regulate' is devolved. The Parliament can enact legislation and the federal government can continue to enjoy a regulatory role in medical education and human resource, but not in service delivery. The regulatory role of the federal government in medicines and technology is currently open to question.

Health Financing

Entry 29 in Part I of the FLL is the only entry related to financing: *"The law of insurance, except as respects insurance undertaken by a province and the regulation of the conduct of the insurance business, except as respects business undertaken by a province; government insurance, except so far as undertaken by a province by virtue of any matter within the legislative competence of the Provincial Assembly.*" This can be the basis for introducing a federally-led health insurance or a social insurance scheme, if needed in the event of that not being the case at the provincial level. All other health financing-related functions stand devolved. The choice of health financing arrangements and mechanisms to pool for resources and purchasing are now provincial prerogatives. This make sense, as these are not independent of service delivery decisions and have to be made in view of existing arrangements or the manner in which service delivery is envisaged to evolve as a result of concomitant reform. It must be noted that revenue collection and its allocation under the National Finance Commission (NFC) Award is already a federal responsibility and will continue to be so after the 18th Amendment.

Key message:

Federal fiscalism stands unaltered except for the size of the provincial share, which has increased under the 7th NFC Award. The choice of individual health financing strategies is largely a provincial prerogative with insurance being the exception where the federal government can intervene in case of a provincial policy void.

Service Delivery

National public health programs

Policy rationale for retaining a national role

In the existing situation, Pakistan's national public health programs are federally-led with provincial and district implementing arrangements (Panel 3). Over the years, these programs have been subject to heavy criticism for their vertical planning, management anomalies and lack of provincial ownership. The move to devolve them is, therefore, well-received. In principle, all their functions should be fully devolved. However, a careful examination of their scope of operations reveals that while there is room for devolving many of their functions, there is need for provincial capacity to take on these functions. Therefore, in the short to medium term, an interim arrangement is required till such time that provincial counterpart arrangements are fully established and start functioning. For this purpose, a unified arrangement for the national programs should be retained at the federal level. In addition, there is also need for a long-term institutional focus since some of the functions where inter-provincial coordination and conformity is needed will also have to be retained at the federal level, over the long term under the oversight of the CCI.

Interim institutional arrangement for national programs

There is need for retaining a federal structure in the interim, till such time that provincial capacity is fully developed to take on the responsibility of the national programs. Five areas where careful planning and incremental devolution may be necessary, are being outlined.

Firstly, considerations relevant to resource mobilization, contractual agreements, conditionality, and donor preferences should be brought to bear as most of the national programs are also channels for mobilizing donor resources. Some are entirely aligned with global programs and are heavily reliant on international support. The impact of completely devolving these programs on their capacity to mobilize resources should carefully be analyzed. Currently, contractual obligations and conditionalities bind the government to one-window operations. For example, the Global Alliance for Vaccines and Immunization (GAVI), which provides X% of the resources for Pakistan's Expanded Program for Immunization, accepts only one application from a country. Pakistan's current contractual obligations under …..extend up-to …..(Year), until which present arrangements need to continue. Pakistan's new application …for …. has been accepted with the assumption that there will be one point of contact for the donor. Similarly, the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) needs to have one Principal Recipient (PR) for a country. Provinces have never applied to be PRs and capacity constraints have been cited by the federal level in this regard. Mobilizing support through these donors in the future will necessitate planning at several levels.

In certain programs, it is not the contractual agreements *per se*, but donor preferences, which lead to the creation of national/federal operations. The German Technical Cooperation-supported National Blood Transfusion Program is an example. Under this, implementation is centered largely at the provincial level, where infrastructure will be updated/created. However, the Ministry of Health is the executing partner and resource flows/reporting relationships have been envisaged as being federally located. Similarly, the Maternal, Neonatal and Child Health (MNCH) Program is funded by the Department of International Development (DFID) and may have similar considerations. Unless there is a change in the modalities of support, there will be need for ongoing engagement at the federal level to tap into support committed through these arrangements.

