HEALTH and the 18th Amendment

Retaining national functions in devolution

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Preamble and Précis

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.

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.

The following key messages have emerged from the analysis:

1. **Context:** the analysis is grounded in Constitutional provisions, which morally bind the state to reduce inequities in a society and uphold redistributive social justice. This is applicable in the present case, both in relation to reduction in health inequities and addressing inequities in capacity, which exist at the provincial level and have implications for their ability to promote health and well being of populations.

2. **18th Amendment**: the 18th Amendment has made six health-relevant changes to the Constitution: i) abolition of the Concurrent Legislative List (CLL); ii) shifting of an Entry from the CLL to the Federal Legislative List (FLL), Part II; iii) insertion of a new Entry into the FLL, Part I; iv) shifting of Entry from Part I to part II of the FLL; v) Amendments in Article 144; and vi) Amendments in Article 270. Although the CLL has been omitted there is still constitutional and legal space for the federal government to assume responsibility for many critical functions in the health sector. A notable exception is the regulatory prerogative, where ambiguity has been inadvertently introduced. Overall, policy oversight and participation of the provinces has been ensured through the Council of Common Interests.

3. **Overall direction:** the analysis recognizes the political and constitutional imperative of provincial autonomy in Pakistan's federating system, and is fully supportive of devolving health. This notwithstanding, it is critical that national

subjects in health are recognized and related responsibilities are entrusted to a federal institution with a health mandate.

4. **National subjects in health:** there are four national subjects in health: i) health information, inclusive of research in health; ii) health regulation; iii) international commitments; iv) national health policy, with respect to federal mandates in health, overarching norms, norms of care, inter-sectoral action, trade in health, health technology and disaster response. It is also a national responsibility to ensure policy coordination, and support provinces with weak capacity. There are strong justifications for retaining the national role in health.

5. **Constitutional rationale for retaining a national role:** despite extensive changes by the 18th Amendment, the Constitution still provides space for national functions and a federal role in health. The only exception is the area of regulation of medicines and service delivery, where there is currently an ambiguity (Panel 1).

Panel 1. National health functions, with a strong policy rationale for a federal role: constitutional position and proposed relationship to an envisaged federal structure

National role	Constitutional position	Envisaged relationship with the proposed Health Division (described below; details of the relationship, Panel 9 on page 21)*
National health policy: -High level norms; norms of care; intersectoral coordination, technology, disasters and policy coordination. -Federal mandates in health policy	Can be enunciated by the Council of Common Interests Cabinet	An independent Health Policy Unit working in close collaboration with the Health Division
Trade in health	Within the federal purview. Enabled through Entry 27, Part I of the FLL	The Health Policy Unit should be tasked with this responsibility
Health information	Totally within the federal purview. Enabling entries are: Entry 19, 24 and 32 of Part I, and Entry 7, Part II of the FLL	Direct reporting relationship of the health information apex agency with the Health Division
Health research	Within the federal purview. Enabled through Entry 16, Part I and Entry 7 Part II, FLL	Direct reporting relationship of a dedicated special cell with the Division
Health regulation	Meant to be a federal prerogative by virtue of Entry 6 of Part II of FLL. However, ambiguity exists as many "subjects" to be regulated have been devolved	Oversight role of the Division in relation to regulatory agencies
International commitments	Within the federal purview. Enabled through Entry 32, Part I of the FLL	Direct reporting relationship of an apex agency with the Health Division
Human resources	Within the federal purview. Enabled through Entries 11, 16, 17 of Part I of the FLL and Entry 11 of Part II of the FLL	Oversight role of the Division in relation to regulatory agencies

6. **Federal structure for health:** the proposition of abolishing the Ministry of Health is not a matter defined in the 18th Amendment but interpretation of the same Amendment. The Constitution did not at any time—before or after the 18th Amendment—include health per se, as a specific legislative subject. A federal institutional structure to serve national health responsibilities and within that context, reform of the Ministry of Health to make it compatible with devolution is an imperative. The new federal structure should have adequate capacity. Ministry of Health was never structured properly for national functions and as a consequence never had the full range of capacities. A review of various policy options, projections for outcomes and Rules of Business of the federal government, when viewed in the context of the devolution drive, call for creating a Health Division.

