

**Presidential Address – 2016/17**  
**College of Community Physicians of Sri Lanka**



## **Strengthening the health system to improve the quality of care and patient safety**

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Health system is defined as all the activities whose primary purpose is to promote, restore or maintain health (1). The health system includes service provisions, health care institutions and organisational arrangements. It is the product of a diverse range of economic, social, technological, constitutional and political factors. Goals of a health system are maintaining good health, responsiveness to population expectations including respect for patient/client dignity and confidentiality, access to social support networks, and autonomy and fairness in financial contributions.

There are six internationally accepted core functions for strengthening a health system. These include human resources for health; health finances; health governance; health information; medical products, vaccines and technologies; and service delivery (2). I would like to focus on three out of these six functions namely health governance, health information and service delivery. Strengthening a health system comprises three strategies: essential services, a package of high-quality prevention, promotion, treatment and care services available to all (2); population coverage, so that those who are poor and underserved have the same access to essential health services as other people; and responsiveness, quality health services delivered in a timely and confidential manner that ensures dignity and respect for each client. The framework for strengthening health systems focuses on four strategic outcomes: building a consumer focused and integrated primary health care system; improving access and reducing inequity; increasing the focus on health promotion and prevention, screening and early intervention; and improving quality, safety, performance and accountability (3). Of these, I would like to emphasize two strategic outcomes, which are relevant to my topic; quality, safety, performance and accountability of a health

system, and building a consumer focused and integrated primary health care system. Evidence demonstrates that those health systems with strong primary health care are more efficient, have lower rates of hospitalization, fewer health inequalities and better health outcomes including lower mortality (2).

Now I am going to present two practically useful definitions for quality. First definition is Donabedian's framework where he described it as structure, process and outcome (4). Structure is the physical and organizational setting in which care takes place. Process is the method of delivering care while outcome is the result of care. Second definition is based on accountability (5). It consists of two components. First, the obligation of an individual or organization to account for its activities, accept responsibility for them and to disclose the results in a transparent manner. Second, the accountability which is a condition in which individuals who exercise power are constrained by internal norms (rules and regulations within the health system) and external means (external institutions or general public). Healthcare professionals are accountable before the law, the Hippocratic Oath, medical ethics, peers, patients, the public and the government agencies. The quality of healthcare is one that is safe, efficient, effective, patient-centred, equitable and timely. It is described as "doing the right thing for the right patient at the right time with the right results". Therefore, dimensions of the quality can be described as the access to health care, the acceptability of care to the patient, the efficiency with which care is delivered, the effectiveness of the care, the appropriateness of the care, and safety issues.

The World Health Organization ranked health systems according to its quality in year 2000 (6). By

effectiveness, Japan was ranked as number one and by efficiency; France was ranked as number one. Sri Lanka's position was 80 and 76, respectively. I assume it has gone down further now.

Quality and safety is inextricably linked. Quality in health care can be defined as the degree to which its processes and results meet or exceed the needs and desires of the people it serves. Those needs and desires include safety (7). Therefore, patient safety emerges as the central aim of quality. Patient or client safety is the prevention of errors and adverse effects to patients/clients that are associated with health care (8). Medical errors are the failures of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. An adverse event in health care is a clinical incident in which unintended or unnecessary harm has resulted (9). The adverse events can be 'diagnosis related' – a delay in diagnosis or wrong diagnosis, 'treatment related' – error in the dose or method of using a drug, and 'prevention related' – failure to monitor or follow up treatment or other failures of communication or equipment (10).

### **Incidence of adverse events**

In Europe, 8-12% of patients admitted to hospital suffer from adverse events whilst receiving healthcare (11). Twenty five percent of respondents in the European Union survey report that they or their family experienced an adverse event with healthcare. In UK, prescribing or monitoring errors were detected for one in eight patients, with an overall figure around one in 20 for all prescription items (12). In USA, a report revealed that paediatric inpatients medication-related harm occurs in 11 per 100 admissions. Hospital-related harm occurs in high risk neonatal intensive care units (ICU) at a rate of 74 per 100 admissions. Incidence of adverse events among medical ICU and coronary care unit patients was 20%, of which 45% were preventable. Thirteen percent of adverse events were life-threatening or fatal. Most serious medical errors occurred when ordering or executing treatment, especially medications (61%) (13). In Brazil, medication-related incidents in an ICU during the prescription stage was 45.4% (14). In Sri Lanka, we do not have data on the prevalence or severity of adverse events in healthcare. There is a substantial need to explore it. Is it a public health problem in Sri Lanka?