Secondly, in principle, procurements in national programs should be decentralized to the provinces. In some programs, such as the MNCH and the National AIDS Control programs, that is already the case while in others, such as the blindness and hepatitis control programs, there is room for further decentralization. However, there could be two exceptions to the rule, which might, in certain cases, serve as the justification for centralizing procurements. Both can be illustrated in the example of vaccine procurement. One, if a cost advantage is gained through economies of scale—WHO's Eastern Mediterranean Region's resolution to develop a common procurement system for the region is an example; and two, quality standards. Presently, there is only one centrally located laboratory, the National Control Laboratory for Biologicals, where vaccines are tested for quality control. Corresponding institutional infrastructures are not present at the

provincial level to enable that. In this case, appropriate capacities will have to be developed at the provincial level as a starting point.

Thirdly, the interim arrangement for national health programs at the federal level should ensure the creation of counterpart arrangements for all programs. In some areas such as in case of the National Nutrition Program, there are no provincial counterpart arrangements. It is important to ensure that these areas are not marginalized. Lastly, institutional modalities have to be brought to bear. The Directorate of Malaria Control was established through an Act of Parliament—the implications of abolishing such structures will have to be carefully thought through.

Fourthly, whilst there is support for devolving most functions, there is need for taking provincial capacity into account. Provinces have a poor track record of implementing national public health programs. A large percentage of the primary healthcare units are still non-functional despite efforts to reform service delivery. There are numerical inadequacies and issues of mal-distribution at the human resource level—no one wants to serve in the rural areas. Provinces have not been able to tackle these issues; additionally, graft is pervasive at all levels, which is why there is need for fundamental reform at the provincial level. Devolution of programmatic functions *per se*, will not improve service delivery unless there is a concerted effort to ingrain mechanisms for improved performance.

Lastly, while restructuring of the national health programs provides an opportunity to devolve functions, they also present an opening for integrating their programmatic activities with other cross-cutting interventions, which are also in the process of being reshaped. The opportunity to maximize synergies and eliminate duplication in various health information streams becomes particularly relevant as the national programs are re-cast in the post-18th Amendment scenario. Several programs have silo surveillance systems, which can either be combined in the Integrated Disease Surveillance and Response (IDSR) system—there have been announcements by the government that IDRS is being planned—or the Health Management and Information System (HMIS). For example, EPI's case-based surveillance for AFP, its sentinel surveillance sites for Bacterial Meningitis and Rotavirus surveillance, and its Measles case-based surveillance for suspected case confirmation, can be combined in IDRS for notifiable diseases, or its sub-set, the Disease Early Warning System (DEWS). Many aspects of routine EPI surveillance such as immunization coverage, stock position and monthly reporting can be integrated with HMIS, as can the MIS components of all other programs. The National Nutrition Survey and population-based risk factor surveillance of NCDs can be piggy backed on existing population-based instruments.

Individual strands of research within the national health programs could be promoted through better linkages with and strengthening of the Pakistan Medical Research Council (PMRC). The blindness program includes a school health component, which can be housed more appropriately under provincial education departments. Furthermore, 'mobile' service delivery components—both preventive and curative—which are part of many programs, can be consolidated and integrated with the larger field outreach of the family planning program, which has also been fully devolved to the provinces. There is already a platform for integrating field activities—the Lady Health Worker Program—which can be strengthened further.

Long-term institutional arrangement for national health programs at the federal level

While most responsibilities can be incrementally devolved, there are some that will have to be retained nationally over the long-term. Harmonization of norms and standards at the programmatic level is an area, where inter-provincial synergies can and should be exploited. All of the national health programs refer to the following functions as part of their mandate: policy formulation, strategic planning, establishing standards, guidelines and tools, technical support, and coordination. It would be an unnecessary duplication to try and resurrect four parallel structures for that purpose when resource constrains are so pervasive in the country. In addition, there are many normative areas where inter-provincial uniformity is necessary. Immunization schedule is one example, where it may become difficult to implement uniform National Immunization Days (NIDs), thus further undermining polio eradication efforts. Lack of uniform guidelines can lead to irrational use and potential resistance, particularly in the case of anti-malarial and anti-tuberculosis therapy. This is an area where inter-provincial conformity is needed even in the event of complete devolution of the national health programs.

Every effort should be made to make the operations of the federal entity less cumbersome and to avoid duplication. One option is to fold the administrative arrangements of all programs into one entity so that duplicative administrative arrangements are eliminated. The technical and normative strands of each program can be retained under the overall entity. These can be housed under one umbrella—a disease control entity, or a Center for Disease Control (CDC). The NIH has the construct to morph into that role. Such a structure will need to have close linkages with the agency responsible for collecting and collating information.

