Report on the Patient Safety Symposium in Uganda - 6th September 2018

Uganda is advancing patient safety through a multi stakeholder engagement strategy which brings together national and international decisions makers as well as patients.

The patient Safety Symposium participants

ACKNOWLEDGEMENT

It was remarkable to see such a great participation of all stakeholders at the event organized and supported by Ministry of Health Uganda, Community Health and Information Network (CHAIN), Human Rights and Peace Centre as well as Nottingham Law School, Nottingham Trent University. Special thanks also go to participants from key institutions including Infectious Disease Institute (IDI), National Drug Authority (NDA), Uganda Cancer Institute (UCI), Uganda Heart Institute (UHI), Medical Access (MAUL), Uganda Protestant Medical Bureau (UPMB), Makerere School of Public of Health (MSPH), Center for Health, Human Rights & Development(CEHURD), Ernest Cook Ultrasound Research &Education Institute (ECUREI), Mulago Hospital, Uganda Lung Institute, Wide Spectrum, patient organizations from sicklecell, Hepatitis B, Cancer Associations.

Organizing and supporting partners

:

THE REPUBLIC OF UGANDA
Chain Chain Chain Chain
HUMAN RIGHTS AND PEACE CENTRE
HURIPEC
NOTTINGHAM
TRENT UNIVERSITY

GLOSSARY

ADRs – Adverse Drug Reactions
CDC – Center for Disease Control
CEHURD-Center for Health, Human Rights & Development
CHAIN – Community Health and Information Network
EAT – East African Time
ECUREI-Ernest Cook Ultrasound Research &Education Institute
HFQAP – Health Facility Quality of Care Assessment Programme
HIV – Human immunodeficiency virus
IDI – Infectious Disease Institute
MAUL- Medical Access
MCQs – Multiple Choice Questions
MoH – Ministry of Health in Uganda
NDA – National Drug Authority (Uganda)
NHS – National Health Service (UK)
OECD – Organisation for Economic Co-operation and Development
OTC – 'Over-the-counter' (medicines)
PS – Patient Safety
PMO -Principal Medical Officer
QAID- Quality Assurance & Inspection Department
RRHs –Regional Referral Hospitals
UCI- Uganda Cancer Institute
UHI- Uganda Heart Institute
ULI- Uganda Lung Institute
UPMB - Uganda Protestant Medical Bureau
TB – Tuberculosis
WHO – World Health Organization

EXECUTIVE SUMMARY

Patient safety has been defined as 'the absence of preventable harm to a patient during the process of health care and reduction of risk of unnecessary harm associated with health care to an acceptable minimum' (World Health Organisation, 2017). The consequences of failures in patient safety are diverse and far-reaching: pain, suffering and even death for patients; the loss of loved relatives, or extra caring responsibilities, for families; the temporary or permanent loss of active members of the community; additional strains placed on already limited healthcare resources. There is an increasing acceptance in countries across the world that medical errors can occur across the whole spectrum of health services and treatments and can be attributed to both human and system factors. Developed countries are not immune to the effects of patient safety incidents: it is estimated that, in the UK, a preventable adverse incident occurs every 35 seconds. However, two-thirds of all adverse events across the globe occur in low- and middle-income countries. It is in these countries, including Uganda that the combination of a number of factors contributes towards healthcare systems that are vulnerable to patient safety failings.

Because patient safety is a complex, multi-dimensional challenge the solutions to providing safer, high quality care cannot be found through the isolated efforts of interested stakeholders. Rather, there must be ongoing, concerted actions by all those with responsibilities, experience and expertise in healthcare. These stakeholders are diverse and are drawn from all levels of national and international organisations, including: governments, policy-makers, regulators, healthcare providers, healthcare professionals, researchers, educators, lawyers, civil society, community health workers and patients. Such groups, working together, can develop regulatory frameworks, leadership, and organisational management alongside the on-the-ground capacity to successfully implement and maintain safety strategies, procedures and practices.

On 6th September 2018, the *Ugandan Patient Safety Symposium* was held in the Infectious Diseases Institute at the Mulago Hospital Complex, Kampala. The event was collaboratively organised by the Ministry of Health (MoH), the Community Health and Information Network (CHAIN), the Human Rights and Peace Centre- Makerere University and Nottingham Law School (Nottingham Trent University, UK). The aim of the event was threefold:

1. To bring stakeholders together in an inclusive dialogue about patient safety;
2. To evaluate past and present patient safety initiatives within Uganda, including identifying successes and weaknesses;
3. To begin to develop a framework for future action in response to identified priorities.

The event took the form of a variety of presentations by patient safety experts, along with several opportunities for questions, discussions and interactive debates. Presentations were delivered on a range of safety issues, including: an introduction to Ministerial efforts to develop patient protections; an overview of the emerging paradigm of global patient safety; sharing of experiences from outside Uganda, most notably the UK; medication safety; safety in radiology; community engagement with safety strategies; the role of healthcare providers in developing cultures of safety; the role of regulatory agencies, such as the National Drugs Authority in delivering and monitoring safer healthcare products; and the various ways that patients, their behaviors and beliefs, can influence the safety and quality of the healthcare interaction.

The Way Forward

By the end of the symposium, a number of key themes had been identified which should be used to structure the development of further safety interventions in Uganda:

1. There is an apparent need to develop a national system for collecting, monitoring, sharing and learning from patient safety incidents
    a. The evaluation of different models of *national reporting and learning systems* is a key priority
2. Whilst the paradigm of patient safety has shifted away from an individualised system of blame and liability, and towards a systemic approach, there is still an urgent need to dispel the persistent *culture of blame* that hinders uptake of safety measures
3. Those with *legal expertise* can provide keen insights into the legal regulation of safety in its reactive sense – through litigation – but also proactively through the development of legislation and regulation
    a. Legal experts should be included in the stakeholders engaged for patient safety development
4. A *broad, inclusive approach* must be taken forward into the development of patient safety policies and initiatives. These dialogues should be given a national platform.
5. National stakeholders should be involved in *international patient safety collaborations*, whether those convened by agencies such as the World Health Organisation, or through continued collaboration with overseas partners.
    a. Where existing collaborations exist at the governmental or policy level, other stakeholders should be actively included within these pathways of communication
6. The model of Ugandan *community engagement* should be celebrated for its essential role in disseminating patient safety information and practices and for its work in the empowerment of patients in the healthcare system.
    a. Community organisations must be supported in their work by other high-level stakeholders
    b. It must be recognised that community-level action and engagement is not a replacement for, but a supplement to, the development of an organised, effective central healthcare system

The national symposium was designed as the first platform for collaborative, concerted discussion about patient safety in Uganda. It is hoped that such events can become a regular forum for the review of ongoing safety development which will lead to systemic improvement in the overall health of Uganda.

