

**December  
2013**

**EVALUATION OF THE APPROACH  
TO  
CHRONIC KIDNEY DISEASE OF  
UNKNOWN AETIOLOGY**



**GMOA**

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## Executive Summary

Sri Lanka experiences an emerging disease entity, over twenty years, mainly affecting the kidney. Even though the official prevalence is not available, it is endemic in some parts of North Central Province and now geographically extending to Uva, South, East, North West and even to the North. Authorities have failed to declare the morbidity data, and at least the mortality, which is probably significantly escalating.

This issue is primarily a health issue with multi-sectoral relevance. Health authorities have taken two steps to date. One is to establish and enhance few treatment units in and around Anuradhapura. Secondly, launching several research projects in collaboration with WHO, one after another, with the aim of detecting aetiology of this emerging disease.

In addition, health authorities have a responsibility to contribute to other sectors in their decision making, in order to safeguard the health concerns of the public. Fields of agriculture, irrigation, trade, water supply, social services and education etc, are depending on the expert opinion of health. Government policy on agrochemicals is one such example of high value. However, these tasks are performed mostly by health administrators than by the medical experts in the relevant field, without reaching adequate consensus.

Patient care delivery is not essentially aetiology-based. Aetiology of Epilepsy, Diabetes mellitus, hypertension etc, is not clear worldwide. Still patient-care is delivered using Evidence Based Approach (EBA), instead of an aetiology based approach. Evidence models are best developed by clinical epidemiologists. However, no such initiative is taken up to now by Sri Lankan health authorities.

By evaluating the current context, we wish to strongly recommend initiating a Public Health strategy to address this dangerous situation. Clinical care and research need to be guided by the findings of this public health strategy for a focused outcome.

Despite media, politicians and public, who expressed concerns over more than 10 years, health authorities have failed to recognize CKDu as a national health priority. Budget 2014 made financial allocations for safe water supply to CKDu endemic areas. It is said that 13 people are dying daily due to this deadly ailment. Still health authorities have not even initiated surveillance for CKDu. The same health structure does surveillance for polio, which was almost eradicated 20 years ago. As such, it is simply due to lack of vision and commitment of the health authorities towards CKDu, for reasons unclear to us.

We hope these twelve proposals would create a good platform for brainstorming, planning, implementation and periodic reviews in order to address CKDu better.

**Proposal            01**

**Establish a comprehensive health programme on CKD due within the Ministry of Health**

Present health care system of the country is not oriented towards responding to this national issue. Hence a comprehensive health programme should be established as a fresh approach within the Ministry of Health in order to facilitate the implementation of targeted interventions to control and prevent CKD due.

**Proposal            02**

**Develop strategies to prevent and control CKD due based on the best available evidence**

An evidence based approach will encompass a rational decision making process by taking the best available evidence, experience of the clinicians and patient attributes into consideration.

**Proposal            03**

**Establishing a surveillance system for Chronic Non-Communicable Diseases**

A surveillance system dedicated for CKD due will facilitate a better understanding of the nature of the illness, the disease burden and its risk factors. In addition, such a system will help to evaluate the effectiveness of the interventions done which has a relevance to CKD due.

**Proposal            04**

**Establish a common research agenda to streamline scientific research conducted with the funds of the government sector institutions**

Published scientific literature reveals that there is no consensus over the findings in relation to aetiology or the cause of the disease. Due to the discrepancies of the methodologies adopted a meta-analysis is also not possible.

**Proposal            05**

**Establish a mechanism for collection of specimens needed for further evidence gathering for CKD due**

Biochemical, histological and hematological Specimens collected from the public, patients and from postmortem specimens will provide valuable evidence for a definitive aetio-pathogenesis of the illness.

**Proposal            06**

**Improving the resources available for laboratory diagnosis for evidence gathering on CKD**

A mechanism to collaborate the College of Pathologists, College of Forensic pathologists and other relevant professional organizations should be established in order to strengthen the process of laboratory diagnosis. The necessary resources should be allocated for the Medical Research Institute (MRI) and for the other related laboratories (eg: Industrial Technology Institute – ITI, Government Analyst Department) for the analysis of the samples collected.