The overall objective of restructuring and devolving the national health programs should be to garner provincial ownership and integrate them with the district health system in ways that improve performance. However, there are some programmatic activities, which need to be retained nationally, and space should be created to enable that.

Enabling Constitutional mechanism

The institutional mechanism provided for by the CCI in Article 154 of the Constitution enables policy agendas to be coordinated with the four provinces at the national/federal level. In addition, Entry 32 of Part I of the FLL is relevant to many of the national public health programs due to the interplay of international agreements, which need to be honored at the national level.

Key messages:

There should be a plan for incrementally devolving all except those functions within the national health programs where inter-provincial policy coordination is needed or where a specific advantage is gained through collaborative action. To achieve this purpose, there is need for retaining a unified interim federal structure for these programs till such time that provincial capacity is fully developed. In doing so, administrative arrangements of all

programs should be folded into one entity, an NIH morphed as Centers for Disease Control, so that duplicative administrative arrangements are eliminated. Over the long term, a lean and minimal federal structure should be maintained for programmatic functions, which must be served nationally. Programmatic activities such as research, health information and mobile service delivery can be integrated with other cross-cutting interventions, which are also in the process of being reshaped.

Hospitals

The Ministry of Health's existing service delivery role is largely centered on the national public health programs. The exception is its role in managing a numbers of hospitals, which have been marked with an asterisk in Panel 3. From a policy stand point, these should be handed over to the provinces so that the related administrative burden can be minimized. However, constitutionally, the situation is such that if the federal government wants to retain them, it will be able to do so to the extent that they have been created under Entry 16 of the FLL Part 1: *'Federal agencies and institutes for the following purposes, that is to say, for research, for professional or technical training, or for the promotion of special studies.'* Hospitals serving the federal territory and dedicated to federal government employees should be restructured so that the administrative burden on the ministry is reduced. They should be placed under the Division, which is being created to deal with matters related to the Islamabad Capital Territory.

Key message:

Hospitals under the administrative control of the Ministry of Health should be handed over to the provinces. Federal government hospitals should have enhanced level of autonomy to decrease administrative burden on stewardship agencies; they should be placed under the Division, which is being created to deal with matters related to the Islamabad Capital Territory.

Human Resources for Health

The Federal Legislative Lists, Part I and II, have many entries related to human resource in general; these also apply to human resource for health. Together, they potentially enable the federal government to assume any human resource regulatory function. There should, therefore, be no issue with regard to the reporting relationship of several human resource regulatory agencies, provided the Ministry of Health or another federal structure is retained.

Human resource hiring and career structures can be enabled under Entry 11, Part I of the FLL: "*Federal Public Services and Federal Public Service Commission"* but this will require creation of a federal cadre comprising human resources for health. Training and ongoing education can be enabled under Entry 16 of the FLL: *'Federal agencies and institutes for the following purposes, that is to say, for research, for professional or technical training, or for the promotion of special studies'* and Entry 17: "*Education as respects Pakistani students in foreign countries and foreign students in Pakistan*." However, it must be appreciated that Entry 11, Part II of the FLL: "*Legal, medical and other professions*" has been moved to Part II

of the FLL from the CLL (now omitted), which is more than symbolic in the sense that the federal level will now need provincial concurrence in terms of formulation and regulation of policies—at the forum of the CCI—in relation to human resource decisions at the federal level. Related institutions (such as the Pakistan Medical and Dental Council) will be subject to supervisions and control by the CCI.

This notwithstanding, several issues can arise with regard to human resource in health, if implementation of the 18th Amendment in health gets underway in the present form. The Ministry of Health's current strength is 450 with 493 sanctioned posts. Additionally, there are ….functionaries employed in federal institutions. With transfer of function and devolution of responsibilities, the provinces will be expected to absorb these employees. This raises issues of fiscal capacity within the provinces on the one hand, and concerns related to service protection vis-à-vis seniority, on the other. The Implementation Commission is currently trying to devise a mechanism for the education sector to absorb its employees after devolution of the Ministry of Education.[11] Lessons will be instructive for the health sector. Transfer of corresponding budgets to the provinces will obviate fiscal concerns but service protection issues will still have to be addressed.

Key message:

The 18th Amendment does not alter federal functions related to human resource. However, the exercise of executive authority in this respect will now be subject to provincial concurrence and policy oversight at the forum of the CCI. Related institutions will also be subject to supervision and control by the CCI. More than the constitutional prerogative, it is the implementation of devolution of human resource service structures, which will be problematic and will need careful management.