7. **National health policy:** post-18th Amendment, the national role in health policy should have two dimensions. First, the national health policy should be limited to high level norms—values and principles—and coordination standards. This can be enunciated through the inter-provincial mechanism provided by the CCI. Secondly, subjects with a truly national character should be within the national policy purview. Some but not all are included in Part II of the FLL. 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.

8. **Health regulation:** post-18th Amendment, federal health related regulatory powers stem from Entry 6 of Part II of the Federal Legislative List, which gives the Parliament Legislative powers to develop a federal regulatory authority. Article 151 could also potentially serve as the basis for a federal mandate in regulation. The problem arises when the subject, which the federal regulatory agency is created to 'regulate' is devolved, as is the case in service delivery and drugs and medicines. This is not the case with medical education and human resource, which continue to be in the federal regulatory ambit.

9. **Federal fiscalism:** stands unaltered except for the size of the provincial share, which has increased under the 7th National Finance Commission Award. As taxation remains a federal function, options to mobilize resources, including through innovative means, will continue to be a federal prerogative. 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.

10. **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, a unified interim federal structure should be made responsible for devolving functions. This

structure should be maintained till such time that provincial capacity is fully developed. Over the long term, a lean and minimal federal structure should be maintained for programmatic functions, which need to 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.

11. **Hospitals:** under the administrative control of the Ministry of Health should be handed over to the provinces. Federal government hospitals should be placed under the newly established Islamabad Capital Territory Division. All hospitals should be made autonomous, albeit with oversight to decrease administrative burden on stewardship agencies.

12. **Human resource:** the 18th Amendment does not alter federal functions related to human resources. However, provincial concurrence is mandatory for human resource decisions at the federal level, which relate to subjects that have been devolved.

13. **Drug regulation:** 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.

14. **Health information:** Constitutional provisions potentially enable health information 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 International Health Regulations, 2005.

15. **Provincial capacity and the local government system:** whilst supporting devolution of health related responsibilities, the analysis also flags several capacity building imperatives. The importance of building institutional competencies to devolve responsibilities, being the foremost. It also lays emphasis on in-tandem capacity building at the provincial level while devolving functions. Most importantly, it recalls the need for due attention to reform of the local government system, where there have been many uncertainties over the last decade. The latter is necessary to decentralize management to smaller management units, from provincial to the district level.

16. **Immediate next steps:** from this analysis, it is apparent that there are two immediate next steps. One, creation of the Health Division and definition of its appropriate mandate so that it can serve national functions in health. And secondly, grant of regulatory prerogatives to the federal level by the provinces under Article 144 of the Constitution. In tandem a range of measure need to be undertaken to restructure/establish many institutions, which are meant to have a reporting relationship with the Health Division and others where the Health Division is meant to exercise oversight. Of these the following appear most imminent: creation of an independent Drug Regulatory Authority, establishment of a small unified interim structure for the national programs to assist with their devolution, grant of an appropriate mandate to an apex institutional arrangement for health information and revitalization of the health policy unit.

This paper has a focus on health's post 18th Amendment national functions. The imperatives for devolution at the provincial end are outside of the purview of this analysis. The paper also does not delve into broader systemic constraints, or their implications for devolution. For this the author's previous work, which provides an analysis of health systems issues and a roadmap for reform should be referred to.[1] Addressing systemic impediments is critical to fulfilling the premise enshrined within the 18th Amendment. Retaining a national role in health is just one aspect of the needed transformation.

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

Health and the Constitution of Pakistan

Unlike 115 countries of the world, the Constitution of Pakistan does not explicitly recognize the right to health. Prior to the 18th Amendment, most of the fundamental rights fell within the domain of civil and political rights. Through the 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.

Other than the right to education, socio-economic rights feature in two areas in the Constitution. The Objectives Resolution, which forms the preamble to the Constitution 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—entitled Principles of Policy—refers to 'Equality of citizens' and 'Promotion of social and economic well being of the people', respectively. Other articles of relevance to health include Article 9 on 'Security of a person' and Article 14 on 'Inviolability of the dignity of man.' It can be argued that although the preamble to the Constitution and its Principles of Policy refer to socioeconomic rights, courts cannot enforce these. However, courts in Pakistan have previously handed down progressive decisions in public interest through the application of an expansive definition of 'right to life'[2,3]—Article 8 and 9 read with Article 199 providing the basis for the enforcement of fundamental rights. Article 9, in particular, has been broadly interpreted in case law in this regard.