**Proposal            07**

**Redefining safety regulatory guidelines for water, food etc., in relation to dissolved materials**

Sri Lankan standards for safe water should be established. Analysis of water, Food and agro chemicals should be done regularly and the relevant legislations should be redefined to encompass handling of water, food and agrochemicals and for a mechanism of certifying organic food products.

**Proposal        08**

**Establish a CKDue advocacy initiative through the Health Education Bureau to facilitate health Promotion initiatives.**

Establishment of a core group for advocacy initiatives, development of new Health Promotion material based on scientific evidence available and formation of a systematic strategy to disseminate health promotion information to the public are mandatory components of a public health approach.

**Proposal        09**

**Program to look after the children who lost their parents due to CKDue.**

A multi sectorial professional approach in collaboration with relevant stake holders will address the physical, psychological, educational and financial needs of the children and youth who have lost their parents due to CKDue.

**Proposal        10**

**Building the capacity of the Ministry of Health to contribute adequately to other health related sectors in order to safeguard health concerns of the public.**

Government sector institutions concerned with agriculture, trade and industry need to take health into account as an essential factor when formulating their policies. The expertise needed should be provided by the Ministry of Health. These sectors should be accountable for the health consequences of their policy decisions.

**Proposal        11**

**Appointing clinicians with expertise in toxicology to support the CKDue public health programme**

The expertise of clinicians qualified in Toxicology (MSc in Toxicology at the PGIM) should be utilized for the public health care programme against CKDue.

**Proposal        12**

**Enhancement of the Curative Settings at the local level**

The local health infrastructure needs strengthening at all levels of care. Whilst enhancing the capacity of secondary and tertiary level institutions, the primary level also must be strengthened to provide continuous care close to home.

Editors

## **Proposal 01**

### **Establish a comprehensive health programme on CKD due within the Ministry of Health**

#### ***Background:***

CKD due is a significant health problem in Sri Lanka with increasing prevalence, healthcare costs and poor health outcomes. Nevertheless, the current health system is not yet oriented towards responding to this national issue. There is an urgent need to identify and implement a national strategy to be responsive to the country's need. An effective response to this significant health problem can best be attained through a well-structured public health programme. Such a programme can enhance health system capacity to meet challenges imposed by this health issue and ensure good health outcomes for people.

Establishment of a sound public health programme for Chronic Kidney Disease would facilitate the implementation of targeted interventions to prevent and control CKD due.

#### ***Hence we suggest to:***

1. Declare CKD due as a national health priority.
2. Develop national policy / goals and action plan to streamline efforts and improve outcomes.
3. Establish a focal point for Chronic Kidney Disease in Sri Lanka in the Ministry of Health.
4. Identify the roles and responsibilities of such individuals who hold posts in the above programme.
5. A mechanism for multi-sector monitoring that reflects accountability of other relevant sectors to be instituted (further reference is made in proposal 10).
6. The policies and the strategies need to be governed by a mechanism of administration and accountability

*We hope this proposal would create a good platform for brainstorming, planning, implementation and periodic reviews in order to address CKD due better*