Why do people make mistakes? Several reasons can be given such as deficient leadership and management, poor communication, poor infrastructure, intolerance to

criticisms, deficient skill bases, poor team work, unmotivated staff, diffusion of responsibility with multiple individuals and departments involved in the care of the patient, inadequate systematized and formalized procedures and protocols, and preoccupation with targets and goals other than quality. There are two general approaches to assess the causes of poor quality. One is an individual failure while the other is system failure (15). Many clinical conditions, treatments and interventions are hazardous. Many patients are in vulnerable biophysical states; people being fallible, make mistakes frequently. Therefore, defences are built into the patient care processes and the organizations providing care to prevent or mitigate these errors. The problem of accidental injury is serious; the cause is not careless people but faulty systems. Therefore, deficiencies in design, organization, maintenance, training and management create conditions in which persons are more likely to make mistakes. The Institute of Medicine (IOM) states "To Err is Human; Building a Safer Healthcare System" emphasizing the need for system reforms (16). The system approach emphasizes that the same situations provoke the same errors regardless of who is involved. There is no single best way to prevent error. To protect against errors, health systems establish processes, rules, procedures, regulations and organizational culture. We need to re-design our systems and patients safety must become a national priority.

### **Healthcare quality improvement methods in Sri Lanka**

Up to 2009, the main focus on improving quality was through implementation of 5S concept and improving productivity. The Ministry of Health (MoH) guidelines were issued in 2010 (17). According to this guideline, the following were to be established: a quality management unit (QMU) within each hospital and work improvement team (WIT) in each ward/unit. The quality management team consisting of the hospital director, QMU staff and leaders of the WITs serves as the decision making body. This guideline highlighted three aspects. First is the internal and external customer environment (implementation of 5S concept). Second is the services involving patient contacts such as reception area, immediate service points and frontline services, responsiveness – appointment system, clean drinking water, dining area, clean linen, suggestion box, inpatient care services summary statistics, systematically arranged emergency tray, completeness of the bed head ticket, ward round frequency, functioning ICUs, diagnostic

services-equipment, 24-hour laboratory services, medical/pharmaceutical supplies and equipment management, availability of drugs and mortuary service. Third is the overall quality and safety improvement; infection control – infection control protocols, waste management, medical records, health education activities, leadership and management – training duty list, kitchen management and ambulance maintenance. The MoH established the National Quality Assurance Programme in 2012. Directorate of Healthcare Quality and Safety was established, which also emphasized on the 5S concept. The National Quality Assurance Programme Published ‘Manual for Master Trainers Healthcare Quality and Safety’ in 2015 which included some aspects of safety and responsiveness (18).

### Healthcare quality improvement methods in developed health systems

The quality improvement methods used in developed health systems are incident reporting and analysis, conducting medical audits, monitoring for statistical variation (rate of hospital mortality and rate of wound infection), practice of evidence-based management including use of clinical practice guidelines, accreditation – inspection from an outside independent body of experts to ensure that certain specified standards are being met, and empowerment of patients including disseminating patients’ rights, leadership, and re-certification and validation. However, the last one is beyond the scope of my address today.

### Reporting clinical incidents

Every healthcare organisation should have a system for reporting clinical incidents including near misses. How does incident reporting lead to improved patient safety? Recognizing and reporting the incident and analysis of it, enables to take action to prevent it from happening again. What is root cause analysis (RCA)? It is a process for identifying contributing/causal factors that underlie variations in performance associated with adverse events. Further, RCA is a class of problem solving methods aimed at identifying the root causes of problems or events. It is a process that features inter-disciplinary involvement of those closest to and/or most knowledgeable about the situation. RCA is a tool designed to help identify not only what and how an event occurred, but also why it happened. Understanding why an event occurred is the key to developing effective recommendations. Answering the ‘why’ question helps to

identify root causes to prevent recurrences. The MoH issued ‘Guidelines for Adverse Events /Incident Reporting’ and ‘Guidelines for Reporting of Readmissions’ in June 2016. However, reporting itself is not enough. The MoH accepted as a policy, the importance of incidence reporting through Strategic Framework for Development of Health Services 2016 - 2025 (19).