Constitutional provisions also morally bind the state to reduce inequities in the society and uphold social justice. In the present context, this is relevant both to reduction of health inequities as well as addressing inequities in capacity, which exist at the provincial level and which can have implications for their ability to promote health and well being of respective populations.

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.

2. Miss Shehla Zia and others vs. WAPDA [PLD 1994 Supreme Court 693]
3. Syed Mansoor Ali Shah vs. Government of Punjab [2007 C. L. D.533]

Prior to the 18th Amendment, the Constitution contained two legislative lists—the Federal Legislative List (FLL) and the Concurrent Legislative List (CLL).[4] These lists laid out the distribution of legislative powers between the Parliament and the four provincial assemblies.[5] 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.[6]

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, 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 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:

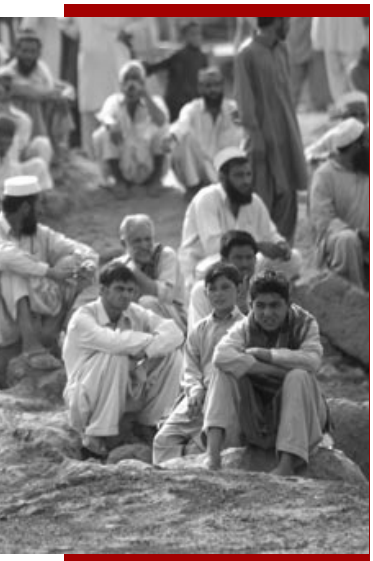
1. Changes in the Concurrent Legislative List:

The Concurrent Legislative List of the Constitution was a list of subjects over which both the Parliament as well as provincial assemblies were competent to legislate in the pre-18th Amendment situation. The 1973 Constitution envisaged the CLL as an interim arrangement and stipulated its revision after ten years, as provinces were expected to develop their capacity by that time. The 18th Amendment has omitted the CLL in its entirety after 37 years of the Constitution's framing. Subjects which now stand omitted are listed in Panel 2. 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

4. Fourth schedule of the Constitution of the Islamic Republic of Pakistan
5. Chapter 1 of Part V of the Constitution of the Islamic Republic of Pakistan
6. Article 142(a), 142 (b) and 142 (c) of the Constitution of the Islamic Republic of Pakistan

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.[7] 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. Although two separate structures still persist at the provincial level, it may now become easier to exploit synergies.



Panel 2: 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

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

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 3 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 3: 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)
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 I, E 57)
	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	Import and export across customs frontiers as defined by the federal government, inter-provincial trade and commerce, trade and commerce with foreign countries, standards of quality of goods to be exported out of the country (P 1, E 27)
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)
	National planning and national economic coordination including planning and coordination for scientific research (P II, E 7)

3. Changes/amendments in Article 144

Article 144 of the Constitution now 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

Pre 18th Amendment Ministry of Health and its weaknesses:

In the pre-18th Amendment scenario, the Ministry of Health 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 4.

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/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. Disease surveillance was not developed in an integrated and organized fashion—a key federal/national function.

Panel 4: 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 ofAutonomous 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

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.

In relation to health policy, the Ministry of Health produced four policies over the last 15 years, two of which were approved by the Cabinet as National Health Policies, as described later. 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, capacity constraints were evident. Ministry of Health's systems capacity building role remained inadequate. Major health systems development project were led in the past either by the Planning Commission, development partners or special channels, e.g. Ministry of Special Initiatives. 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 5). 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 consolidate in one institutional arrangement.

Panel 5: 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 and with some multilateral donors such as World Bank
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 has, therefore, become an imperative. These weaknesses will have to be addressed in any new federal institutional arrangement for health.

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 a number of national functions, inclusive of health information, health regulation, international commitments, and certain streams of national health policy (Panel 6).

Panel 6: National functions in health

1. Health information and research
    a. Disease security
    b. Monitoring health indicators and health systems performance assessment
    c. Evidence for policy
    d. Health research
2. Health regulation
3. International commitments
4. National health policy
    a. Policy in areas that are federal mandates, constitutionally
    b. Overarching norms
    c. Norms of care
    d. Intersectoral coordination
    e. Trade in health
    f. Health technology
    g. Disaster response
    h. National policy coordination to
        i. Establish standards for inter-provincial conformity
        ii. Obviate unnecessary duplication

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.[8] 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.

