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## Local and International Health Regulations

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BY

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### ABSTRACT

*The IHR are a framework that will help countries minimize the impact and spread of public health threats. As an international public health importance, countries are using the IHR frame work to prevent and control global health threats while keeping international travel and trade as open as possible. The IHR, which are coordinated by the World Health Organization (WHO), aims to keep the world informed about public health risks and event. One of the most important aspects of IHR is the requirement that all countries will detect and report events that may constitute a potential Public Health Emergency of International Concern (PHEIC). In the US, and as applicable to Nigeria, four main principles define the ethical duties that health care professional owe to patients. They include: autonomy, non-maleficence, beneficence, and Justice. All 4 principles are considered to be in effect at all times. The study concluded that the International Health Regulation (IHR) are legally binding regulations that forms the international law, which aims at assisting countries to work together to save lives and livelihoods endangered by the spread of disease and other health risks. Ethical issues in health care must therefore be upheld. The study recommended that every country should adhere to international health and regulation and report outbreak of diseases to protect against spreading infection to other part of the country.*

**KEYWORDS: Local, International, Health Regulations, Medical Malpractice, and Jurisprudence**

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### Introduction

The idea that a health threat in one part of the world can impact other parts of the world is not new. Over time, there have been a series of agreements between countries to address the potential spread of disease, beginning with the International Sanitary Convention in 1892 and continuing until today with the International Health Regulations (Michon, 2014).

The International Health Regulation (IHR) are legally binding regulation that form the international law, which aims at assisting countries to work together to save lives and livelihoods endangered by the spread of diseases and other health risks. IHR prevent countries from outbreak of diseases, protect against spreading infections to other countries. It controls infections in countries where there is outbreak, provide a public health response to the international spread of disease in ways that are commensurate with international traffic and trade (Michon, 2014).

Ogono (2015) submitted that the IHR include specific measure that countries can take sea port, airport and ground crossings to limit the spread of health risks to neighboring

countries. IHR requires countries to consider the possible impact of all hazards, whether they occur naturally, accidentally, or intentionally concern (PHEIC).

### **History of International Health Regulations**

The International Health Regulations originated with the International Sanitary Regulation adapted at the International Sanitary Conference in Paris in 1851. In response to the cholera epidemics that hit Europe in 1830 and 1847 made apparent the need for international cooperation in public health. In 1948, the World Health Organization Constitution came about. WHO adopted, revised and consolidated the International Health Regulation in 1969. This was further revised in 1995 due to narrow scope of notifiable diseases such as cholera plague yellow fever. By 2005 IHR made binding to 194 countries across the globe including all 193 Member State of WHO (WHO 2005).

### **The Principles Embodying the IHR (2005)**

The implementation of IHR (2005) shall be:

1. With full respect for the dignity human rights and fundamental freedom of persons;
2. Guided by the Charter of the United Nations and the constitution of the World Health Organization;
3. Guided by the goal of their universal application for the protection of all people of the world from the international spread of disease;
4. States have in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to legislate and to implement legislation in pursuance of their health policies. In doing so they should uphold the purpose of these Regulations.

According to Appelbaum (2007), the IHR require that all countries have the ability to do the following: DARR

- **Detect:** Make sure surveillance systems and laboratories can detect potential threats.
- **Assess:** Work together with other countries to make decisions in public health emergencies.
- **Report:** Report specific diseases, plus any potentials international public health emergencies, through participation in a network of National Focal Points.
- **Respond:** Respond to public health events.

Under IHR a PHEIC is declared by the World Health Organization if the situation meets 2 of 4 criteria:

- Is the public health impact of the event serious?
- Is the event unusual or unexpected?
- Is there a significant risk of international spread?
- Is there a significant risk of international travel or trade restrictions?

Once a WHO member country identifies an event of concern, the country must assess the public risks of the event within 48 hours. If the event is determined to be notifiable under the IHR, the country must report the information to WHO within 24 hours. WHO (2005) wrote that some diseases always require reporting under the IHR, no matter when or where they occur while other become notifiable when they represent an unusual risk or situation.