THE DESCRIPTION OF THE EVENT

INTRODUCTION

During the third Global Ministerial Summit on Patient safety, and following the ***Tokyo Declaration on Patient Safety***, countries were prompted to welcome the vision and leadership in building momentum at the highest levels of government to address patient safety challenges globally as well as locally. In response, Uganda is already endorsing the call for countries to accomplish the patient safety declaration. The MOH and its partners convened the international and national stakeholders from a range of sectors to propose and assess solutions, as well as emphasize the role of each stakeholder in addressing the patient safety challenge. On the 6th of September 2018, the patient safety symposium was organized in Uganda. The event is elaborated in the next sections.

The patient safety symposium was organized on the 6th of September 2018 by MOH, CHAIN, the Human Rights and Peace Centre(Makerere University) and Nottingham Law School and hosted at the IDI, started from 8:30am until 4:00 pm EAT and attracted ***40 participants****, including the academia, decision makers, service providers, healthcare professionals, supply chain organizations, regulators and patient leaders/organizations; these stakeholders' groups comprised of both national and international experts and decision makers from the public and private sectors. With this multi-stakeholder and expert engagement a very practical and solution-based event was achieved, with features such as expert insights and education, examination of the roles and participation of both the private and public sector and solutions to address patient safety challenges including aspects of medical errors, and adverse event reporting procedures.

****The participants list is attached in the annex.***

Table 1: Summary table for the event activities (presentations and participatory session)

MINUTES	ACTIVITY	RESPONSIBLE OFFICER
10	Welcome remarks: Makerere School of Law	Dr. Zahara Nampewo
10	Remarks - Commissioner Quality Assurance And Inspection – MoH	**Dr. Joseph Okware**
10	Official Opening: Ag. DHS Clinical and Community Services-MoH	Dr. Charles Olaro
20	Overview Patient Safety in Uganda	Dr. Ssendyona Martin PMO QAID- MoH
20	Global Patient Safety – Governance, practice and law – Uk Experience of Patient safety in NHS; Lessons and Challenges	Mr. John Tingle Nottingham Trent University , UK
35	Discussion	All
15	Legal Perspectives to Patient safety in Uganda- Law school	Dr. Zahara Nampewo Makerere School of Law
15	Advocates for Patient Safety in a large HIV outpatient facility: feasibility and impact of a pilot training program in Uganda	Ms. Mercy Kukundakwe-Infectious Disease Institute(IDI)
30	The role of healthcare providers in promoting patient safety	Dr. Tonny Tumwesigye, ED UPMB
15	The role of National Drug Authority(NDA)in promoting Patient safety	Ms. Dona Kushemererwa ES, NDA
45	Discussion	All
	Chairperson: Dr. Frederick Nakwagala –Senior	

	Consultant Mulago University	
15	'Medication Without Harm': The WHO Patient Safety Challenge, the UK Response and the role of Falsified Medicines	Mr.Morgan Shimwell-Nottingham Trent University,UK
15	Patient Safety and Community Engagement	Mrs. Regina Kamoga (CHAIN)
15	Patient safety in radiology in Uganda.	Prof. Michael Kawooya, Dir. ECURI Mengo Hospital
15	Patient Safety English Law and Informed Consent.	Dr. Clayton Ó Néill-Nottingham Trent University,UK
30	Discussion	All
30	Way forward	All

PRESENTATIONS

The presenters welcomed the participants and acknowledged the efforts invested in organizing the event, also using examples, they acknowledged the work that has been done so-far to address the patient safety challenge. The experts came from both international and national communities, not only were they informed of policy issues but also well versed with patient safety at the patient's level.

Dr. Charles Olaro- Ag. DHS Clinical and Community Services-MoH

The symposium was opened by Dr. Olaro, with his best wishes for fruitful discussions. He made several insights including despite challenges facing the country, excellent work is being done by community workers, clinicians, healthcare professionals, and health leaders; patient safety is a vitally important issue, but is very challenging to manage and protect, this is not least because safety and quality are incredibly complex issues which are not readily diagnosed and treated; It requires multiple and diverse experts to come together to share their experiences; the efforts to tackle adverse medical harms need to start at the basics, such as the infrastructural design of health facilities; It requires increasing the capacity of health carers to ensure that their numbers increase in population size; waste management programmes need to complement and support the care that hospital provides; communication between healthcare providers is a simple improvement but plays a vitally important role in developing and disseminating policies and practices among others.

Dr. Joseph Okware- Commissioner Quality Assurance And Inspection – MoH

Dr. Okware described the case of patients being at risk of being harmed whilst in the care of a hospital, for example for developed countries this currently stands at approximately 10% whilst in

developing nations, this can rise to 20 times higher this number.

Below is a highlight of the insights from his presentations:

- Patient safety is not just a medical issue but is a moral, ethical and economic issue.