In view of these considerations, it is hoped that the decision to 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.

Options to restructure Ministry of Health:

There are two schools of thought about establishing an appropriate institutional structure, which can have the necessary competency to build capacity and provide normative support. According to one view, Ministry of Health does not have the track record of investing in health systems capacity building, nor does it have the

8. 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/

institutional competency for that purpose. Proponents of this view cite major health systems developments, led by agencies outside of the Ministry of Health, as an example to substantiate their argument. They argue that competencies can be established at the provincial level and that normative support from within the provinces is more likely to have ownership rather than technical inputs from "elsewhere", which have previously been the bone of contention.

The other point of view promotes the idea of stepping up normative health systems capacity at the national level. They argue that the costs of developing parallel structures in the provinces would be exorbitant and that 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. They also refer to capacity constraints, which currently prevail in the country and cite the National Health Policy Unit as an example. They are of the opinion that central normative coordination by the Ministry of Health in a fully devolved health set up can spare provinces from unnecessary duplicative work for which they neither have human resource capacity nor the institutional arrangements in place and that 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.

Notwithstanding the debate and divergence of views, relating to the capacity building role referred to above, there should be clarity about national functions in health, which have been summarized in Panel 6 and the need for a corresponding institutional structures. Lessons from other countries with federating structures are instructive. Most have ministries of health or equivalent institutions, e.g., departments of state, with clear and meaningful missions whilst corresponding institutions at the sub-national level technically have the 'health service delivery mandate' (Panel 7).

Within the context of these divergent views, two options are currently being mooted with respect to the way forward:

At the time of completing this paper, the Implementation Commission had a roadmap, which intended '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, vital health statistics under the Federal Bureau of Statistics, 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 a "cut and chop" 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.

Panel 7: 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	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.
Venezuela	23 states	Venezuelan Institute of Social Security

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 Zayed 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 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.

It is evident that the currently mooted views with reference to replacements for the Ministry of Health are not appropriate and will further fragment health systems capacity. A federal institutional structure to serve national health responsibilities and within that context, reform of the Ministry of Health to make it compatible with devolution is an imperative. Here it is important to recognize that the proposition of abolishing the Ministry of Health is not a matter defined in the 18th Amendment but interpretation of the same Amendment. The Constitution did not at any time—before or after the 18th Amendment—include health per se, as a specific legislative subject.

Ideally, the Ministry of Health should not be abolished; it should be recast so that its service delivery functions are scaled back and it is made compatible with devolution. 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. This should now be the objective of planning in the health stream, post 18th Amendment. It is within this context, that the idea of the Health Division becomes plausible, as described later.

In sum, therefore, there are five options with respect to the way forward—i) status quo, i.e., the Ministry of Health stays as it is; ii) abolishing the Ministry of Health and giving its functions to other federal entities; iii) creation of a Health Commission; iv) retaining the Ministry of Health as such, but scaling back is role; or v) recasting the Ministry and scaling it down as a Health Division. Panel 8 gives a summary evaluation of each option using nine evaluation criteria.

Panel 8: Options for the way forward, post 18th Amendment: federal institutional structure for health

	Ministry of Health: Status quo option	Ministry of Health: Cut and chop formula	Health Commission	Ministry of Health retained, recasted, scaled back	Ministry of Health re-casted as Health Division
Conformity with 18th Amendment constitutional provisions	1	3	0	3	3
Spirit of devolution	1	1	0	1	3
National unity and spirit of federalism	3	1	3	3	3
National equity	1	0	1	3	3
Health security	1	0	1	3	3
Capacity to play a role in serving national functions	1	1	2	3	3
Policy consistency and conformity in norms of care	1	0	2	3	3
Appropriateness of executive powers	3	0	0	3	3
Cost containment	1	3	0	2	2
	13	9	9	24	26

Each option is scored with respect to its appropriateness in relation to an individual criterion. A cumulate score is generated. The idea of the Health Division gets the highest scoring. It is in conformity with constitutional provisions and government of Pakistan's Rules of Business 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 ideal option is to recast the Ministry of Health as a Division. The proposed Division will have the same executive powers as the Ministry of Health and therefore the risk that restructuring will be to the detriment of desired executive authority—as in the case of the health commission—will not be a consideration.