Always notifiable diseases include smallpox, poliomyelitis due to wild-type poliovirus, human influenza caused by a new subtype, severe acute respiratory syndrome (SARS). Other may include cholera, pneumonic plague, yellow fever, viral hemorrhagic fever, and West Nile fever.

Since the revised IHR were put into place, four PHEICs have been declared by WHO:

- HINI influenza (2009)
- Severe Acute Respiratory Syndrome (SARS) (2003)
- Polio (2014)
- Ebola (2014)
- Zika Virus (2016)
- Lasar fever

When a PHEIC is declared, WHO help coordinate an immediate response with the affected country and with other countries around the world. Only about 1/3 of the countries in the world according to Applebaum (2017) currently have the ability to assess, detect, report and respond to public health emergencies.

### **Ethical Issues in Health Care**

Ethics is concerned with moral principles, values and standards of conduct. The field of health and health care raises numerous ethical concerns, related to health care delivery, professional integrity, data handling, use of human subjects in research, and the application of new techniques, such as gene manipulation.

Health care ethics or bioethics at its simplest according to Applebaum (2007) is a set of moral principles beliefs and values that guide us in making choices about medical care. At the core of health care ethics is the sense of right and wrong and individual's beliefs about rights one possess and duties one owes others. Thinking carefully about the ethical aspects of health care decision helps one to make choices that are right, good, fair, and just.

Lusardi (2009) submitted that health care in the 21<sup>st</sup> century is governed by a challenging array of rules, regulations, laws and ethical standards. Issues that involve confidentiality, informed consent and patient relationships can appear out of nowhere, even when health care workers have the best of intentions. What's legal today might not be considered ethical, and there is the ever-present threat of being sued for negligence and malpractice.

### **The Core Principles of Health Care Ethics**

Jessica (2002) opined that the health personnel ethical responsibilities in a given situation depend in part the nature of the decision and in part the roles they play. For example, a patient and his or her family play different roles and owe different ethical obligations to each other than a patient and his or her physician. In the US, and as applicable to Nigeria, four main principles define the ethical duties that health care professional owe to patients. They are:

**1. Autonomy:** In medicine, autonomy refers to the right of the patient to retain control over his or her body. A health care professional can suggest or advise, but any actions that attempt to persuade or coerce the patient into making a choice are violation of this principle. At the end, the patient must be allowed to make his or her own decision whether or not the medical

provider believes these choices are in that patient's best interests independently and according to his or her personal values and beliefs.

**2. Beneficence:** This principle states that health care providers must do all they can do to benefit the patient in each situation. All procedures and treatments recommended must be with the intention to do the best for the patients. To ensure beneficence medical practitioners must develop and maintain a high level of skill and knowledge, make sure that they are trained in the most current and best medical practices, and must take their patient's individual circumstances into account: what is good for one patient will not necessary benefit another.

**3. Non-Maleficence:** Non-maleficence is probably the best known of the four principles. In short it means, "to do no harm." This principle is intended to be the end goal for all of a practitioner's decisions, and means that medical providers must consider whether other people or society could be harmed by a decision made, even if it is made for the benefit of an individual patient.

**4. Justice:** The principle of justice states that there should be an element of fairness in all medical decisions: fairness in decisions that burden and benefit, as well as equal distribution of scarce resources and new treatments, and for medical practitioners to uphold applicable laws and legislation when making choices.

All 4 principles are considered to be in effect at all times. In theory, each is of equal weight or importance. In practice however respect for patient autonomy often takes priority over the others. Other ethical issues are:

### **1. Patient Confidentiality**

Information about a patient's medical condition is considered private. Violating a patient's confidentiality can hurt the patient and have legal and ethical consequences for the health care worker. These laws state clearly the type of patient information that can be released to third parties and which information must be kept confidential.

### **2. Patient Relationships**

Health care providers are ethically prohibited from entering into personal relationships with patients in the course of providing treatment. Entering into a sexual relationship with a patient is considered a serious violation of that patient's rights and an act of misconduct and abuse of power on the part of the health care, a patient is considered vulnerable and unable to define or protect themselves.