## Proposal 2

### Develop strategies to prevent and control CKD due based on the best available evidence

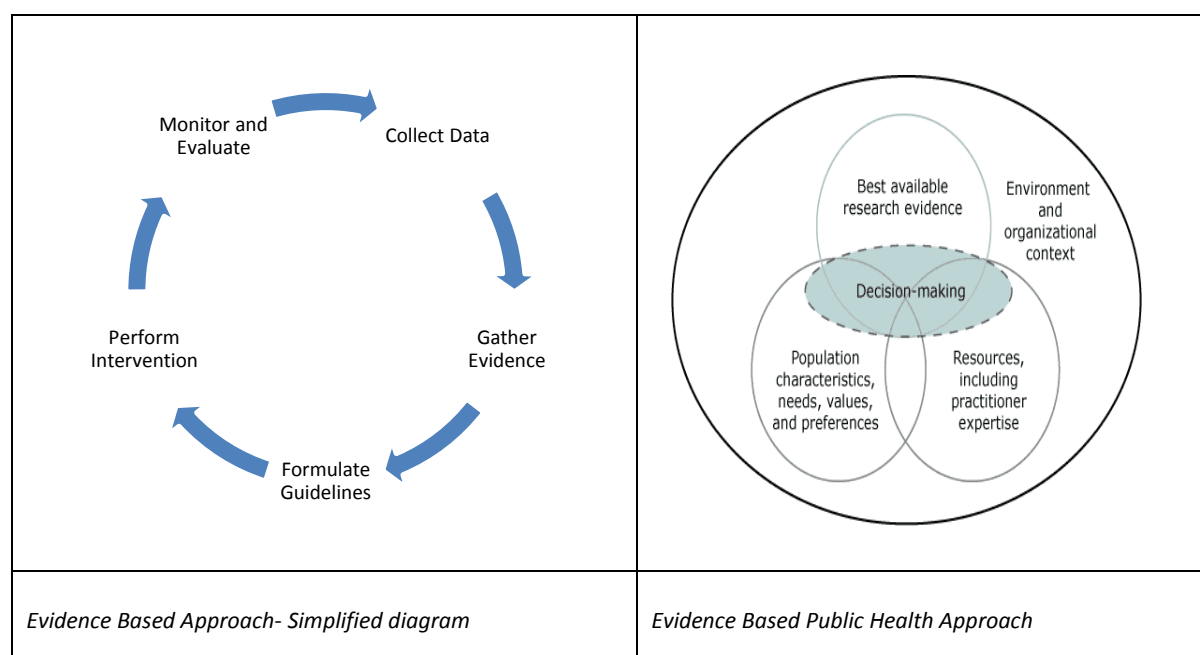
#### Background:

Almost all research done so far are to discover an aetiology. No attempts have been made to combat CKD due from a public health point of view. There is a reasonable doubt that the public health strategy was deliberately ignored.

With regard to CKD due, Evidence based preventive strategies should be developed by clinical epidemiologists. However, no such initiative is taken up to now by Sri Lankan health authorities. It is evident that patient care delivery is not essentially aetiology-based. Though the aetiology of diseases such as Epilepsy, Diabetes mellitus, hypertension is not clear worldwide, still patient care is delivered using Evidence Based approach <sup>1</sup> (EBA), instead of aetiology based approach.

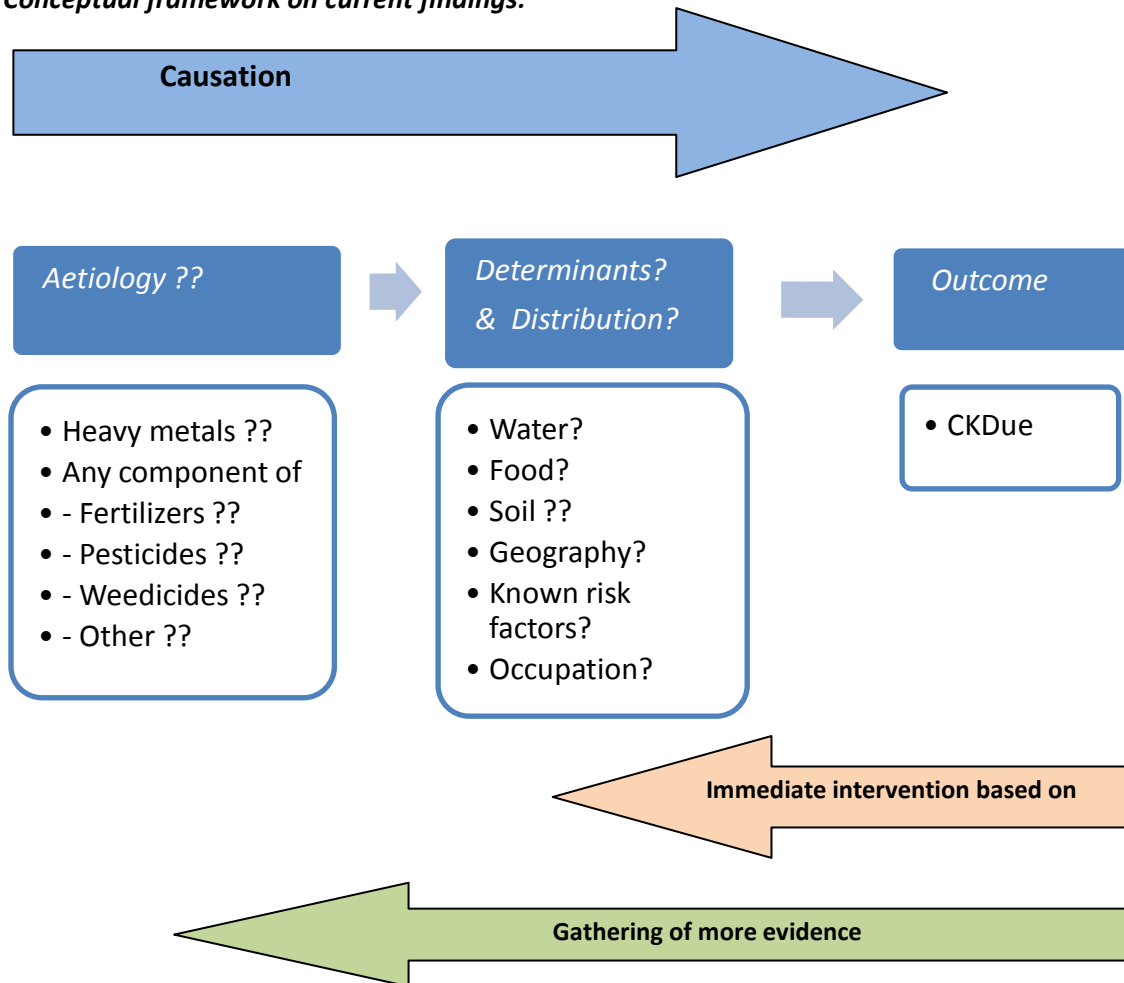
It is more rational to combat this public health burden through an evidence based approach based on the currently available best evidence on “associated factors”/determinants by:

<sup>1</sup> Evidence-Based Approach (EBA) in patient management and Evidence-Based Public Health Approach (EBPHA) in public health decision making could be utilized in combating this issue. EBA encompasses a rational decision making process, taking into consideration the best available evidence, experience of the clinician and patient's attributes. A further step forward will lead the system towards EBPHA which will combine the best available evidence, resources, patients' attributes and environment contexts:





**Conceptual framework on current findings:**



**Hence we suggest that:**

1. Surveying of epidemiological data, such as water sources, food sources, occupations, geographical areas of the affected patients with CKDu with the aim of identifying determinants of CKDu.
2. Dissemination of such information among the public in order to prevent exposure to determinants of CKDu.
3. Planning the interventions according to the potential source.  
Eg:
  - Preventing water usage from sources identified as potential sources
  - Preventing intake of food items identified as potential sources
  - In the event of strong justification, based on geographical risk factors, take measures to evacuate from geographical areas with high disease burden
4. Develop a monitoring and evaluation mechanism to assess the effectiveness of the interventions.

*We hope this proposal would create a good platform for brainstorming, planning, implementation and periodic reviews in order to address CKDu better.*

## Proposal 3

### Establishing a surveillance system for Chronic Non-Communicable Diseases

#### **Background:**

Surveillance is the systematic and continuous collection, analysis, interpretation and timely dissemination of data to plan, implement and evaluate public health activities necessary for effective control of health problems. A surveillance system contributes to control health problems by recognizing the distribution of cases in a population, detecting trends in disease incidence/prevalence, assessing the public health impact, monitoring effectiveness and evaluating the impact of interventions (*Bonita et al., 2006*).

The communicable disease surveillance system of the Epidemiology Unit is well established and has been the key to achieving successful disease control especially with regard to vaccine preventable diseases. One example is elimination of Polio with zero incidence since 1993. An effective surveillance is still being carried out along guidelines of the Global Poliomyelitis Eradication Initiative (*Epidemiology Unit, 2013*). Efficiency and effectiveness of this system is recognized regionally and internationally.

Nevertheless, such a surveillance system does not exist for non-communicable diseases including chronic kidney disease leading to ad-hoc decision making resulting in waste of resources leading to physical and human resource mismatch & financial loss. Since health financing is a local and global challenge a structured mechanism should be in place to avert such waste of resources.

It is timely to establish a comprehensive surveillance system for chronic non-communicable diseases which dominate as diseases causing the highest burden of ill health in the population (*Wickremasinghe, 2013*).