Medicines and related products

Policy rationale for a national role

There are three aspects of drug regulation—quality and product regulation, price regulation and Intellectual Property Rights Regulation. The latter currently exists at the federal level and existing arrangements will not be affected, since Entry 25: *"Copyrights, inventions, designs, trade-marks and merchandise marks"* is already one of the subjects in the FLL. With the elimination of Entry 20*: "Drugs and medicines*" as part of the CLL, product, quality and price regulation are envisaged as provincial subjects. However, there are many arguments against devolution of regulation in this area.

Internationally prevailing trends are particularly instructive. Drugs and related products are regulated centrally in almost all countries of the world including those that are federations. Notable examples are the USA, Germany and Switzerland. A central organization is charged with the regulatory mandate in such cases. This is usually a ministry, most commonly, the

11. According to press reports, the matter of the devolution of the Education Ministry has been challenged before the Supreme Court very recently. As of the date of this paper the Supreme Court had not passed any order on that Petition.

Ministry of Health or a semi autonomous public regulatory authority. In the USA, although not a federal subject, the Federal Food and Drug Administration has been established under the FDA Act of 1938 to regulate drugs. Even countries where some (but not all) aspects of drug regulation were previously decentralized, as in India, are now moving towards centralized regulatory arrangements. In other parts of the world such as in the Gulf Cooperation Council (GCC) countries, ASEAN, Latin America and the European Union (EU), regulation is moving from national to regional models. In the EU, mutual recognition of new drug registrations is already a norm. The European Medicines Agency harmonizes, but does not replace the work of national medicines regulatory bodies. There is, therefore, a global trend towards harmonization of policies in order to obviate work in each individual country. The move to decentralize drug regulation in Pakistan would, therefore, be a unique experience in contrast with internationally prevailing trends. Pakistan would become the first country in the world to devolve drug regulation.

Secondly, devolving drug regulation would entail unnecessary duplication. Each of the four provinces will replicate work currently being done by one organization in every other country of the world. This would have resource implications in the current fiscally-constrained environment. Capacity constraints at the institutional level also have to be considered.

Thirdly, the currently envisaged model of provincial regulation is also flawed *per se*. Three out of the four provinces have expressed interest in taking on the responsibility of drug regulation. The provinces appear to be interested in registrations but not price regulation. However, registration and pricing should not be considered in isolation but as elements of a comprehensive pharmaceuticals/medicines policy, which in the post-WTO era cannot be extricated from IPR regulation, which in our case is to be retained centrally, in any case.

In the fourth place, the inter-provincial trade norms guaranteed by Article 151 of the Constitution obviate the need to devolve drug regulation. Drugs registered in one province will be available in the other province in any case.

In the fifth place, and importantly, the devolution of drug regulation is not likely to have a profound impact on bridging some of the key impediments, which currently exist at all regulatory levels.[12] Many institutional regulatory arrangements are in place at the federal and provincial levels.[13] The real issue is at the level of capacity and transparency since there are systemically ingrained mechanisms, which enable collusion at different levels, thus defeating the core goal of a drug policy. Several *suo moto* actions on spurious drugs by the Supreme Court are illustrative in this regard in terms of the pervasiveness of collusion and graft in this area. These systemic issues, which need to be at the heart of reform objectives, may become even more difficult to address if drug regulation is devolved due to capacity constraints. Further erosion of oversight is inevitable as a consequence.

12. These gaps have been described in detail in the Chapter on Medicines and related products (Choked Pipes)
13. At the governance, oversight, and normative levels, the Central Licensing Board, Drug Regulatory Board, and the Drug Appellate Board exist at the federal level and Quality Control Boards have been established at the provincial level, each with a dedicated mandate.

The policy imperative, therefore, is to retain drug regulation nationally under a unified federal drug regulatory arrangement. The core priority should be to address weaknesses of existing regulatory arrangements rather than creating duplicating structures. A plausible way forward is to replace the Drug Control Office with an independent drug regulatory agency. Extensive spadework has been done in the last ten years to plan and strategize such transformation. In July 2002, the Economic Coordination Committee (ECC) decided on a summary submitted by the Ministry of Industries and Production to create an independent Drug Regulatory Authority. The technical and analytical process and scrutiny by the Ministry of Health and the Regulatory Authorities Wing of the Cabinet Division was completed thereafter and a draft act was prepared. Subsequently, however, progress was stalled due to change in government.