### **3. Malpractice and Negligence**

Health care providers are always at risk for being charged with malpractice and negligence. A patient who is harmed by defective medical equipment or products, injured in course of a medical treatment or placed in danger because of medication errors can sue to recover their losses. Patients can also sue when health care providers fail to provide a critically needed treatment or service. Due to the ever-present threat of litigation, health care providers must carefully cover all the bases in the course of providing patient care.

### **4. Informed Consent**

Informed consent means that a patient has had all of their questions answered and freely agrees to a treatment or procedure with full knowledge of the risks benefits and possible

consequences. Informed consent also means that patients are informed about other options as well as about the option of doing nothing.

### **5. Issues Related to Physician Assisted Dying Suicide (PAD)**

Most health care professionals are aware that physician assisted dying is already legal in states like California and Oregon. Support for PAD is growing in momentum as the baby boom generation gets older. Surveys show that roughly 50 percent of doctors now support some form of physician assisted dying. These days, physicians are broadening the concept of “Do no harm” to include providing relief for those who are dying and suffering as a result of a fatal illness.

### **10 Challenges Faced by Clients in Hospitals**

1. Disagreement between patients’ families and health care professionals about treatment decision.
2. Waiting lists.
3. Access to needed health care resources for the aged chronically ill and mentally ill.
4. Shortage of health care personnel.
5. Medical error.
6. Without holding or withdrawing life sustaining treatment in terminal illness.
7. Achieving informed consent.
8. Ethical issues-participation in research.
9. Substitute decision making.
10. Ethics of surgical innovations and incorporating new technologies for patient care.

### **Top 10 Ethical Challenges Faced by Clients in Health Care:**

Dazedey (2016) postulated that disagreement between patient/families and healthcare professionals about treatment decision, waiting lists, access to needed health care resource for the aged, chronically ill and mentally ill, with holding/withdrawing life sustaining treatment in the context of terminal or serious illness, achieving informed consent, ethical issues related to subject participation in research substitute decision making, the ethics of surgical innovation and incorporating new technologies for patients care.

### **Informed consent**

Informed consent is the process by which the treating health care provider discloses appropriate information of a competent patient so that the patient may make a voluntary choice to accept or refuse treatment (Appelbaum 2007). It basically means a health care giver telling a patient all of the potential benefits risks and alternatives involved in any surgical procedure or other course of treatment and must obtain a patient written consent to proceed. It originates from the legal and ethical right the patients have to direct what happens to her body and from the ethical duty of the physician to involve the patient in her health care.

### **The Roles of the Physician**

The roles of the physician is to speak with the patient about informed consent, including the diagnoses, nature and purpose of the proposed treatment or procedure, benefit and the risks of the proposed procedure, and the alternatives to the proposed treatment or procedure regardless of their cost.

### **The Role of the Patient**

Although a physician is required to inform a patient about benefits, risks, and alternative treatment, patients must also play a part in the informed consent. Patients must listen to the physician and should ask question of the physician if they do not understand, or if they would like more detailed information.

### **What Treatment Need Informed Consent?**

Medical procedures that may require you to give written informed consent include:

- Most surgeries, even when they are not done in the hospital
- Other advanced or complex medical tests and procedures, such as an endoscopy (placing a tube down your throat to look at the inside of your stomach) or a needle biopsy of the liver
- Radiation or chemotherapy to treat cancer
- Most vaccines

### **What are the Elements of Full Informed consent?**

The most important goal of informed consent is that the patient has an opportunity to be an informed participant in her health care decision. It is generally accepted that informed consent includes a discussion of the following elements:

- The nature of the decision/procedure
- Reasonable alternatives to the proposed intervention
- The relevant risks, benefit, and uncertainties related to each alternative
- Assessment of patient understanding

### **Exceptions to Full Informed Consent are:**

- If the patient does not have decisions-making capacity, such as the person that have dementia, in which case a proxy, or surrogate decision-maker, must be found.
- A lack of decision-making capacity with inadequate time to find an appropriate proxy without harming the patient, such as a life-threatening emergency where the patient is not conscious.
- When the patient has waived consent.
- When the competent patient designates a trusted loved-one to make treatment decisions for him or her.
- The mentally ill patient (Bord 2014)

### **Is there such a thing as presumed/Implied Consent?**

The patient's consent should only be "presumed," rather than obtained, in emergency situations when the patient is unconscious or incompetent and no surrogate decision maker is available, and the emergency interventions will prevent death or disability.