### Clinical audits

Clinical audits are systematic critical analysis of the quality of medical care, including the procedures used for diagnosis and treatment, the use of resources, and the resulting outcome and quality of life for the patient. An audit is a quality improving cyclical process that seeks to improve patient care by defining standards, collecting data, identifying areas for improvement, making necessary changes, and re-audit to define new standards if necessary. There are several advantages of conducting audits such as maintaining participant and staff safety, maintaining data quality, encouraging teamwork, improving patient care and protecting the reputation of staff. The characteristic of an effective audit can be described as an educational activity, promotes understanding, helps to ensure an efficient use of resources, raises standards, promotes change, a source of information, peer-led, involves patients and based on evidence based practice (20).

### Clinical indicators

Clinical indicator is defined as a measurable element in the process or outcome of care whose value suggests one or more dimensions of quality of care and is theoretically amenable to change by the provider (21). It is a measure of the clinical management and outcome of care. Following are some of the examples for internationally accepted clinical indicators (22): proportion of patients with acute myocardial infarction (AMI) requiring thrombolysis who receive thrombolytic therapy within one hour of presentation to the hospital out of the total number of patients with AMI requiring thrombolysis who receive thrombolytic therapy, urinary tract injury during a gynaecological operative procedures, proportion of induced labour other than for defined indications, proportion of patients undergoing primary caesarean section for failure to progress after a period of labour with cervical dilatation of 3 cm or less, proportion of babies born with an Apgar score of four or below at five minutes post-delivery, proportion of term babies transferred/admitted to a neonatal ICU for reasons other

than congenital abnormality, proportion of patients with a recovery room stay of longer than 2 hours, proportion of in-patients having wound infection on or before the fifth post-operative day following clean surgery, proportion of cancellation of the “day procedures” after arrival and unplanned admission to ICU. Hundreds of validated indicators are available. We need to assess the impact on health and importance for policy making in each indicator. Clinical Indicators have to capture important performance aspects. Nevertheless, there is a need to select valid and appropriate indicators based on criteria. It has to be scientifically sound (validity) and measure (capture) meaningful aspects of quality of care. Construction of an indicator has to be potentially feasible in terms of data availability and be on par with international standards, and the value of the information contained should outweigh the cost of data collection and reporting (23). Using these indicators, we are able to compare the performance of hospitals/medical officer of health (MOH) areas. If the clients have access to relevant, up to date information about health care providers (both public and private), then they can select the best hospital/s and provider/clinician. Therefore, the clients will be able to access transparent and internationally comparable performance data and information on hospitals and other health services. However, the indicators should be nationally consistent and locally relevant.

The MoH had selected 20 indicator-based themes such as sanitation, diet services, neonatal care etc. However, there are differences between internationally accepted indicators and local indicators. Most of those are not clinical indicators. Some are routine job functions of a medical officer and basic requirements for any institution. Some are useful. These indicators should be implemented by QMU and WITs. However, only some hospitals established these QMUs and selected wards in these hospitals established the WITs. Therefore, the coverage is very low and the overall impact is questionable. Sri Lanka College of Microbiologists submitted three indicators namely hand hygiene compliance rates, post-caesarean surgical site infection rate and staphylococcus aureus bacteraemia rates for the MoH in 2014 along with instructions and data collection form (24). However, the level of the implementation is not known. Strategic Framework For Development of Health Services 2016-2025 indicated the need to strengthen the clinical information management system to help in decision-making (19).