In addition to being an option with a constitutional color, the option to create a Division is also in keeping with the spirit of the times vis-à-vis provincial

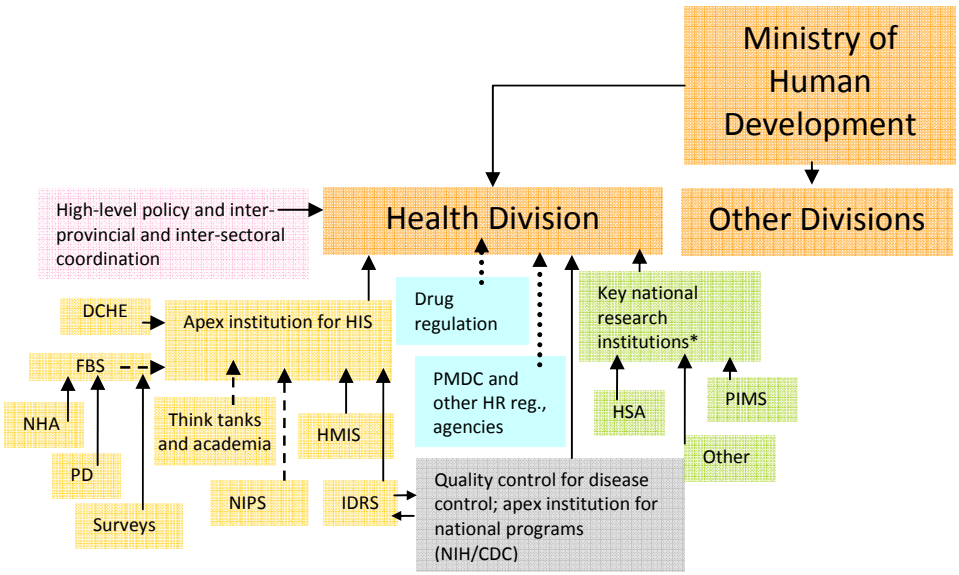
empowerment and devolution of powers. Converting a 'Ministry' into a 'Division' would mean stepping down hierarchically in the federal government's organgram and therefore, indicative of its intent to relinquish powers. However, at the same time, it will enable retaining a coherent institutional structure with the needed executive powers 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, 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. Since the Division will have 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.

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.[9] Panel 9 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 latter represents the second institutional stream. 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 having a reporting relationship with the apex information arrangement (Panel 9). 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 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.

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

Panel 9: Reporting relationships and linkages of federal health organizations with the proposed Health Division



DCHE: Directorate of Central Health Establishment
FBS: Federal Bureau of Statistics
NHA: National Health Accounts
PDS: Pakistan Demographic Survey
NIPS: National Institute of Population Studies
IDRS: Integrated Disease Surveillance and Response
HIS: Health Information Systems

HMIS: Health Management and Information System
HSA: Health Services Academy
PIMS: Pakistan Institute of Medical Sciences
PMDC: Pakistan Medical and Dental Council
HR: Human Resource
NIH: National Institute of Health
CDC: Centers for Disease Control

Linkage with other agency
Direct reporting relationship
Oversight role in independent regulatory arrangements

* Linkages with the heath information apex agency

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, the fifth institutional stream, 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.

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. The NCGR recommended the creation of a Ministry of Human Development, with responsibility for health, education, capacity building, labor and overseas Pakistanis. It appears, that the ideal option would be to have the Division for Health and other devolved subjects placed under the Ministry

of Human Development. There are also other less attractive alternatives—such as placing the Health Division under the Ministry of Planning, Ministry of Inter-Provincial Coordination, or the Islamabad Administration and Development Division.

Key message:

It is imperative to retain a federal structure for health to fulfill national health functions. 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, ideally the proposed Ministry of Human Development. Federal health organizations 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.

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 two official health policies (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. They argue for a stewardship role for the federation and the need for an apex policy to give a unified national vision for health. 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 policy. 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 twofold. First, at the stewardship level, it is important to establish overarching norms or a set of values and principles at the national level—the provinces should endorse these as unifying threads in relation to the state's commitment to health. These principles could bring normative clarity to the question of the "right to health" and the extent to which health needs to be part of social protection arrangements. Standards should also be prescribed where inter-provincial conformity is needed or in other areas where national policy coordination can obviate unnecessary duplication. The federal stewardship role in policy is also vital to preserve national equity and solidarity amongst providers particularly from a judicial point of view in case there is litigation between providers and users from different provinces. It is also relevant in cases of national disasters and risk adjustment compensation between provinces in the event of provincial insurance pools being created. These high level norms and coordination standards can serve as the national instrument of policy, which will allow the federation to play a stewardship role in health, albeit without interfering with individual policy choices about service delivery and financing arrangements, which after the 18th Amendment are now a provincial prerogative.