- There is an enduring belief that a sick patient who attends hospital is in safe hands. But, as has been observed, this is not true. Patients can experience harm whilst in hospital, as a result of processes in place, the side-effects of medication or hospital-borne infections. This is a fact. New technologies and ways of handling hospitals have not managed to address this problem; conversely, adverse incidents are increasing as a result of time pressures and the resources available.
- Uganda is still in the phase of attributing medical error to individuals who may have 'caused' the harm – in reality, this individual is most likely only the person responsible for a patient's care and not the cause of harm. But a culture of blame persists. This negatively affects the reporting rate of harmful incidents within hospitals. This also means that patients leave the hospital setting without understanding that they have suffered a medical error. Dr. Okware referenced Heinrich's principle in patient safety: for every 1 major incident in a hospital, there are likely to be 29 minor incidents and 300 cases of 'near misses'. The minor incidents may be acknowledged by hospital staff but not reported, whilst the near misses are rarely addressed at all. In this region, there is not a culture of reporting, even for major incidents. A recent example of a reported incident was the skull of the incorrect patient being opened in surgery. There needs to be a paradigm change allowing health professionals to feel comfortable in reporting so that mistakes lead to learning opportunities, rather than individuals being punished by the police or by the courts. Currently, errors which are reported, especially if these reach the media, typically leads to disciplinary action taken against health professionals without further inquiry into the underlying reasons for the error. The medical error also has severe economic implications for patients and for the health system: patients have longer stays in hospitals and cannot return to work whilst more resources have to be expended on their prolonged care and treatment. This must be addressed for everyone's benefit.

Dr. Zahara Nampewo: Human Rights and Peace Centre- Makerere University

Dr. Nampewo emphasized the current efforts by the school of law towards addressing the patient safety challenge and health as a whole, several activities have been implemented and these include:

development of a Masters program which includes health law content; Professor Ben Twinomugisha undertook studies and published the first book on Ugandan Health Law in 2016 to international recognition; the law school trains law students to engage practically with patient considering the emotional, social and psychological well being while using real-life scenarios in moots, among other. She further acknowledged Commissioner Okware who has ensured that there are meaningful, collaborations engaging the legal sector, initially health lawyers were not actively engaged because of the negative associations between lawyers and medical error as reported in the media. Below is a summary of legal perspectives to patient safety as explained by Dr. Zahara;

- In the patient safety framework, we need to determine the role that lawyers can play. The key question is: what is of concern to lawyers with regard to patient safety?
- In the Ugandan Constitution Chapter IV contains the Bill of Rights. The right to health is not a substantive provision. Rather, this is reflected as an objective under the preamble of the Constitution. Legally, objectives of national principles are not actionable by patients for 'violations'. This is an expression of the State's commitment to health standards, rather than a legally binding clause. Under Chapter IV only children are guaranteed medical treatment. The law has fairly weak grounds to realize the 'right' to health for every citizen. Other legal provisions interact with patient safety. Two examples include the Mental Treatment Act. This legislation is important for PS yet is very outdated and has little sensitivity for human rights. Patients are conceptualized as objects, rather than the subject, of medical treatment. Those patients with limited decision-making capacity are not guaranteed involvement in the healthcare process.
- The other legislation of interest is the HIV Prevention and Management Act. This criminalizes the transmission of HIV. From a legal perspective, the language of the law is problematic for being overly broad. Almost every one of HIV status could be regarded as a potential 'criminal', capable of the transmitter of HIV. This negatively colors the patient safety environment from the outset for HIV-positive patients. It is likely to hinder the reporting of HIV status, but also discourage people from undergoing diagnostic tests, for fear of having 'knowledge' of their condition, which is a prerequisite of the crime of transmission. The closed fora of the clinical environment are challenging.
- Alternative medicines and practitioners are not engaged in the 'legitimate' healthcare process. These need to be integrated into the patient safety framework to ensure that significant gaps in the scope of protection are closed. Medication safety is an increasingly important issue. Self-medication by patients is difficult to track by health practitioners. Health problems may be caused or exacerbated before these patients even reach the doctor; yet, should harms be suffered under the doctors care then liability may attach.

▪ Regulatory and professional bodies, such as the NDA and the Pharmacist Association, need to be engaged to avoid duplication and the application of different standards to professionals. Harmonization and cooperation need to be achieved to ensure that the regulatory environment is effective and efficient.
▪ The policy on public-private partnership needs to be addressed. Whilst the aim of Private Public Partnerships is to improve service by exploiting the comparative advantages of each sector, the experience is that the private sector usurps the role of public health providers. Patients may be compelled to use private services, or referred to private facilities unnecessarily. This has significant cost implications but also can be damaging for the healthcare experience of patients. The balance of priorities between public and private interests needs to be readdressed in favor of ordinary citizens.
▪ Empowerment of patients is essential. Awareness of patient rights and healthcare provider duties is currently minimal. The relationship between doctor and patient is heavily paternalistic. The end-user capacity must be strengthened to ensure that patients are able to engage meaningfully with the healthcare process. The Patients Charter has the potential to improve empowerment, but must be disseminated effectively to ensure that this objective can be met.
▪ The law is often used to punish and discipline. However, it should be used to inform the debate about patient safety. The law can be a powerful tool to drive change.

Dr. Martin Ssendyona – Principal Medical Officer(PMO) Quality Assurance & Inspection Department QAID- MoH

Dr. Ssendyona shared updates from the MoH, on the work done on infection control practices and patient safety. From his presentation it is critical to note the following:

▪ Throughout the healthcare process there is an inherent degree of unsafety. There is a need for clear policies, organisational leadership and the provision of data to drive safety improvements.
▪ WHO recognises that healthcare-associated infection is a 'silent pandemic', acknowledging the challenge of making patient safety more visible to health practitioners and policymakers. Attention must be turned to these issues.
▪ In Uganda, there is limited documentation available for patient safety.
▪ The MoH launched the Health Facility Quality of Care Assessment Programme which developed tools for assessment. Currently, assessments have been conducted in 85% of districts in Uganda. In the assessments, facilities are given a star-rating which is reported, however, the HFQAP aims to build capacity within health facilities to conduct internal assessments, for example, ***5s philosophy*** which has led to improvements in the working environments especially in RRHs for clinicians and healthcare clients. From May to June 2018 there has been an overall improvement in the 5s performance since 2017, with the majority of the health centers exceeding the required baseline.