If appropriately structured, a Drug Regulatory Authority can overcome existing capacity and resource constraints by taking advantage of the experience of established regulatory agencies. There are many examples from the developing countries where regulatory agencies, despite being fully autonomous and having the mandate to evaluate and register drugs, choose not to do so but to act as followers of main drug regulatory agencies, such as FDA and EMEA. Instead, they concentrate their limited technical expertise and capacity on industry and market inspections for quality control and other locally-relevant field activity. This approach can be employed, but with safeguards—as not all drugs approved elsewhere are relevant for registration and may even cause market and price distortions.

There is yet another strong argument in support of an independent drug regulatory arrangement in the post-WTO scenario. None of the key flexibilities under the TRIPS agreement in terms of the rights of member countries—compulsory licensing, parallel importation, bolar exceptions—can be availed unless there is an independent regulatory authority. In view of this, the rationale for independent regulation becomes even stronger.

Constitutional basis

The policy rationale for retaining regulation of medicines at the national/federal level is robust. However, the constitutional mechanisms to enable that, without the consent of the concerned provincial legislature(s), are less clear. At this point in time in the transition, various factions are interpreting Entries in the FLL from their own vantage point. One view states that drugs and medicines can be regulated federally and that there are mechanisms in the Constitution, which allow drug regulation to be retained at the federal level. The opinion argues that there is a law in force—the Drug Act, 1976; that Article 270AA(6) of the 18th Amendment saves all laws with respect to any matter contained in the omitted CLL, which were enacted prior to the 18th Amendment; and that these laws will continue to remain in force until altered, repealed or amended by the 'competent authority.' This view argues that Articles 270AA(8) and/or 270AA(9) of the Constitution deal with implementation of the 18th Amendment and not interpretation of the Constitution or prevailing laws and that the judicial power to do so continues to lie with the courts of law and not the Implementation Commission. Reference is made in particular to Entry 6 of Part II of the FLL, in terms of it being the basis for creation of the Drug Regulatory Authority of Pakistan.

A legal analysis, however, reveals that this view is subject to several concerns: first is the question of sub-constitutional vs. the Constitutional law. It is clear that in the event of a conflict, the latter is supreme. Some legal viewpoints opine that if a particular Entry has been explicitly deleted from the CLL and has not been added in the FLL, then the intent of the Parliament with respect to devolving the subject to the provinces is clear. Also, the expressions 'saved' and 'competent authority' have legal connotations in Article 270AAA. As stated above, the 'saved' laws continue to remain in force until altered, repealed or amended by what is referred to as the 'competent authority.'[14] The expression 'appropriate legislature' is not defined but would, on a reasonable and purposive interpretation, be taken to refer to the legislature to which the legislative authority now stands devolved (where the subject was in the CLL and has not been transferred to the FLL) rather than the Parliament. While laws have been saved, there are questions about who the 'competent authority' is with reference to the power to amend laws. With the relevant Entry omitted, provincial assemblies and not the Parliament may now be the competent authorities with respect to the Drug Act, 1976.

Secondly, a larger question looms—centered on the validity of creating a regulatory authority to regulate a subject, which has been devolved by the 18th Amendment. An analogous question has arisen in the Sindh High Court with filing of a case against the Pakistan Standards and Quality Control Authority, a federal authority prescribing standards in an area—sugar—which, as an agricultural produce, has always been a provincial subject[15]. There is, therefore, a question and cloud over the legality of jurisdiction conferred on federally-established regulatory bodies with mandates to 'regulate' subjects that are devolved *per se*, under the 18th Amendment. In view of the foregoing, the constitutional legality and validity of a federal law to create a regulatory authority for regulation of drugs and medicines may not be watertight. Ultimately, legal proceedings might have to decide this question.

Thirdly, experts are also drawing on the example of the USA, where the power to regulate medicines can be exercised by virtue of the federal subject of interstate commerce. An analogy is being drawn with the prerogative in inter-provincial commerce and federal powers by virtue of Article 151[16] read with Entry 6 of Part II of the FLL. However, other experts are of the opinion that on a textual analysis, Article 151 does not seem to cover 'regulation,' as understood in the present context.