### **When is a Consent Valid?**

1. The person giving the consent must be 18 years and above.
2. Must be alert (mental state)
3. Informed consent must have been explained
4. Consent must be signed
5. There must be witness to the consent

6. Consent expires after one month
7. One consent for one surgical intervention

## Patients' Bill of Rights

### Patients' Bill of 1973

The best known of patients' right statements was issued in 1973 by the American Hospital Association, backed by the Federal Department of Health, Education and Welfare and the American Medical Association (Lusardi, 2009). All over the world patients are patient. The rights of a patient in the developed countries are also applicable to the patients here in developing countries like Nigeria.

1. **Respect and Non-discrimination:** The patient has a right to considerate, respectful and non-discriminatory care from his doctors, health plan representatives and other health care providers.
2. **Confidentiality of Health Information:** He has the right to talk in confidence with health care providers and to have health care information protected. He also has the right to review and copy his own medical record and request that his physician amend his record if it is not accurate, relevant or complete. He has the right to know by name, the physician responsible for coordinating his care.

### The exception to this rule is where

The law requires that information can be disclosed in public interest, situations which may result to death or serious injury due to non-disclosure of the medical records. Any competent court can order that the doctor releases a patient's medical records. For example, the case of the Ebola nurse who ran to Enugu after being diagnosed with Ebola virus disease, her records were made public because failure to do so will result in death of members of the public.

- i. **Choice of providers and plans:** He has the right to a choice of health care providers that is sufficient to provide him with access to appropriate high quality health care.
- ii. **Access to Emergency Services:** if he has severe pain, an injury, or sudden illness that convinces him that his health is in a serious jeopardy, he has the right to receive screening and stabilization emergency services whenever and wherever needed, without prior authorization or financial penalty.
- iii. **Participation in Treatment Decision:** He has the right to know all his treatment options and to participate in decision about his care. Parents, guardians, family members or other individuals that he designates can represent him if he cannot make his own decisions.
- iv. **Complaints and Appeals:** He has the right to a fair fast and objective review of any complaint he has against his health plan, doctors, hospitals or other health care personnel. This includes complaints about waiting times, operating hours, the conduct of health care personnel and the adequacy of health care facilities.
- v. The patients have the right to leave the hospital against the physicians' advice, regardless of his conditions after signing in his care note, he has the right to request for spiritual services, he also has the right to donate, request or refuse organ and tissue donations and to receive compassionate care at the end of life.
- vi. To receive labeled medications safely without discomfort in accordance with the six rights of medication administration namely: Right medication, Right dose, Right client, Right route, and Right time.

- vii. **Right to knowledge of hospital rules and regulations:** A patient has the right to know the clinic/hospital rules and regulations and charges before getting admitted or treated in that hospital.

### **Right to informed consent**

An informed consent is a voluntary agreement to a medical procedure. Since the doctor in a fiduciary capacity in the relationship with the patients, it is necessary for him to let them know everything concerning the procedure.

### **Right to Self-Decision**

A patient has the right to refuse reasonable treatment even if it is unreasonable to do so. A doctor cannot under any circumstances, force treatment on a patient, not even to save his life. Some persons refuse orthodox treatment, while others reject blood transfusions or organ transplant. No matter how stupid the decision may seem, the right is guaranteed by the constitution of the Federal Republic of Nigeria.

### **Responsibilities**

A patient has the responsibilities to:

- ❖ Provide correct and complete information about himself, his health, allergies and any other information the care givers need to know.
- ❖ Discuss and share views about care given.
- ❖ Follow agreed-upon care plan and report any changes in his condition to the nurse/doctor.
- ❖ Respect the property, privacy, dignity and confidentiality of all patients, visitors, physicians and hospitals staff.
- ❖ Keep environment free of illicit drugs, alcohol and weapons.
- ❖ Provide information on what medication he is taking and why he is taking them.