The way forward:

▪ Develop patient safety guidelines and continue to develop the Client Charter Implementation guidelines.
▪ Continue to build capacity through training.
▪ Engage the community through the dissemination of Patient and Client Charters and advocacy campaigns. Feedback is required to develop effective policies.
▪ Continued supportive supervision

Associate Prof. John Tingle – Lecturer NTU : Not only did Prof. Tingle present on his lessons and also made recommendations on patient safety but also emphasized the achievements of Uganda towards addressing the patient safety challenge and Universal Health Coverage. Below are the considerations from his presentation:

▪ Uganda was recognized in the recent (2018) WHO S*tate of Health in the African Region* report that its health performance status is exceeding its classification as a low-income country: rather, its health performance indicators suggest that it is working to the capacity of a lower-middle income country. This is due to the commitment to health at all levels. This must be celebrated as a starting point for patient safety policy development.

▪ The patient safety approach has shifted from a localized approach to a more global appreciation. This is, in part, due to the fact that patient safety affects all countries, regardless of socio-economic development. In the OECD and WHO report (2018) it was noted that poor quality health services are holding back progress in healthcare performance.

▪ Unfortunately, healthcare failures are more predominant in developing countries. Whilst such countries are striving hard towards universal healthcare coverage, there must be a parallel development of quality and safety to ensure that the care provided is safe. Any compromise in quality will undermine the whole endeavor and will waste the scarce resources being invested. Quality is undermined by unwarranted variations in health care provision and delivery and lack of evidence-based care. There are huge variations in e.g. influenza vaccinations rates (from 1% to 78%).

▪ In developing countries, there remains a problem with sanitation and the lack of clean water in health facilities.

▪ Lawyers have a role in the patient safety development framework. Lawyers are taught and practice clinical negligence. Claimant lawyers have a well-defined role in patient safety by holding those who fail patients to account. This is a powerful tool if used in the right way. It is a reactive mechanism and should be used to complement proactive and preventive safety policies and procedures. But, this experience of bringing and defending against, claims is valuable to the formation of policy guidelines, not least for identifying recurring themes in failures and errors.

▪ In the UK, errors occur every 35 seconds in the NHS. There are 150 avoidable patient deaths per week. Patient safety remains the top priority of the Care Quality Commission, the national regulator and inspector for healthcare facilities. Developed countries, unfortunately, have not successfully responded to the patient safety challenge. There are lessons to be learned from the UK/European/US experience. But, there is no demand for exporting the patient safety policies of these countries/regions. Rather, there is a need for the sharing of good practice but the careful, critical examination of what went wrong so as to know what to avoid in the development of emerging patient safety frameworks.

▪ The dynamics of health and healthcare is changing and will continue to do so in the future – there is an aging population; multi-morbidities; complex health profiles; and further resource constraints. These will all have significant impacts on patient safety and must be accounted for in the development of robust policies and regulations. Regulators and government agencies and inspectorates have important roles to play as leaders and watchdogs. But, over-regulation has proved to stifle innovation without bringing substantial improvements in quality and safety. Any top-down approach must be met with bottom-up experiences and engagements – with health professionals, community workers, volunteers, and patients/clients. The UK is currently developing new patient safety legislation, which will establish further inspection and assessments frameworks but will also introduce innovative regulatory concepts such as the

'safe investigative space' and the 'duty of candor'. It is to be seen whether these new approaches to transparency, reporting, and learning will prove to be effective.

- The solutions to patient safety lie in collaborative and multidisciplinary efforts.

Ms. Mercy Kukundakwe - IDI : With the scaling up of HIV treatment in sub-Saharan Africa, treatment is becoming heavily standardized and protocol-driven, being delivered to large volumes. This leads to little opportunity for patient involvement in the treatment pathway. In a pilot study organized by the IDI, young adults were trained, empowered and engaged with patient safety activities. The MoH Patient Safety Charter was a useful guide for empowering activities. 5 Young adult advocates were enrolled through an interview process. Training sessions were carried out weekly between June and November 2016. These were delivered via presentations, group discussions, online course, and trainee research presentations. Resources from the CDC and WHO were used in training and the topics included: hand hygiene, medication safety, patient charter, learning from error, communication skills, and research participant rights. The 5 advocates were placed in 6 major clinic areas – patient waiting for areas, urgent care, TB clinic, sexual and reproductive health, laboratory and pharmacy. During this time, they were observing patient safety practices. They were also intended to disseminate health education materials to patients. Finally, the advocates were asked to document patient safety incidents they witnessed or were involved in. Advocate knowledge was assessed before and after training, using anonymous questionnaires including written answers and MCQs. They also evaluated the training they received and the general experience of challenges during the process. The perceived impacts of their training on patient safety were also assessed. The results show that all 5 advocates acquired new skills in advocacy, presentation, and communication. 3 of the 5 felt that they were accepted by health workers whilst 4/5 felt accepted by patients. They all felt very prepared to advocate for patient safety issues and had the most impact on hand hygiene, safe disposal of phlebotomy swabs, patient rights and empowering patients. The challenges described included feeling like the clinic regarded them as 'spies' and there was limited understanding of their role. Advocates reported 16 incidents, of which 12 were detected by advocates. 5 incidents involved medicines, 3 involved infection risk, 8 involved lack of patient understanding. 7 incidents resulted in advocates referring patients to a clinic worker. Overall lessons learned: training on PS and rights is very important for clinic staff and patients. There is a need for further definition of the role of advocates. The active reporting of safety incidents in a transparent way allows for better planning and ongoing improvement of services. Advocates played key roles in recognizing and reporting issues, leading to resolution and quality improvement. Many of the incidents reported resulted from discussions with patients, emphasizing the importance of patient involvement on patient safety. This all suggests that this type of training programme is both feasible and useful in detecting, resolving and reporting safety issues, but also for developing links between healthcare workers and patients. Embedded advocates in the patient safety framework can lead to improvements in the safety and quality of the healthcare system, and also the patient experience of the healthcare process. Since the pilot, 78 more trainees are being trained.