## Evidence-based management

Evidence-based medicine (EBM) is the integration of best research evidence with clinical expertise and patient values. Conclusion of a research article may not provide evidence. Quality of evidence is assessed by appraising the research critically, according to acceptable criteria. Every decision will have to be based on a systematic appraisal of the best evidence available in the context of the prevailing values and resources available. Cochrane collaboration is an academic organization, which promotes evidence-based management. Main product of Cochrane collaboration is the Cochrane Library, which is an e-library and the single most reliable source for evidence on the effects of health care. It is the gold standard in EBM and provides access to the most objective information on the latest in medical treatment. It offers high-quality evidence for health care decision-making. Health professionals at all levels including researchers, policy makers, clinicians, care givers and patients benefit from the Cochrane library. However, a study revealed that knowledge on EBM and systematic reviews was poor among our doctors (25). GRADE stands for Grades of Recommendation Assessment, Development and Evaluation. The GRADE is for grading evidence (26). This is acceptable by all guideline developers including the WHO. According to GRADE, there are four levels of evidence (High, Moderate, Low and Very Low) and two categories of strength recommendations (Strong and Weak). According to the GRADE, the level of quality of evidence is independent of the strength of recommendation of a treatment for a patient. Interpretation of GRADE evidence profile is essential to practice EBM. One of the methods of practising EBM is by using clinical practice guidelines. Those are systematically developed statements to assist practitioner and patient; decisions about appropriate health care for specific clinical circumstances that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options (27). The guidelines may be developed by government agencies, institutions, or by the convening of expert panels. Well acceptable methods are available for developing clinical guidelines. Guideline development committees should include individuals from all the relevant professional groups. The group should include individuals from all the relevant professional groups and the patients' views and preferences should be sought such as clinicians, researchers (epidemiologist/ statisticians), service managers, health economists and patients/carers.

The guideline should indicate recommendations and its rationale. It should indicate the quality of evidence and the strength of recommendation according to GRADE. In addition, it should describe the role of patient preferences when a recommendation involves a substantial element of personal choice or values. Tools are available for appraising those guidelines. The AGREE II tool (Appraisal of Guidelines for Research and Evaluation) is an accepted one for appraising guidelines (28). It assesses methodological rigor and transparency in which a guideline is developed. All the guidelines have to be updated. We cannot use the evidence directly from other countries. It should be customized to our patients. Even if the best evidence is available, the settings, health systems, inclusion criteria and/or outcomes may not be relevant or applicable to one's evidence needs. The intervention/s proposed may not be available, accessible or affordable in the context one wishes to use them in. The preferences and values of the people wishing to use the evidence may not necessarily reflect the recommendations in the systematic review.

The use of the best available evidence to inform health policy within the constraints of locally available resources, health systems, values and competing priorities is called 'evidence informed health policy formulation' (29). Health policy that is not well-informed by the best available evidence can lead to errors that adversely affect public health, is wasteful of scarce resources and decreases confidence in health services, leading to poor health and an increase in health inequity. Some interventions do more good than harm. Therefore, those policies should continue. Some interventions do more harm than good and those should be eliminated from the system. Of some, the effect is unknown. We need to promote relevant research to find evidence.

Guideline development will take about two years. Therefore, another method is guideline adaptation. That is a systematic approach to considering the use and/or modification of guidelines produced in one cultural and organizational setting for application in another context (30). Advantages of adaptations are reduced duplication of effort, especially for the systematic review portion of guideline and potentially less time and fewer resources required than for de novo development. For that too, there is a systematic method to be followed.

Using the term 'evidence based' is a fashion. Do we practise EBM or eminence based medicine, which can be described as making the same mistakes with

increasing confidence over an impressive number of years or opinion based medicine or consensus based medicine or profit based medicine? Several academic colleges developed about 90 guidelines in 2008. However, those were not developed by multi-disciplinary groups. This was funded by the Sri Lanka Health Sector Development Project IDA/ World Bank. However, these are not evidence-based guidelines. There was no plan for implementation. Still, those have not been updated. In addition to those guidelines, some public health institutions develop guidelines.

The MoH should have a system/process with the capability to generate evidence and flexibility to incorporate that evidence into practice. Health care professionals, who are able to find, appraise and use knowledge from research as evidence, need to develop the appropriate system to incorporate evidence and build a research culture. Unfortunately, there is no such mechanism in the MoH. An evidence based health service should promote and practise evidence based policy making, evidence based management, evidence based public health, evidence based medicine, evidence based diagnosis, evidence based nursing, etc.