Another potential mechanism, which is also subject to certain reservations and not as legally certain as that provided by Article 144, may be to have any draft law to create a Federal Drug Regulatory Authority approved by the CCI *prior* to promulgation by the Parliament.

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14. Competent authority has been defined in the *Explanation* to Article 270AA(2) in respect of Orders, Ordinances and all other laws as the 'appropriate Legislature.'

15. Constitution Petition No. 2515 of 2010 before the Sindh High Court at Karachi filed by various sugar mills based in Sindh. As of the date of this paper, a pre-admission notice has been issued in the Constitution Petition and no final judgment had been rendered in the CP. However, an interim order passed earlier (on 26-8-2010) continued to hold the field in terms of which the Sindh High Court suspended the notification pursuant to which the standards of sugar prescribed by the Pakistan Standards and Quality Control Authority in exercise of the powers under a Federal law (i.e., the Pakistan Standards and Quality Control Act, 1996).

16. The import, effect and scope of Article 151 of the Constitution is likely to be examined by the Supreme Court in Petitions pending before it involving interpretation and application of article 158 of the Constitution. However, there does not appear to be any reported Judgment on Article 151 which gives it the same meaning as that of the "commerce clause" in the Constitution of the United States of America.

Subsequent to enactment, such regulatory authority would be subject to supervision and control of the CCI at which the four Chief Ministers and the federal government are represented. Based on this, it could be argued that through the forum of CCI, the provinces have acquiesced in the federal government, regulation of an otherwise devolved subject. However, one key weakness in this approach is the counter-argument that the Chief Ministers, whilst participating in the CCI, do not directly represent or are synonymous with the provincial assemblies to which the 'legislative authority' in respect of the relevant subjects has been devolved and hence, on a strict interpretation, do not posses the authority and power to empower the Parliament to enact a law which is the constitutional prerogative of the provincial assemblies. Such approach could also be criticized as a circumvention of the mechanism expressly provided in Article 144.

In sum, therefore, all the constitutional mechanisms being cited as the basis for retaining drug regulation at the federal level, are fraught with some degree of uncertainty. Article 144 is the only valid and non-controversial mechanism in the Constitution, which can grant a regulatory mandate to the federal government in this area. It is now imperative that provincial assemblies recognize the imperative and grant the federal government a legislative mandate related to drug regulation. The federal government must, in turn, reform its own ability in this area by building further on the work already done to create a Drug Regulatory Authority and structure it in ways that will enable it to address weaknesses in drug regulation. The provinces will still continue to play a role in drug regulation in this arrangement through policy oversight enabled through the CCI. Additionally, their role in market inspections for quality control will stay as in the present arrangement.

Key messages:

The policy rationale for retaining drug regulation at the national/federal level is robust. The appropriate constitutional mechanism to enable that is Article 144 through which provinces can mandate the federal government to legislate and create a Drug Regulatory Authority, therefore giving credence to Entry 6 of Part II of the FLL. In this event, drug policy can also be coordinated at the federal level with oversight by the CCI. All other constitutional mechanisms being cited as the basis for retaining drug regulation at the federal level, are fraught with some degree of uncertainty. The primary focus of restructuring drug regulatory arrangements should be to overcome weakness in drug regulation so that the core objectives of the medicines policy are served.

Health information

Retaining health information as a federal function: policy rationale

Several important provincial and sub-national roles in health information are centered on information collection, surveillance and ensuring compliance with stipulated norms and standards. Notwithstanding, health information needs to be a national/federal mandate, both in terms of collection, collation and consolidation of health information, as well as analysis and dissemination of information for policy and planning. Uniform measures, methods and instruments need to be used nationally. Federating countries need to have centralized systems for health information so that common tools, indicators and standards

can be developed and maintained. Pakistan, in particular, needs to enhance its capacity in this area in view of the country's abysmal performance in terms of ensuring compliance with IHR 2005, a WHO-negotiated global inter-governmental treaty. This was confirmed in the under-reporting of H1N1 last year and evident in many cases previously. Pakistan is a signatory to IHR 2005—as part of its stipulations, countries are expected to build institutional capacity to strengthen global public health security and management systems for addressing public health emergencies and risks of international concern. Pakistan does not have an integrated disease surveillance system or an apex coordinating arrangement to collect, consolidate and analyze health information. The role of the Ministry of Health in these areas is a strong rationale for building its capacity further—far from abolishing it.