James Mwesigwa- UPMB: Mr. Mwesigwa who represented the Executive Director of UPMB, explained that patient safety is a personal approach with features including identification of a bad outcome; determining who is at fault; the individual is blamed for the error; the person is told not to do this again and is provided with remedial training and finally the policy language is strengthened. James also described the 7 steps of PS, namely: safety culture; leading and supporting staff; integrated risk management; promotion of incident reporting; the involvement of patients and the public; learning and sharing lessons as well as implementing the solutions. He referenced the 'Swiss Cheese Model' of Risk Analysis (Reason 200) and also explained the Manchester Safety Framework model which was originally developed for use in primary care. He explained the benefits and challenges of such systems

but also recommended that feedback from all levels of the healthcare system (from supra-organizational level to individual level) must be integrated. Feedback can serve to identify system vulnerabilities, which should lead to improvements in the design of those systems.

Pius Ariho-NDA : Mr. Ariho who represented the ES of NDA ,explained the role of the NDA in promoting Patient Safety. NDA was established on a statutory footing National Drug Policy and Authority Act. The NDA ensures the availability of essential, efficacious and cost-effective drugs to the entire population of Uganda. Part of this responsibility is to proactively avoid harms caused by inappropriate drug use by guaranteeing the quality of licensed drugs. The NDA has a number of roles: importation, licensing, registration and distributions, inspection and enforcement and the areas directly addressing patient safety are: licensing and Registration, pharmacovigilance, monitoring of drug use experience and post-market surveillance as well as monitoring and response to problems with products. Health providers are strongly encouraged to report any ADRs, including when there are concerns about the quality of a product. Medicines should only be procured from NDA-licensed companies and distributors. Patients, similarly, should report to their health professionals any problem with their experience of taking the drug. They should avoid self-medicating and should only purchase medicines from approved premises.

Morgan Shimwell- Lecturer NTU: Mr. Shimwell introduced the new WHO Global Patient Safety Challenge 'Medication without Harm' which was launched in March 2017. This strategic framework is specifically focused on medication errors, which are defined by WHO as 'any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient or consumer'. This is a very broad definition that includes medication incidents which lead to severe or moderate harm but also includes 'near misses' which did not lead to direct harms to patients. While referencing the WHO, he explained several aspects including: the cost and causes of medication errors, and the aim of WHO to reduce medication errors by 50% over the next 5 years, the WHO's primary objectives, which in summary, include: determining the scope and nature of the problem, creating a framework for action, developing expert guidance and tools to support medication systems, engaging stakeholders, and, lastly, empowering patients to become actively involved in medication management. On this latter point, patients and the public have been identified as one of the four key problem areas, which translate into four domains of work. The WHO raises concerns about the lack of knowledge that some patients have about medications and medication safety. This problem is compounded by the complexity of medicines themselves, which can be poorly labeled, confusingly named and accompanied by inadequate instructions. Together, this can lead to those who take medicines to be incapable of protecting

themselves against avoidable harms. Rather, they have to rely on health professionals, who are themselves already working in highly pressured, resource-constrained healthcare systems and having to balance their roles in the medication process with wider caring responsibilities. As a response to the WHO Challenge in the UK, the government has since September 2017, through the Department of Health established a working group to develop their own strategy for improving medication safety. In assessing the size of the problem in the UK, the working group has estimated that approximately 235 million medication errors occur each year, at a cost to the National Health Service of £188.4 million each year. Addressing the four domains of work, the working groups' recommendations are, broadly, to increase medication awareness of patients and the public through campaigns and tools, utilizing information technology such as social media. This information should be generated by medication experts before dissemination. It was also recommended that patients are encouraged to be more critical of decisions to prescribe medications, using 5 key questions as posed by the General Medical Council guidelines *Choosing Wisely*:

- Do I really need this treatment?
- What are the risks or downsides?
- What are the possible side effects?
- Are there simpler, safer options?
- What will happen if I do nothing?

The other key strategy to improve health professional knowledge is to partner primary carers with community pharmacists for knowledge exchange and training sessions. Pharmacists would also be linked to doctor's practices to regularly review patient medication records to ensure appropriate, rational prescribing. Again, this would be facilitated using software which would proactively review patient data to identify at-risk patients. The recommendations for reducing medication complexity, particularly labeling and packaging, are to engage pharmaceutical manufacturers in simplifying safety instructions and avoiding the use of 'sound-alike, look-alike' names. Mr. Shimwell suggested that the pharmaceutical industry had more responsibility for this issue than the UK Working Group had implied. However, the industry partnership is a vital part of addressing medication safety.

Mr. Shimwell then introduced what he described as an apparent flaw in the WHO Global Challenge framework: the failure to explicitly address the problem of falsified medicines. Offering an overview of the different terms and definitions which have been used to describe these products, Mr. Shimwell made the distinction between substandard products (those which fail to meet the specifications of the regulatory approved products), falsified medicines (those which intentionally mislead as to the identity, composition and source of the product) and counterfeit medicines (those which infringe intellectual property rights through unauthorized use of brand names or packaging). Whilst there are important safety implications of these different types of product, all present particular risks of patients. In failing to include falsified/substandard medicines within the scope of the Medication without Harm challenge, Mr. Shimwell argued that the WHO had missed an opportunity to coordinate medication safety and falsified medicines activities. The supply and consumption of falsified medicines is largely happening beyond the scope of the global medication safety programme, as it is currently outlined. Whilst accepting the need to try to limit the scope of an already complex programme, falsified medicines can and will have huge implications for medication safety. This is especially so when the WHO appears to be working under the assumption that patients lack knowledge, rely on health professionals to educate them and do not take an active interest in their healthcare. The assumption that patients can access health professionals, and trust them to provide them with, and educate them about, safe and good quality medicines could be proved deeply flawed if the medication safety framework fails to appreciate the dangers of falsified medicines. Further, falsified medicines have their own medication process, which is not visible, is poorly understood and is resilient to regulatory intervention. Excluding this from the strategic framework will only exacerbate these problems.

Mr. Shimwell recommended that those country developing medication safety practices, such as Uganda, seriously consider addressing this omission by incorporating mechanisms to address falsified medicines alongside other medication safety measures. This was especially necessary for programmes to educate patients about medicines and medication safety. Falsified medicines should not be treated as a distinct issue in such awareness-raising campaigns, but should be embedded as another dimension of medication harms.