Secondly, 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 described later 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 technical inputs would come from the proposed policy unit assisted by the apex health information structure (Panel 9). However, instead of the Cabinet, the national health policy will have to be in the purview of the CCI, which must now be viewed as a "super cabinet".

Key message:

Post-18th Amendment, the national role in health policy should have two dimensions. First, the national health policy should be limited to high level norms—values and principles—and coordination standards. This can be enunciated through the inter-provincial mechanism provided by the CCI. Secondly, subjects with a truly national character should be within the national policy purview. Some but not all are included in Part II of the FLL. 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. In most federating countries regulation is a national/federal subject as it obviates the need for agreements regarding acceptance of each others standards. Constitutional covenants stipulating inter-provincial/interstate trade usually serve as the basis for a federal mandate in the area. The case of USA is illustrative where the commerce clause has served as the basis for a lot of federal/national level health regulation, including drug regulation.

Currently, federal health related regulatory powers stem from Entry 6 of Part II of the FLL, which gives the Parliament Legislative powers to develop a federal regulatory authority. Technically, Article 151 "…trade, commerce…throughout Pakistan shall be free", which obviates the need to devolve health regulation can also serve as the basis for a federal mandate in regulation. However there is divergence of opinion over this.

Some experts are of the opinion that the federal level has powers by virtue of Article 151 read with Entry 6. 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 and that there is no 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.[10] Hence, there is ambiguity in this area.

There is also another ambiguity in terms of how the Constitution can be interpreted with respect to regulation. As already stated, Entry 6 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 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.

These ambiguities pose a problem in the area of regulation of service delivery and medicines and related products, which stand devolved after the 18th Amendment. 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 regulatory role in these areas.

10. The 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.

Key message:

Post-18th Amendment, federal health related regulatory powers stem from Entry 6 of Part II of the FLL, which gives the Parliament Legislative powers to develop a federal regulatory authority. Article 151 could also potentially serve as the basis for a federal mandate in regulation. The problem arises when the subject which the federal regulatory agency is created to 'regulate' is devolved, as is the case in service delivery and drugs and medicines. This is not the case with medical education and human resource, which continue to be in the federal regulatory ambit.

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 makes 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.

As taxation remains a federal function, options to mobilize resources, including innovative financing options, will continue to be a federal prerogative. 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 National Finance Commission 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

As a starting point, the paper recognizes the political and constitutional imperative of provincial autonomy in Pakistan's federating system, and stemming from it the need to devolve functions. Health service delivery has always been a provincial subject; however, over the years, a federal interplay in service delivery became increasingly evident.

The analysis is fully supportive of devolving service delivery responsibilities in health and regards it as being complementary to the democratic process. It does caution though that decentralizing Pakistan's health system would be a complex process with many prerequisites. At the institutional level, there is need for strong administrative infrastructure, technical expertise at the planning level and managerial capacity within local institutions.

Within the normative space, balance of authority and accountability and a clear separation between centralized and decentralized functions are necessary. Designated roles for management, quality assurance and evaluation, and community oversight need to be established. The latter are particularly important since devolution of responsibilities from the federal to the provincial level also has another dimension—Provinces are dependent on districts for delivering services. The idea should be to decentralize management to smaller management units and focus on purchaser-provider separation and intra-organizational contracting between the province as the purchaser and the district as provider. This can enable the introduction of elements of competition as an incentive for improving performance and quality. Within this context lack of clarity at the local government level is an impediment. Even when the post-2001 devolution plan was underway, districts were at different stages of implementing the plan. Since the process has been stalled, post 2008, there is lack of clarity in relation to where the process is going. This and the large-scale leakage of funds and lack of accountability at the local government level are systemic challenges, which will also have to be addressed in tandem.

National public health programs

Policy position in relation to devolution

In the existing situation, Pakistan's national public health programs are federally-led with provincial and district implementing arrangements (Panel 4). 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. Six areas are being outlined where careful planning and incremental devolution may be necessary in this regard.