Constitutional position

Entry 22 was the health information-relevant Entry in the Concurrent List: *"Prevention of the extension from one province to another of infectious or contagious diseases or pests affecting men, animals or plants."* Despite its abolition, health information will remain a federal responsibility by virtue of the mandate cumulatively granted by the following Entries in the FLL: "*International treaties, conventions and agreements and international arbitration"* (P 1, E 32); "*Port quarantine, seamen's and marine hospitals and hospitals connected with port quarantine"* (P I, E 19); "*Inquiries and statistics for the purposes of any of the matters in this part"* (P II, E 7); and "*Matters incidental or ancillary to any matter enumerated in this part*" (E 59 PI and E 18 PII). The Entry related to international treaties is of particular relevance in the case of health information in the post-18th Amendment scenario. Pakistan has, in principle, agreed to comply with IHR 2005 by building and reinforcing effective mechanisms for disease outbreak, alert and response at the national level. The success of that, amongst other things, also depends on a functioning health information backbone.

Pakistan's health information infrastructure comprises several population-based surveys, a vital events surveillance system, the HMIS, a biostatistics division to which hospitals report, several cancer registries, a National Health Accounts Unit, and 14 infectious disease surveillance systems.[17] There are many gaps, which need to be bridged in the country's health information landscape—current fragmentation of infectious disease surveillance, donor dependency, antiquated systems, and inability to leverage technology, with undue delays and quality issues being a consequence, are the foremost. There is also no apex agency to collate, consolidate and analyze information. A detailed account of needed actions to bridge health information systems' gaps has been published elsewhere.[18]

The opportunity to reform the health information-related institutional landscape should be used as an entry point to define and dedicate a clear institutional entity for collection, collation and analysis of health information. The capacity of the existing National Health Information Resource Centre (NHIRC) can be stepped up to play this role. Close linkages with the agency responsible for the national public health programs, the CDC being recommended, can enable it to also play the needed role in relation to IHR and pandemic

17. Acute Respiratory Infections, AFP/Polio, Bacterial Meningitis, Diarrhea, Hepatitis, HIV/AIDS, Malaria, Measles and Tuberculosis, and the Disease Early Warning System (DEWS)
18. Chapter on Health Information. Nishtar S. Choked Pipes: Reforming Pakistan's Health System. Oxford University Press, 2010.

preparedness. The NHIRC can be used as a hub for integrating infectious disease surveillance. Recently, there has been high-level commitment to invest in Integrated Disease Surveillance and Response (IDSR) as a way of overcoming current fragmentation of infectious disease surveillance and as a step towards ensuring disease security. The NHIRC can be used as the institutional structure under which this arrangement can be situated, with reporting relationships with the Health Division. The relationship of the apex arrangement for health information with other entities has been shown in Figure 1.

Key message:

Health information is an important federal responsibility in the wake of concerns centered on disease security. Constitutional provisions potentially enable the function to be retained federally. However, there is need for reform of the health information institutional landscape to bridge current weaknesses in individual streams and create an overall apex mechanism in order to comply with IHR 2005. The NHIRC and CDC can be used as the institutional structures under which this arrangement can be situated, with reporting relationships with the Health Division at the federal level.

Conclusions

Overall on devolution: It is recognized that provinces have the right to organize and restructure the district healthcare system along the principles of decentralization, local self-governance and subsidiarity. The provincial mandate in this area should further be strengthened by devolving all remaining service delivery responsibilities from the federal to the provinces level, unless a specific advantage is to be gained by retaining a defined role at the national level.

National roles and responsibilities in health: The above notwithstanding, a national/federal role needs to be retained in the health sector in the following five areas: evidence, health information and disease security; international agreements, partnerships and conventions, including trade in health; in the regulatory stream, regulation of medicines and related products and certain aspects of human resource regulation; in the normative and policy sphere, i) overarching norms to establish standards for the state's commitment to health, ii) establishing standards where inter-provincial conformity is needed, iii) areas where national policy coordination can obviate unnecessary duplication, and iv) support to provinces with weak capacity; and service delivery where a specific advantage is to be gained through a national/federal role.

National/federal institutional structure for health: It is imperative to retain a federal institutional structure for health to fulfill national health responsibilities. Constitutional provisions and Rules of Business of the federal government, when viewed in the context of the present devolution drive, call for creating a Health Division. The latter can either be placed under a Ministry of Human Development, a Ministry of Inter-Provincial Coordination or a Planning Ministry. Organizations that have to be retained federally to serve national functions need to undergo reconfiguration, as relevant, and develop appropriate reporting

relationships with the Health Division in a 'recast' arrangement so that national health functions are better served.