Prof. Michael Kawooya- ECUREI: Radiation has the potential to damage the cells of the body in a normal course of treatment. It can have 'deterministic' effects (damage to cells) and 'stochastic' effects (damage to genetic material). The use of radiation is on the rise in Africa following the increase in the number of diagnosable cancer and tumor abnormalities. However, this raises questions about the increase in harms suffered by patients. This has led to programmes which attempt to protect patients from harm. Pregnant women and children have been identified as the target population given their increased susceptibility to greater harm from radiation. The first line of protection is to avoid radiation wherever possible by ensuring that radiation treatment is actually needed. This requires patients to be e.g. scanned by ultrasound first. There needs to be better education about what radiation is, where it comes from and why it is harmful – this can allay fears about its dangers. This is complemented by fully informing patients about the benefits of radiotherapy. This should allow patients to make the right choice for them, rather than demanding or refusing treatment inappropriately. AFROSAFE is an African campaign to use ionizing radiation safely. Radiation imaging can be used inappropriately where there is a lack of information and understanding about radiation and its risk/benefits. There are two principles of radiation protection: *justification* (having a clear clinical need to use radiation rather than alternative treatments) and *optimization* (making sure that radiation personnel is trained in minimizing harm and maximizing benefits, by e.g. selecting the appropriate dosage – 'As Low as Reasonably Possible').ESRiGUIDE has been developed by the European Society of Radiology. This has been open to African states free of charge as corresponding members of ESR. This Guide prescribes recommended dosages for countries/regions. Good practice would be to adopt these standards

- In Uganda, the Atomic Energy Regulation Act 2012 is part of the legal framework. This requires that in healthcare facilities there is a trained Radiation Protection Officer; trained personnel for implementing justification and optimization in the facility, use of Clinical Imaging Guidelines, yearly inspections by Atomic Energy Council. The Council will issue a certificate once a facility has been inspected. Good Radiation Facility Practice should also be followed, including appropriate safety equipment and clothing and the use of clear signage in hospital wards.
- There is a range of international standards and recommendations, including the 'Bonn Call for Action' (2012) 10-point objectives. The International Atomic Energy Agency (IAEA) Basic Safety Standards – all countries which subscribe to the IAEA must meet these standards.
- Challenges remain for Uganda for safe radiation practices. These include insufficient risk/benefit awareness; partial adherence to standards; limited safety culture in healthcare facilities; patient self-presentation and self-referral.

In summary, Prof. Kawooya recommended the adaptation and adoption of global standards and recommendation into national standards and guidelines. The principles of justification and optimization must be at the heart of good radiation practice. Finally, it must be remembered that the patient is the best protector of their interests.

Regina Mariam Namata Kamoga: She shared her personal relationship with patient safety and her joining the WHO Patients for Patient Safety programme(PFPS) in 2011. Person-centered care places the values and needs of the patients and families at its center. It also gives power to patients to be involved in the medical process. Importantly, patients are able to raise questions and may be better placed to notice when harmful actions are about to take or have taken, place than busy health professionals. Community engagement is about true partnerships, with collaborative relationships between patients, families and healthcare professionals. This requires relationships of mutual trust and respect facilitated by open, honest communication. Patients can be experts in their own right, with a wealth of experience of their health conditions and treatments. This knowledge and experience should be harnessed by health professionals for more effective treatments.

Patient and family engagement can have benefits for patients, healthcare professional and healthcare providers, including more effective and efficient management of health conditions (especially chronic illnesses), safer healthcare environments, a reduction in the diversion of patients to traditional healers, better trust and confidence in the medical process and reductions in complaints and litigation. CHAIN has engaged and empowered patients and communities on different patient safety issues including medication safety, hand hygiene, injection safety, participation in clinical trials, maternal and child health issues. Its approach is collaborative: with patients, healthcare professionals, healthcare providers, regulators and WHO. CHAIN utilizes a diverse range of activities to raise awareness such as SMS text information dissemination, dramas, music, community outreaches, school debates among others. Patient Safety is being recognized in Uganda and has been prioritized in the National Development Plan 2015/16 – 2019/20 and there is now a global patient safety agenda. However, developing countries need to engage and be engaged in these high-level policy meetings to ensure that policies under development reflect the health needs of these countries.

Dr. Clayton Ó Néill: Patient safety is made up of jigsaw pieces of a number of issues and factors. Patient empowerment and knowledge is just one of them, but others include the increasing duties of care on healthcare providers and a culture of blame and litigation. In the UK, patients are becoming more empowered than ever before and the law is beginning to recognize patient rights to be involved in the decision-making process and to be well informed about the risks and benefits of treatment so that they can decide whether or not to be treated. In English negligence law, the failure to respect those wishes and information needs could now give rise to successful litigation case; following the recent Supreme Court case *Montgomery v Lanarkshire Health Board* [2015]. Traditionally, the English approach to deciding negligence in medical treatment has been very paternalistic. Doctors would only be found to be negligent if it could be proven by the patient that the doctor acted unreasonably according to medical opinion. This was a relatively high standard, meaning that fewer patients were able to bring claims but also, more significantly, contributed to a culture of 'doctor knows best'. There was relatively little opportunity for patients to intervene in the treatment decision-making process, especially when doctors had their own beliefs or recommendations for treatment. This legal approach, which informs clinical practice, was contentious but the change was slow to come. This was in spite of the medical profession, guided by the General Medical Council, becoming more aware of the need for a collaborative approach to decision-making. In 2015 the Supreme Court of England and Wales explicitly criticized any sense of the 'doctor knows best' attitude in the medical profession and the heavily paternalistic tendency in negligence cases. In this case, the Court ruled that a doctor could be found to be negligent if they did not inform patients of 'material risk' before making decisions about

treatment and then went on to suffer harm by the manifestation of inherent risks of the treatment. Material risks are to be assessed by what the reasonable patient would regard as significant, or what the particular patient has expressed as important to the medical professional. This strongly recommends that medical professionals engage in meaningful discussions with patients about proposed treatments, informing them of the risks and benefits of treatments, alternative options but also seeking the patients' views and beliefs about how they want to be treated. In this era of informed consent, patient safety must embrace the empowerment of patients to have a greater understanding of their rights to have, choose, or refuse treatment. Whilst the prospect of negligence is now a reality which exists in the background of the healthcare environment, a patient-centered approach should take important steps to avoid the possibility of litigation. Patients who work closely with medical professionals are more likely to have a better relationship of confidence and trust. It should also lead to 'better' decision being taken by patients, or at least decisions which they are less likely to regret and regard as injurious of their autonomy.