First, 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 conditionality bind the government to one-window operations in many cases. For example, the Global Alliance for Vaccines and Immunization (GAVI), which provides resources for Pakistan's Expanded Program for Immunization, accepts only one application from a country. 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 through provincial donors in the future will necessitate planning at several levels.

Donor preferences, also 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. One of them is efficiency gain. WHO's Eastern Mediterranean Region's resolution to develop a common procurement system for the region is one example. The Pan American Health Organization's (PAHO) revolving fund is another example. This has been operating for several decades and enables quality assurance and administrative cost and price reduction, the latter through negotiations. Many countries in Latin America have requited that drugs be purchased through PAHO's revolving fund. The second justification is 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 infrastructure is 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. In the fourth place, 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.

In the fifth place, whilst there is support for devolving most functions, there is need for taking provincial capacity into account. Provinces need to step up their capacity to implement these 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 are concerted efforts to improve 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 IDSR is being planned—or the Health Management and Information System (HMIS). For example, EPI's case-based

surveillance, 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 management information systems components of all other programs. Additionally, 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.

There is a second justification for a national role at the federal level. There has been a burgeoning trend of non-communicable diseases in Pakistan, to which attention has not been accorded in the past. In wake of the upcoming September Summit on NCDs and the drive to place them higher on national agendas, Pakistan will have to strategize for action in this area. However, solutions to preventing NCDs lie largely outside the health sector and involve trade policy, taxation, international regulation;

the agriculture and environment sectors, in addition to general working and living conditions. Multisectoral action to address risk factors of NCDs is outside of the purview of the provinces and needs national action.

Every effort should be made to make the operations of the federal entity less cumbersome and 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, a unified interim federal structure should be made responsible for devolving functions. This structure should be maintained till such time that provincial capacity is fully developed. Over the long term, a lean and minimal federal structure should be maintained for programmatic functions, which need to 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 centered on managing national public health programs and a number of hospitals (Panel 4). From a policy standpoint, 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 since most of them 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, post 18th Amendment.

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). This 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 thousands of 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. 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 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.

In the third place, 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.

Lastly, and importantly, 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.[11] Many institutional regulatory arrangements are in place at the federal and provincial levels.[12] 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.

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 stalled due to change in government.

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11. These gaps have been described in detail in the Chapter on Medicines and related products (Choked Pipes)
12. 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.

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 drug regulation 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."[13] 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[14]. 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 read with Entry 6 of Part II of the FLL. [15] 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. Subsequent to enactment, such regulatory authority would be subject to supervision and control of the CCI at which the four

13. 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.'
14. 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).
15. 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.

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 International Health Regulations 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 I, E 57); and "Matters incidental or ancillary to any matter enumerated in this part" (PI, E 59 and PII, E 18). 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.[16] 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

16. Acute Respiratory Infections, AFP/Polio, Bacterial Meningitis, Diarrhea, Hepatitis, HIV/AIDS, Malaria, Measles and Tuberculosis, and the Disease Early Warning System (DEWS)

information. A detailed account of needed actions to bridge health information systems' gaps has been published elsewhere.[17]

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 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 Panel 9.

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.

Concluding note

This qualitative analysis was performed against a tight timeline in context of the understanding that devolution of health, under the 18th Amendment to the Constitution of the Islamic Republic of Pakistan, was not taking cognizance of health's national role—with the decision to abolish Pakistan's Ministry of Health, as a consequence. Within this context, the analysis has attempted to underscore the salience of national functions in a federating state where health is a devolved subject. Key messages of the analysis, center on defining national roles and articulating their policy rationale in the first place. The constitutional rationale for retaining these roles in the post 18th Amendment situation has been analyzed and where impediments existed, solutions have been proposed to overcome constraints.

17. Chapter on Health Information. Nishtar S. Choked Pipes: Reforming Pakistan's Health System. Oxford University Press, 2010.

The discussion relating to the federal structure for health and the proposed course of action has evolved within the context of the national functions being promoted in this analysis—and not the other way round.

From this analysis, it is apparent that there are two immediate next steps. One, creation of the Health Division and definition of its appropriate mandate so that it can serve national functions in health. And secondly, grant of regulatory prerogatives to the federal level by the provinces under Article 144 of the Constitution. In tandem a range of measure need to be undertaken to restructure/establish many institutions, which are meant to have a reporting relationship with the Health Division and others where the Health Division is meant to exercise oversight. Of these the following appear most imminent: creation of an independent Drug Regulatory Authority, establishment of a small unified interim structure for the national programs to assist with their devolution, grant of an appropriate mandate to an apex institutional arrangement for health information and revitalization of the health policy unit.

