NIGERIAN INSTITUTE OF ADVANCED LEGAL STUDIES
LAGOS, NIGERIA

ROUNDTABLE ON HEALTH LAW AND POLICY

14th July, 2011

COMMUNIQUE

Introduction

Health policies are aimed at protecting patients and medical staff and promote optimum working conditions and standards of patient care and service. There are different areas within the healthcare policy and new policies are introduced frequently, in line with new research, recommendations from relevant authorities and organizations.

Policies are implemented in order to regulate providers and professionals, protect patients, encourage healthier living and improve the functioning of healthcare providers. Policies are legally binding if they are written and approved in legal documents. Some policies, are law-based while others, often more idealistic, strategy-type policies, are merely designed to encourage people to adopt a healthier lifestyle.

The Nigerian Institute of Advanced Legal Studies mindful of the importance of health to life, the well being of citizens and in furtherance of its mandate held a one day roundtable on Health Law and Policy on Thursday 14th July 2011 at the Institute's premises Lagos.

The Roundtable aimed at identifying how law and policy can best influence healthy life outcomes in our communities. In realization of the fact that Law and policy are critical tools in ensuring safe, vibrant and healthy communities and environment the roundtable came out with recommendations for appropriate law and policy for our country.

The Perspectives for the Roundtable included:

- Public Health and Access to Medicine: Role of Patent System
- The National Health Bill: Opportunities for Health IT
- Pharmacovigilance, Adulteration and Harmful Drugs
- Health and Human Rights
- Legal Aspects of Clinical Trials
- Intellectual Property Rights and Clinical Trials
- Privacy and Confidentiality of Health Information
- Medical Negligence
- Nigeria's integrated Disease Surveillance and Response System
- Health Insurance

At the end of the deliberations the following observations were made:

1. Without law and policy it is difficult to monitor and regulate any aspect of societal needs
2. There is a National Health Bill which was passed by both chambers of the National Assembly on May 19 2011. It has seven Parts and 64 sections. It stipulates the guidelines for the formulation of the National Health Policy.
3. Among its many provisions, the Bill constructs the framework of a cohesive National Health System, provides access to basic health care, and sets outs the right and responsibilities of the heath care consumers and providers in Nigeria.
4. Outlined in the seven parts and sixty four sections, the legislation "…stipulates the guidelines for the formulation of a national health policy" concerning the variety of appropriate needs of a congruous health system. Information, being of such needs, received a focused attention in section Thirty Five of the Bill.
5. The National Health outlines the responsibilities of public and private bodies in the health sector which include Planning and Management, Cooperation and Coordination, Patient centred delivery, Regulation and Standardization, Monitoring and Evaluation, Dissemination of Information and reporting
6. In order to meet the information needs of the National Health System, pursuant to the fulfilment of its objectives, the framers of the National Health Bill called for the establishment of a National Health Management and Information System (NHMIS) and accordingly require the Federal Ministry of Health to "facilitate and coordinate the establishment, implementation and maintenance by state ministries, local Authorities and the primary health sector of the health information systems at national, state and local government levels"
7. The Information system will facilitate and transform the national health systems to achieve remarkable improvements in the coordination, quality, safety, and effectiveness of care as well as in reducing costs, health disparities and other nagging problems to which new tools of work had to be applied
8. These information technology tools enable the intelligent capturing, processing, transmission, exchange, and storage of data to provide new insights, beneficial to both at the point of care, as well as for longitudinal and secondary uses, such as comparative effectiveness research.
9. Health IT solution replace paper laden systems and aid improvements in quality safety and effectiveness of care by enabling:

a. The accessibility and electronic sharing of health information relevant at the point of care;
b. Medication safety through electronic prescribing(e - prescribing), and drug allergy interactions;
c. Diagnostic efficiency and accuracy through electronic lab reporting, clinical decision support and other auxiliary systems (such as mobile and Tele health solutions) that enable remote delivery of care;
d. Reduce health disparities;
e. Security and Privacy of Protected Health Information;
f. Early and Proper Diagnosis; and
g. Coordination of care across the continuum