QUESTIONS AND ANSWER SESSION

Dr. Nakwagala facilitating The Question ,answer and comments session

Has the government been asked to review the contentious legislation that has implications for patient safety, particularly the HIV Act?

- *The HIV Act certainly needs review to ensure that HIV positive patients are not unjustly targeted by the criminal law and are able to seek diagnoses and treatment openly and without fear of reprisal.*
- *Public Health Act regulates smoking in public, movement of animals/products during outbreaks of infectious diseases.*

How should the law deal with instances of patients being forced into treatments, such as C-sections or to take particular medicines?

- *Compelled C-sections cases – could be handled by regulators for the medical profession. There is a need to respect the sensitivity of these cases, which are incredibly problematic for both patients and healthcare professionals.*
- *Herbalists and traditional medicines need to be regulated to ensure that the harms do not outweigh the benefits. South Africa has begun to regulate the products and professionals – it may be time for Uganda to take a similar approach.*

Is there a role for legal departments in issues concerning patient safety and reporting? Can incidents be reported to legal departments?

- *The role for legal departments is in raising awareness of rights and duties. This could proactively manage safety issues, incidents and complaints without further recourse to litigation.*
- *Lawyers should be involved in patient safety from the beginning of the healthcare process, rather than being sought at the end when the harm has already been suffered. At this point, their involvement is reactive and can only lead to reprisals. Lawyers should be involved with patient complaints from the early stages to advise how to manage patient needs and expectations, but also to seek the insight of the medical professions who are involved. There must be neutrality at this stage to ensure that justice can be reached before the doors of the court. More often than not, patients want to be acknowledged and their harm recognized by the medical professionals. Litigation rarely brings this result, but is far more likely to result*

in financial compensation and disciplinary actions which is not in the interests of patient or health provider.

- *The patient sues to ensure that the harms that they suffered are not visited upon others. Compensation without systemic learning will not address this aim.*

If it is 'human to err', how does the legal system protect health professional who make errors?

- *Actionable errors must go beyond those actions which a reasonable health practitioner would take. If another professional would take the same steps or make the same omissions, then this will not give rise to liability. Only the most egregious and blameworthy errors should be dealt with by the civil (or criminal) law.*

The NDA regulates conventional drugs, but does is it involved with traditional and alternative drugs? How does the NDA deal with the health implications of these products?

- *Herbalists provide outside-of-the-law products. The NDA tried to engage with these professionals to foster a degree of cooperation, rather than a hostile and combative environment. Sensitization meetings are underway to try to build relationships and to encourage research on the products which are in circulation. This should allow the NDA Enforcement teams to identify those suppliers who are not genuinely concerned with the health of consumers.*
- *The NDA does register and license herbal medicines for sale in pharmacies.*
- Responsible self-medication can be very useful for patients but also for the healthcare system. The important question is: why do patients self-medicate? In what circumstances would this be acceptable and rational?

There is confusion about 'fake' medicines, as compared to 'diverted' medicines e.g. hepatitis vaccines, especially in the media reportage of these incidents, but also by the NDA in its press releases. This has implications for (vaccine) suppliers – a fake vaccine must be removed from supply. But one that is otherwise legitimate could still be supplied to patients. How does the NDA manage this situation?

- *Could not comment on particulars of hepatitis vaccinations. But, clarification is necessary and the perpetrators of pharmaceutical crimes need to be dealt with to restore confidence in legitimate products.*

Does the NDA have a role in ensuring that distribution centers supply particular health facilities and/or charities?

- *The NDA does not regulate how suppliers deal with their buyers. Rather the NDA makes sure that the distributors fulfill their regulatory obligations to ensure that the premises are fit for purpose and the products are stored safely.*

How to report incidents if there is no reporting structure for an institution? How to receive alerts and updates?

- *Reports should be about the drugs themselves. This should not lead to adverse implications for the healthcare worker. Rather, the problem should be with the manufacturers and distributors.*
- *The NDA can be contacted directly. Similarly, the NDA disseminates updates and alerts publicly but may direct some of this information to particular stakeholders.*

How to regulate over-the-counter drugs?

- *The Pharmacy and Drugs Act classifies drug according to safety and risk. Only Class C drugs should be sold OTC. In practice, Class A and B drugs are made available in pharmacies. The Enforcement departments are working in 'high gear' to attempt to close these suppliers to ensure that these drugs cannot be misused. There is an issue about the training and*

qualifications of pharmacy staff to ensure that they are aware of the legal and medical status of the drugs which they are supplying. Working with the professional bodies is an effective means of ensuring that qualified staff working in licensed premise. Failing to hold appropriate qualification can result in pharmacies losing their license.