## Accreditation

Accreditation of health services is an external review. Accreditation is a comprehensive review of organizational competencies to deliver reliable outputs or achieve desired results, based on quality standards. To complete this, we need to use a combination of self and external assessments. A specialized quality assurance body should typically conduct this. The aims of accreditation should guarantee quality, provision of better care and effective resource utilization. The MoH formed an Accreditation Council very recently. The Head is the Director General of Health Services. Other members are the representatives from the academic colleges. Therefore, we need health sector reforms to establish an external body. Then, the accreditation of hospitals, MOH areas and field clinics will be possible in the future. Strategic framework has mentioned under the quality of preventive health services to establish a proper accreditation system for public health services (18).

## Patient/community empowerment

Patient empowerment can be achieved by creation of a patient-centred healthcare environment that respects the rights of patients, and treats all patients and their

families with dignity. An increase in patient involvement in healthcare includes the provision of timely, clear and comprehensive information on the health promotion of preventive methods of diseases, efficacy of drugs and other interventions, and clinical outcomes. There are charters, acts on human rights and patients' rights in other countries. Examples: The Australian Charter of Healthcare Rights, a Declaration on the Promotion of Patients' Rights in Europe 1994, European Charter of Patients' Rights 2002, Patient Rights (Scotland) Act 2011. Health rights are comprehensive, including patients/clients being treated (management) with care, obtaining consent and respecting dignity without discrimination, obtaining a second opinion, accessible to medical records/files from the doctor or hospital, complaining about their treatment and having their complaint dealt with appropriately. Patients are fully informed of the costs of any medical procedure proposed, including any further cost associated with rehabilitation, and contact relatives and clergy for support and to discuss problems. Adequate doctor-patient communication with shared decision making is important. There should be a mechanism for making complaints about their treatment or care and investigations to be done by an independent external committee (31). Family Health Bureau has made progress by proposing client exit survey to quality assessment tool and education of clients on their rights.

## Leadership

Strong leadership is needed to ensure the safety culture. All health staff are to work to avoid causing unjustified risk or harm to the patients, to produce favourable clinical outcomes and to follow procedural rules. However, there are no directors in some hospitals. They are released for postgraduate training while holding substantive post. It compromises accountability. There are enough allegations that some administrators misuse their power, facilities, properties and resources in the government for private purposes. Everybody knows that there are informal roster hours among some doctors and some do private practice during working hours including specialists and academics. They provide facilities to their private patients in government hospital, in collaboration with other units, laboratories and paramedical staff in order to promote their private practices. Further, there is maldistribution of medical officers across the hospitals. Some out-patient departments have more medical officers than the stipulated carder positions. Still, there are some irregularities in transfer schemes. All these reflect poor administration in our healthcare

system. In this context, I would like to talk about clinical governance. It is a framework through which the organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish (32). It encapsulates an organisation's statutory responsibility for the delivery of safe high quality patient care and it is the vehicle through which accountability of performance is made explicit and visible. In order to become a learning organization, a hospital must have a fair and just safety culture, a strong reporting system and a commitment to put that data to work by driving improvement. The safety culture of a hospital is the product of individual and group beliefs, values, attitudes, perceptions, competencies and patterns of behaviour that determine the organization's commitment to quality and patient safety (33). Managerial and clinical leadership and accountability as well as the organisation's culture, systems and working practices ensure that probity, quality assurance, quality improvement and patient safety are central components of all activities of the health care organisation. Clinical governance comprises eight important elements. Those are EBM, continuous professional development, clinical guidelines, clinical risk management, clinical audits, performance assessment, analysis and interpretation of information on current practice, and research and development.

Quality improvement methods can be categorised into two approaches. First one is the administrative approach to change the structure of the health system. The administrative approach comprise 5S concept and health reforms such as primary health care reform to reduce demand on the hospital system, introducing e-Health, electronic prescribing and electronic health record. It will help patients experience smoother transitions between health care providers, reducing waste and inefficiency and enable better and safer care that is more responsive to patients' needs. Second one is the epidemiological approach to change the process and outcome. The epidemiological approach comprises what I presented earlier, the use of clinical indicators and analysis, medical audits, clinical practice guideline, human/patient rights and clinical governance. To minimise the gap between the developed health systems and Sri Lankan health system in terms of quality, implementing the strategic plan for 2016-2025 is optimistic (18). However, the implementation will be a challenge in the present administrative and cultural context of our health

system. Provision of dedicated professional leadership for developing the health system is essential. The College of Community Physicians of Sri Lanka is ready to contribute to that improvement.

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