10. Globally, technology is equally attentive to the discipline of public health. To that end, significant inroads have been made in the evolution of robust systems that address the complexity and scale of the public health domain. Surveillance systems and immunization and disease registries have been effectively used to save scores of lives across the globe by affording governments the proactive leverage of deploying early and scaled interventions.
11. Furthermore, within the public health sector, the crucial areas of syndromic and disease surveillance as well as the applied uses in Pharmacovigilance and food safety have benefitted from the convergence of information. Enabled through the channels of health information exchanges, the influx of reliable data from end-to-end points of care have fostered very robust and agile public health systems.
12. Promising developments in technology include mobile communication, and cloud computing, both of which lessen the initial prohibitive costs of technology adoption from a system perspective. The prevalence of mobile technology show great potential in reaching unserved and underserved populations, with possible contributions to education, early detection and diagnosis.
13. In order to function and be meaningfully used, health information technology require certain infrastructural under pinning such as power supply, network, connectivity, hardware and software, in addition to skilled work force.
14. The United States has recognized the opportunity to recalibrate its national infrastructure, including the health sector, by incentivizing the adoption and meaningful use of health information technology by health service providers spanning all primary care settings and hospitals.
15. Billed as part of the United States initiative for economic recovery, and the reduction of the growing and unsustainable costs of health care, the government articulated a clear vision upon which the national project was founded. Embodied in the Health Information Technology for Economic and Clinical Health Act (HITECH), the initiative is anchored to :

a. the improvement of the quality, safety, and effectiveness of health care, while reducing health disparities;
b. the engagement of the patients and their families in their health care and the coordination of care;
c. assuring the privacy and security of protected health information; and
d. the promotion of public and population health, through the meaningful use of heath information technology

16. One of the cornerstone of public health policy in any given country, be it developed or developing is to ensure adequate health care system including access to medicines by a significant percentage of the policy
17. Patent policy can only fulfil its utilitarian function, not only as an instrument of promoting innovation but also as a catalyst for public goods, if it lends itself positively to the demands of public health
18. One of the important legal and socio economic systems that impacts access to medicines is the patent system within the legal regime of intellectual property. Leveraging the patent system in addressing the problem of access to medicine has become part of the protracted global debate on the relationship between property and public health
19. Patent law and administration in Nigeria is governed by The Patent and Designs Act 1970 cap P2 LFN 2004 , modelled after the United International Bureau for the protection of Intellectual Property
20. Nigeria has no patent policy, this incapacitates the Patent Act from striking a balance between the private interests in patent monopoly and the public interest in access to medicine
21. In Nigeria, compared with other West African Countries, a huge percentage of patents granted by the Patent Registry belong to foreigners. The 2002 data shows that of the 2,544 patents issued, 1458 are for foreign and 986 are to local applicants. Even then some of the local grants are made under licence from foreign owners.
22. Right to health in some jurisdictions is predicated on policies and statutes that are not necessarily human rights instruments e.g. the Scandinavian countries and UK.
23. In these jurisdictions, the recognition of the right to health predates the development of the human rights discourse on the right to health. Here also, the right to health was more founded on socialist and welfarist ideologies
24. Human right to health belongs to the genre of what used to be known as "second generation rights" and this means that they were historically regarded as unenforceable against the state as the duty bearer (except where such was a legal right under domestic law).
25. The International Covenant on Economic Social and Cultural Rights (ICESCR) allows for progressive implementation of economic and social rights. This was generally interpreted as excusing governments from immediate action to fulfill obligations to the fullest
26. The right to health means that governments must generate conditions in which everyone can be as healthy as possible. Such conditions range from ensuring availability of health services, healthy and safe working conditions, to adequate housing and nutritious food
27. A core obligation of states is the adoption and implementation of a national public health strategy and plan of action. This must address the health concerns of the whole population; be revised, and periodically reviewed, on the basis of a participatory and transparent process; contain indicators and benchmarks by which progress can be closely monitored; and give particular attention to all vulnerable or marginalized groups.
28. States Parties must take steps forward in conformity with the principle of progressive realization. This imposes an obligation to move forward as expeditiously and effectively as possible, individually and through international assistance and co-operation, to the maximum of available resources.
29. South Africa is one of the very few countries in the world with a comprehensive array of constitutionally entrenched economic, social and cultural rights in addition to civil and political rights.
30. The right to medical privacy is a basic human right that is guaranteed by international standards. It is legally protected, cannot be waived or taken away, and is universally applicable
31. The right to medical privacy is interrelated with other human rights such as the right to health and information that States in the United Nations are obligated to protect
32. Visual privacy includes protection from unnecessary bodily exposure, which may occur during a physical examination.
33. Auditory privacy means that, to the extent possible, individual consultations should be conducted in private and out of earshot of others, including children, spouses, parents, family, friends, teachers, and neighbors.
34. A provider's failure to observe a client's rights to privacy and confidentiality can mean delays in early diagnosis and treatment, incomplete treatment when clients drops out of services, or clients seeking questionable care from unqualified people. Poor health outcomes resulting from both social stigma and related psychological trauma are well documented.
35. The most benign breach of confidentiality takes place when clinicians share medical information as case studies. When this data is published in professional journals the identity of the patient is never divulged, and all identifying data is either eliminated or changed. If this confidentiality is breached in any way, patients may have the right to sue.
36. The greatest threat to medical privacy, however, occurs because most medical bills are paid by some form of health insurance, either private or public. This makes it difficult, if not impossible, to keep information truly confidential
37. Electronic record systems also create greater risks of data leakage, access by unauthorized staff and 'browsing' by unauthorized people
38. Clinical trial is an investigation in human subjects, other than a non interventional trial intended to discover or verify the clinical, pharmacological or pharmaco-dynamic effects of the medical products; identify any adverse reaction to those medical products; study absorption, distribution, metabolism and execution of one or more such products; with the objective of ascertaining the safety or efficacy of those products
39. Clinical trials are normally only allowed by the Ethics Committees after the product has undergone chemical and animal testing which is usually carried out in four stages known as phases i iv