This paper has a focus on health's post 18th Amendment national functions. The imperatives for devolution at the provincial end are outside of the purview of this analysis. The paper also does not delve into broader systemic constraints, or their implications for devolution. For this the author's previous work, which provides an analysis of health systems issues and a roadmap for reform should be referred to.[18] Addressing systemic impediments is critical to fulfilling the premise enshrined within the 18th Amendment. Retaining a national role in health is just one aspect of the needed transformation.

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

Acronyms

Centers for Disease Control	CDC
Concurrent Legislative List	CLL
Council of Common Interests	CCI
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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"Achieving the optimal balance of responsibilities among different levels of government is the central governance challenge in a federal system. This challenge is particularly complex when it comes to health matters, since it is necessary to address the ethical imperative of equity across different population groups, the control of externalities among the federating units, and the requirement for adequate international presence in the face of global risks and opportunities. For this reason, all decentralized health systems in federal countries retain a vigorous national health entity charged with the stewardship of the entire system. The paper by Sania Nishtar clearly explains the rationale for strengthening federal health responsibilities as an ingredient for successful devolution of health matters to the provinces at the historical juncture facing Pakistan."

Julio Frenk

Dean, Harvard School of public health and former Minister of Health, Mexico

“This amendment would reduce the capacity of Pakistan to articulate a national position on health in the international fora where issues of health and development are debated. But more importantly, the reliance on provincial action in crucial aspects of health will weaken the possibility of ensuring national health equity.”

Sir George Alleyne

Director Emeritus, Pan American Health Organization

A strong Ministry of Health is a prerequisite for successful decentralization and decentralization is a prerequisite for the successful management of public health”

Edgar Rodas

Former Minister of Health, Equador

“Nishtar's comprehensive and considered analysis shines a sober light on the perils and pitfalls of the Amendment 18 that foresees the dissolution of the Federal Ministry of Health in Pakistan. Her informed insights and strategic suggestions on how critical federal functions might not only be salvaged but also strengthened deserve the highest level consideration”.

Timothy Evans Grant

Dean BRAC School of Public Health, Bangladesh

"This study provides a thorough analysis of a complex issue, bringing clarity and insight to the understanding of tough problems. It also offers a useful solution, constructively providing a way forward."

David de Ferranti

Founder and President, Results for Development, Washington

This paper provides a very important insight to policy makers in Pakistan on how to approach the issue of devolution in the health sector keeping public interest paramount. The paper rightly points out that there is sufficient constitutional space available for the federal government to discharge its obligations to the people in terms of leadership for harmonization, standards and equity in health. This responsibility cannot be effectively discharged in a vacuum. It requires a commitment in terms of structures, resources and processes. The paper also correctly points out to global best practice in this regard, especially in federations. Carelessly executed devolution is likely to present additional challenges in a country largely failing or lagging behind in the health sector. This analysis should serve as an invaluable input in persuading decision makers not to "throw away the baby with the bathwater" on the pretext of advancing federalism"

Ejaz Rahim
Former Minister of Health, Pakistan

"Dr Nishtar's well-researched paper builds up a persuasive case for the retention of certain health-related functions at the national level. What is significant is the positive approach in the paper in proposing mechanisms that can be largely accommodated within the framework of the 18th Amendment. While agreeing entirely with paper's rationale for a federal oversight role in the health sector, I do believe that if a federal, or federal-provincial mandate, over a certain function is determined to be in the supreme national interest, it needs to be unambiguously provided for in the basic law.
However, the implementation of the proposals as presented can only strengthen the governance structure and enhance the policy-making and management prospects in the health sector"

Javed Sadiq Malik
Director
Center for Public Administration
Lahore School of Economics

"Governance issues in health care services delivery loom large and have to be addressed at several levels. The Report of the National Commission on Government Reform, 2008 has made specific recommendations on each of these issues, which were supplemented by the Pay and Pension Commission 2010 Report in which the health professionals and paraprofessionals were taken out of the basic pay scale and were given a new cadre, a different pay scale and service structure. And it is time that those recommendations are examined and implemented"

Ishrat Hussain
Dean
Karachi school of Business Administration