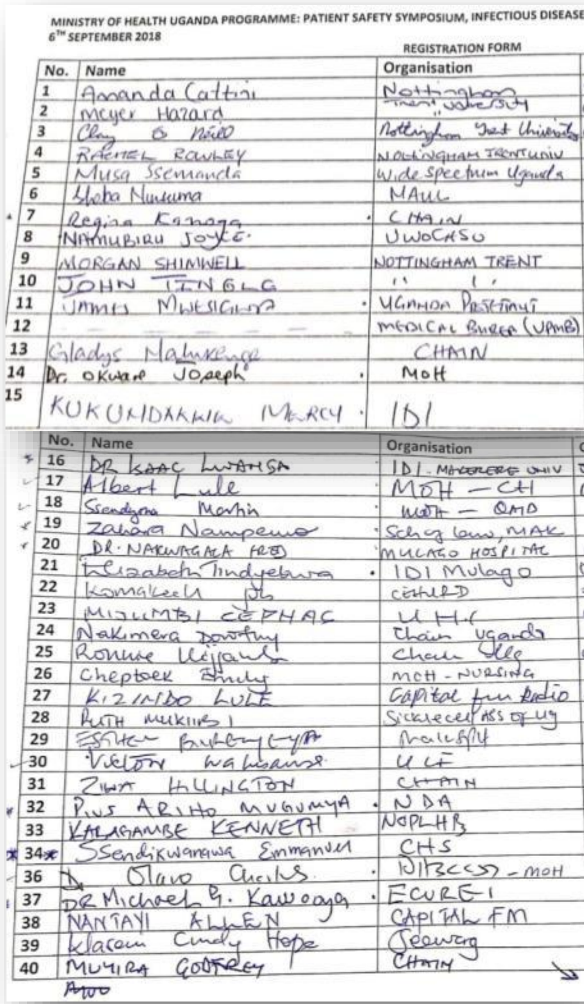
THE WAY FORWARD

- There is a need to be able to identify the patient safety priorities currently facing Uganda. If those prioritizes can be identified and articulated, then progress can begin to be made in developing responses to these pressing issues.
- John Tingle identified a number of recurring themes from the experiences presented in the meeting. Having a robust reporting and learning system seems essential to be able to properly identify and scope and nature of patient safety incidents. Such systems can be voluntary or compulsory: there are advantages and disadvantages to both which have to be weighed.
- Further, attempting to address and dispel a culture of blame in Uganda would remove an underlying obstacle to the development of more open patient safety policies. There are many ways to begin to tackle this culture, not least of which is increased awareness and knowledge of existing patient safety mechanisms, standards and guidelines. Greater collaboration between medical professionals, healthcare providers, regulatory agencies, health lawyers, government ministers, educational institutions, patients and communities is a fundamental strategy paradigm.
- The symposium was a significant step forward towards the development of an inclusive approach to the challenge of patient safety. Safety and quality in healthcare are incredibly complex, multi-dimensional issues, which cannot be dealt with in isolation from the wider difficulties facing healthcare systems. Working towards interventions to improve the management of patient safety requires the collaboration of all interested stakeholders from a variety of backgrounds and disciplines. The sharing of expertise and experiences provides a greater appreciation of the context in which policy development and implementation must take place.
- Whilst the development of a national patient safety regulatory framework is an immediate priority for Uganda, there is also a need to contribute towards the global dialogue on improving patient safety internationally. International health agencies, such as the WHO, have the capacity to bring stakeholders together. However, national patient safety stakeholders have the ability to become regional champions for the development of policy and practice. This can be led by the Ministry of Health, but there is an essential role for civil society organisation such as CHAIN, and academic researchers, which have international reach in their work.
- Uganda can serve as a model to other countries in its innovative approach towards community engagement. This work must be celebrated. This national symposium provided a platform for representatives from community healthcare to engage in a meaningful dialogue with policy-makers, healthcare providers and practitioners, legal professionals, educators and academic researchers. This inclusive framework must continue in the future activities for patient safety improvement.

ANNEX

LIST OF PARTICIPANTS

Participants – Patient safety symposium at IDI, 6th September 2018:



MINISTRY OF HEALTH UGANDA PROGRAMME: PATIENT SAFETY SYMPOSIUM, INFECTIOUS DISEASE
6TH SEPTEMBER 2018

REGISTRATION FORM

No.	Name	Organisation
1	Amanda Cattini	Nottingham
2	Meyer Hazard	Trent University
3	Clay O Neill	Nottingham Trent University
4	RACHEL RAWLEY	NOTTINGHAM TRENT UNIV
5	Musa Ssemanda	Wide Spectrum Uganda
6	Gloria Nuwuma	MAUL
7	Regina Kamoga	CHAIN
8	NAMUBIRU JOYCE.	UWOCASO
9	MORGAN SHIMWELL	NOTTINGHAM TRENT
10	JOHN TINGLE	" "
11	JAMES MWESIGWA	UGANDA PROTESTANT
12	— — —	MEDICAL BUREAU (UPMB)
13	Gladys Malwenge	CHAIN
14	Dr. Okware Joseph	MoH
15	KUKUNDAKWA MERCY	IDI
16	DR ISAAC LWANGA	IDI . MAKERERE UNIV
17	Albert Lule	MOH — CH
18	Ssendyona Martin	MOH — QMD
19	Zahara Nampewo	Sch of law, MAK
20	DR. NAKWAGALA FRED	MULAGO HOSPITAL
21	Elizabeth Tindyebwa	IDI Mulago
22	Komakech [illegible]	CEHURD
23	MIJUMBI CEPHAS	UHC
24	Nakimera Dorothy	Chain Uganda
25	Ronnie Wejjawula	Chain Ug
26	Cheptoek Emily	MOH - NURSING
27	KIZINDO LULE	Capital fm Radio
28	RUTH MUKIIBI	Sicklecell ASS of Ug
29	ESTHER Buhenykya	Malcolm
30	Victor Walusimbi	UCF
31	ZIWA HILLINGTON	CHAIN
32	PIUS ARIHO MUGUMYA	NDA
33	KALAGAMBE KENNETH	NOPLHR
34*	Ssendikwanawa Emmanuel	CHS
36	Dr. Olaro Charles	NRSS - MOH
37	DR Michael G. Kawooya	ECUREI
38	NANTAYI ALLEN	CAPITAL FM
39	Klacam Cindy Hope	Seewang
40	MUYIRA GODFREY	CHAIN

Aroo

Pictorial

Regina Mariam Namata Kamoga making her presentation

Associate Prof. John Tingle – Lecturer NTU and other participants from NTU listening to presentations

Dr. Joseph Okware - Commissioner Quality Assurance And Inspection – MoH delivering his speech to the participants.

Dr. Olaro Charles having a light moment with Regina and Martin

Dr. Zahara Nampewo from Human Rights and Peace Centre- Makerere University making her presentation

Dr. Nakwagala facilitating The Question, answer and comments session

Kabagambe Kenneth Executive Director of NOPLHB contributing to the discussion

A participant raising his question to the panel

James Mwesigwa from - UPMB responding to some of the participant's questions.

Dr Joseph Okware highlighting the insights from patient safety symposium.

Dr. Joseph Okware having a light moment with James and Tingle

THANK YOU!