i) The use of new active substance in healthy volunteers to establish safety and pharmaco kinetic / dynamic profile of the active substance
ii) usually carried out in a limited number of subjects(patients) to assess the short term safety of the active substances in patients suffering from a disease, determine appropriate dosage regimen for the design of wider therapeutic trials
iii) Involves larger (and possibly varied) patient groups with the purpose of determining the short and long term safety/ efficacy, assessing the overall and relative therapeutic value. Also the pattern and profiles of adverse reactions, drug interactions and special features of the product and the circumstances of the trials should be as close as possible to normal conditions of use.
iv) Deals with post marketing surveillance and assessment of therapeutic value or strategies for the purpose of exploring new indications, methods of administration or combinations for possible new medical products

40. There are currently six internationally recognized guidelines for foreign clinical trials
41. For all these guidelines, the primacy of informed consent is a constant. Informed consent entails an explanation of the nature and procedures of the trial in a language that participants can understand and ensuring that they are free to choose whether or not to participate
42. The Nuremberg Code was the first modern effort by the International community to create guidelines governing research on humans
43. Nigeria has no structure or regulation on clinical trial
44. NAFDAC is the governing agency responsible for clinical trials. However the NAFDAC guidelines does not fully reflect the conditions and principles of good clinical practice and protection of clinical trial subjects
45. According to UNESCO Universal Draft Declaration on Bioethics and Human Rights, Benefit Sharing includes: access to health care, provision of new diagnostic and therapeutic modalities or products stemming from research, access to scientific and technological knowledge; and capacity building facilities for research. Mechanisms to take advantage of benefit sharing is not in place in Nigeria.
46. The grounds for liability in clinical trials are lack of informed consent and other abuses
47. The right to respect bodily integrity and to exercise sovereignty over one's body is guaranteed by Section 34 of the 1999 Constitution. Where informed consent is breached this Constitutional provision can be invoked
48. Medical errors, misadventures and negligence are symptoms or effects of fundamental problems in Nigerian Health care delivery system
49. These problems include deplorable state of medical education, collapsing health infrastructure, inadequate continuing medical education, inadequate funding, brain drain etc
50. Medical negligence may be characterized broadly as the breach of a legal duty to take care by the medical doctor and other health workers which results in damage to the patient.
51. The term medical negligence and medical malpractice are interchangeably used. Though the later is broader and include other misconducts which border on medical ethics
52. The lack of well defined malpractice system in Nigeria has undermined and will continue to stultify efforts to improve the quality of health care and patient safety

Recommendations

For effective Health law and Policy in Nigeria the roundtable made the following recommendations:

1. In tackling the myriad of impediments to creating a functional health system, it is important to proceed with careful assessment and phased approach to implementation
2. With the convergence and efficient sharing of data, other collaborative efforts such as the integrated Disease Surveillance and Response System) will become more functional and realize the promise of their compelling visions
3. The diversity of donor sponsored initiatives in the country can become more efficient and beneficial to the collective objectives of all stakeholders.
4. Building synergy with such disjointed initiatives (like disease- focused interventions and capacity building efforts) is a necessary step in the journey of transforming healthcare in Nigeria.
5. Positively incentivize the adoption of health information technology among all stakeholders; establish educational and training opportunities; open doors for specialized international collaboration in capacity building and building synergy with other initiatives.
6. Articulate a vision and policy objective for Health Information Technology and establish a regulatory and governance framework for the sector.
7. Devise a national strategic plan for the meaningful use of health Information Technology and create information oriented architecture to meet the diversity of needs.
8. Availability of medicines, patented or otherwise is crucial to addressing the problem of access to medicine, strengthening the local pharmaceutical industry and capacity to engage in public and private sector partnership is a major step in the direction of finding a lasting solution to the problem of public health and access to medicines in the country
9. The Indian Patent System does not have patent product protection for pharmaceuticals. This has helped its local pharmaceutical industry to grow and address its health problems. Nigeria should adopt this approach
10. Compulsory licensing for patents is a useful strategy for protecting access to medicines, Nigeria already implements this system
11. Constitutional entrenchment of the right to health to facilitate a rights-based approach to health care delivery following the South African model
12. Strengthening judicial capacity for using the constitution and other legal instruments to strengthen the "right to health"
13. Academic curriculum development that fosters interdisciplinary approaches to studies on health e.g. developing health law and policy within law degree programmes; public health degree programmes open to non-health or medical disciplines
14. Provision of globally standard pharmaceutical laboratories in which not only the weight in milligrams or grams of a drug is being tested but also the qualitative analysis i e exact content.
15. Legislation against politicizing, compromising of mandatory internships and voluntary residency training and other related issues.
16. To make it an offence for strike-embarking workers to take control of hospital gates or preventing others who are interested in working from having access to the hospitals or discharging their duty
17. Standardization of minimum requirements for each level of health care, in terms of personnel equipments, structure, ntc.
18. Mandatory creation of quality control team in addition to servicom in each hospital as this regulates and maintains the optimum standard of health care delivery.
19. Sustained, stationed and mobile ambulances should be provided for the FRSC in all our highways and they should work hand in hand with NURTW and other bodies controlling transportation services.
20. Third party users of personal health information should be restricted to requiring authorization only for relevant personal health information.
21. Any personal health information obtained by a third party in a context outside of the healthcare system should not be used unfairly to adversely affect an individual's personal, financial, or professional rights, interests, or opportunities
22. A Health Institution should provide patients with a notice of privacy practices and protect the information from use or disclosure to those not allowed to see it by law or by the patient.
23. Investigate complaints and discipline breaches of confidentiality.
24. Support development activities to ensure that privacy and data protection issues are addressed.
25. Work with Information Systems and other areas of the organization to enhance the health facility's data protection practices and tools.
26. Conduct staff training and communicating with staff on privacy and confidentiality policies and procedures.
27. The National Health Policy needs to be updated and a Strategic Framework for wholistic implementation should be developed.
28. Benefit sharing could provide a means of negotiating favourable terms that could make drugs affordable and available with drug manufacturers during the clinical trial stage. The strong bargaining power which patent monopoly confers on patentee might make this difficult once a drug is approved as medication after the clinical trial stage by drug regulatory agencies. It is recommended that a benefit sharing scheme be included in Nigeria's health policy.
29. Governmental planning and programming to provide basic social amenities and infrastructure that are identified as critical determinants of health.
30. Clinical trials should be carried out in line with conditions and principles laid down in International ethical guidelines
31. The Nigerian government should enact statutes / regulations to regulate conducts relating to clinical trials in line with international standards and best practices
32. That the tort based negligence system be complemented by a no fault liability and enterprise liability in such a manner that where one turns out to be inappropriate to a given medical incident, it is seamlessly substituted by the other. Thus every probable medical liability scenario can be effectively resolved in such a manner that enhances higher quality assurance, greater transparency and accountability
33. The medical liability system must be instrumentally deployed by all legal intermediaries, the judiciary, health care management organizations, state agencies and every stake holder to promote an ongoing quality assurance and continuous improvement in our health care delivery in Nigeria to reduce the actual and potential harm to patients and induce efficiency, transparency and accountability
34. The key health status indicators of Nigeria paint a grim and sobering portrait. They show alarming underperformance, and on some measures, disheartening retrogression. With maternal and child mortality rates that are pushing global records, and declining life expectancy, the moral obligation to act is urgent.
35. The National Health bill is a step in the right direction. Nigeria must leverage the inherent efficiencies of health information technology in addressing its unique challenges to create an enabling environment.

Signed:

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