### **Medical malpractice**

This is an unauthorized, injurious, and unskillful or faculty medical act. Specific medical malpractice includes:

- a) Negligence e.g. a swab is left in the wound after operation. This is so obvious and speaks for itself.
- b) Assault and battery e.g. failure to obtain appropriate consent may make a doctor liable to intentional assault and battery. However, in emergency the doctor is justified in carrying out an elective operation which is clearly indicated.
- c) Fee splitting: when a doctor shares fee with another doctor to whom he has referred to, patient should be informed. The doctor who refers to patient is permitted to get an amount commensurable to his services.
- d) Itinerant surgery: when a hospital doctor operates on a patient away from the hospital, at a place where he may not provide necessary care, and may not be available when he is needed, if the patient dies or is harmed consequently, the doctor may be accused of itinerant surgery.
- e) Abuse of death certificate: Issuing of false death certificate is a serious professional misconduct which if proved may result in a doctor's name being removed from the medical register. The following point are important:
  - i. The occurrence of death should be verified before death certificate is issued



- ii. The doctor must have attended the deceased during his last illness. If the doctor has not seen the deceased within 14 days! The coroner must be informed.
- iii. All sudden death or death associated with suspicious circumstances must be reported to the police or the coroner.
- iv. In case of cremation, another senior doctor must sign the certificate after studying the declaration made by the first doctor. A medical referee must also be involved.
- v. Advertising: A doctor must not advertise himself in such a way that is prejudicial to other doctor.
- vi. Invasion of privacy: A doctor should not release information to mass media unless he has got specific written permission from the patient to do so.

### **The important of jurisprudence**

1. It affects socio – political thoughts
2. It serves to render the complexities of law more manageable.
3. It has great educational value. It sharpens the logical technique of lawyers.
4. It throws light on basic ideas and fundamental principles of law in a society.
5. It helps lawyers ascertain true meaning of law passed by legislature→ interpretation.
6. It helps lawyers to face every exigency of human affairs boldly and courageously.
7. Helps lawyers to bring theory and life into focus i.e human that's in relation to social existence.

### **It is the eye of the law Jurisprudence**

- Jurisprudence straightens out when how the law was developed, origin of the law, development and contribution towards society.
- Ignorance of law is an excuse. Jurisprudence helps people to have sound knowledge of the law.
- Therefore, Jurisprudence is called the EYE OF THE LAW.

### **Medical malpractice**

CDC (2016) noted that medical malpractice cases arise when a patient is harmed by a medical professional who fails to provide proper health care treatment. Some of the ways medical malpractices can occur are:

Misdiagnosis or delayed diagnosis: wrong diagnosis and delayed diagnosis account for a large percentage of medical malpractice complaints. When a doctor misdiagnoses a condition the patient might miss treatment opportunities that could have prevented serious harm or even death.

**Childbirth Injuries** – A number of foetal injuries can be caused by medical malpractice, including brain injuries (such as cerebral palsy and seizure disorders), fractured bones.

**During pregnancy** – Failure to diagnose a medical condition of the mother, such as preeclampsia, Rh incompatibility, hypoglycaemia, anaemia, or gestational diabetes, ectopic pregnancies. During labour, failure to anticipate birth complications due to the baby's large size or because the umbilical cord got tangled, failure to respond to signs of foetal distress and failure to order a caesarean section one was appropriate.

**Medication Errors** – Medication errors can occur, many was of the initial diagnosis to the administration of the drug, including giving too much anesthesia to the patient in the theatre,

damage to internal organs, operating on the wrong body part, or leaving surgical instruments in the body during surgery.

### **Conclusion**

The International Health Regulation (IHR) are legally binding regulations that forms the international law, which aims at assisting countries to work together to save lives and livelihoods endangered by the spread of disease and other health risks. Ethical issues in health care must be upheld. Other important issues that govern health care such as informed consent, patients and medical malpractice should be given its right of place.

### **Recommendations**

- Every healthcare practitioner must uphold the principles of health care ethics.
- Every country should adhere to international health and regulation and report outbreak of diseases to protect against spreading infection to other part of the country.
- The IHR, which are coordinated by the World Health Organization (WHO) should maintain their objectives by keeping the world informed about public health risks and events.

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