National health policy: It is legitimate to pronounce an overarching national health policy in areas and subjects that should have a national character; some but not all are included in Part II of the FLL. The national health policy should now be limited to high-level norms and standards, and can be enunciated through the inter-provincial mechanism provided by the CCI. Subjects in Part I of the FLL are national/federal prerogatives and can be dealt with at the level of the Cabinet. All other policy matters stand devolved after the 18th Amendment.

Health regulation: Post-18th Amendment, the Parliament can enact legislation to create a federal regulatory authority. The problem arises when the subject for which the federal regulatory agency is created, is devolved. The Parliament can enact legislation and the federal government can continue to enjoy a regulatory role in medical education and human resource but not in service delivery. The constitutional validity of the direct regulatory role of the federal government in medicines and technology is open to some questions. This can, however, be achieved through the mechanism provided in Article 144.

Health financing: Federal fiscalism stands unaltered except for the size of the provincial share which has increased under the 7th NFC Award. The choice of individual health financing strategies is largely a provincial prerogative, with insurance being the exception where the federal government can intervene in case of a provincial policy void.

National public health programs: There should be a plan for incrementally devolving all except those functions within the national health programs where inter-provincial policy coordination is needed or where a specific advantage is gained through collaborative action. To achieve this purpose, there is need for retaining a unified interim federal structure for the programs till such time that provincial capacity is fully developed. In doing so, administrative arrangements of all programs should be folded into one entity, an NIH morphed as Centers for Disease Control, so that duplicative administrative arrangements are eliminated. Over the long term, a lean and minimal federal structure should be maintained for programmatic functions which must be served nationally. Programmatic activities, such as research, health information and mobile service delivery can be integrated with other cross-cutting interventions, which are also in the process of being reshaped.

Hospitals: Hospitals under the administrative control of the Ministry of Health should be handed over to the provinces. Federal government hospitals should have enhanced level of autonomy to decrease administrative burden on stewardship agencies; they should be placed under the Division, which is being created to deal with matters related to the Islamabad Capital Territory.

Human resources for health: The amendment does not alter federal functions related to human resource. However, provincial concurrence is mandatory for human resource decisions at the federal level, which relate to subjects that have been devolved. More than the constitutional prerogative, it is the implementation of devolution of human resource service structures, which will be problematic and will need careful management.

Medicines and related products: The policy rationale for retaining drug regulation at the national/federal level is robust. The appropriate constitutional mechanism to enable that is Article 144, through which provinces can mandate the federal government to legislate and create a Drug Regulatory Authority, therefore giving credence to Entry 6 of Part II of the FLL. In this event, the drug policy can also be coordinated at the federal level with oversight by the CII. The primary focus of restructuring drug regulatory arrangements should be to overcome weaknesses in drug regulation so that the core objectives of the medicines policy are served.

Health information: Health information is an important federal responsibility in the wake of concerns centered on disease security. Constitutional provisions potentially enable the function to be retained federally. However, there is need for reform of the health information institutional landscape to bridge current weaknesses in individual streams and create an overall apex mechanism in order to comply with IHR 2005. The NHIRC and CDC can be used as the institutional structures under which this arrangement can be situated, with reporting relationships with the Health Division, at the federal level.

Acronyms

Centers for Disease Control	CDC
Concurrent Legislative List	CLL
Council of Common Interests	CII
Department of International Development	DFID
Disease Early Warning System	DEWS
Economic Coordination Committee	ECC
Federal Legislative List	FLL
Global Alliance for Vaccines and Immunization	GAVI
Global Fund to Fight AIDS, Tuberculosis and Malaria	GFATM
Health Management and Information System	HMIS
Integrated Disease Surveillance and Response	IDSR
International Health Regulations	IHR
Ministry of Health	MoH
National Commission for Government Reform	NCGR
National Finance Commission	NFC
National Health Information Resource Center	NHIRC
National Health Policy Unit	NHPU
National Institute of Health	NIH
Peoples/Presidents Primary Healthcare Initiative	PPHI
Pakistan Medical and Dental Council	PMDC
Pakistan Medical Research Council	PMRC

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