A surveillance system for chronic non-communicable diseases would facilitate;

- A better understanding of the nature and extent of the burden of chronic NCDs and its risk factors overtime to inform policy decisions.
- Evaluation of the effectiveness of interventions to prevent, detect and manage chronic NCDs including CKD.

The surveillance system will gather information on all important manifestations of a disease; epidemiological data: timing of disease, location, persons affected and at risk; magnitude and severity, to guide policy and medical and public health action. For chronic illnesses like CKD, in addition to enumerating cases, information on progression of the illness and its complications also need to be collected (*Powe et al., 2009*).

***Hence we suggest to:***

1. Establish a national surveillance system for CKDue.
  - a. Implementation of this must be handed over to the Epidemiology Unit, which has the technical competency in surveillance, ideally under the purview of Deputy Director General of Public Health Services. This surveillance system must provide information on baseline data, disease trends in terms of morbidity and mortality
  - b. This system must be utilized to provide information on the impact of interventions implemented and provide evidence for policy and funding.
  - c. It is strategically important to place all surveillance systems within one accountable unit rather than establishing fragmented surveillance systems in different units as it allows collation of data from different sources and generating more valid evidence. It is also a long term investment for developing public health expertise in designing and maintaining different surveillance systems that is fundamental to improve health outcomes.
  - d. Quality assurance mechanism should be in built into this surveillance system.
2. Establish a working committee in the Epidemiology Unit with preventive and curative sector involvement to evaluate the preventive and curative strategies in relation to surveillance, for chronic NCDs including CKDue.
3. Strengthen the Management Information System (MIS) at the hospital level by establishing “Public health units” within hospitals, for which a Consultant Community Physician will be appointed in future. Specialists of the Public Health Unit could supervise the record room functions in addition to other public health related activities within the hospital.
4. Strengthen the Management Information System (MIS) at the district level through the District Consultant Community Physician. The MIS at the district level must have a mechanism to collect data from the private sector and other relevant health care providers.

*We hope this proposal would create a good platform for brainstorming, planning, implementation and periodic reviews in order to address CKDue better.*

## **Proposal 4**

### **Establish a common research agenda to streamline scientific research conducted with the funds of the government sector institutions**

#### ***Background:***

Published scientific literature is mostly appraised individually with limited efforts at amassing evidence especially with reference to CKD. Furthermore, the analysis of much of the available literature reveals that there is no consensus over the findings in relation to the “aetiology” or the cause of the disease. The extracted findings suggest the following as possible “associated factors” and the possibility of a “multifactorial” origin.

- Water
- Food
- Occupation
- Geography
- Agrochemicals
- Other

A meta-analysis is not possible due to the discrepancies of the methodologies. As a result, the fact whether the expected objectives are achieved is questionable.

#### ***Hence we suggest to:***

1. A group representing experts and all stakeholders should be formed by the Ministry of Health to identify priority areas for research based on scientific methodology guided by the surveillance data. The transparency of the process is mandatory with research teams required to be accountable to the government and the public.
2. Form an advisory panel with necessary qualifications from the Ministry of Health to promote collaborative research.
3. Periodic research symposia should be organized by the Ministry of Health with collaboration of other sectors to engage relevant experts to evaluate research evidence, to disseminate findings and to inform policy directives and action.

*We hope this proposal would create a good platform for brainstorming, planning, implementation and periodic reviews in order to address CKD better.*

## **Proposal 5**

### **Establish a mechanism for collection of specimens needed for further evidence gathering for CKDue**

#### ***Background:***

Collections of specimens are needed for hematological, biochemical and histo-pathological investigations. These investigations need facilities in the form of equipments, request forms, trainings for collection of specimens. Furthermore, the latter form of investigation can be done in post mortems as well. Carrying out post mortems reveal many covered evidence of the cause of death. Uncovering them by conducting post mortems would guide the planning of interventions to address the identified “risk factors” and “associated factors”. A post mortem requires the consent given by the relatives as well as the resources for conducting it.

#### ***Hence we suggest to:***

1. Establish a mechanism to collect specimens for further evidence gathering for CKDue.
  - a) The stipulated mechanism should include the collection of specimens from the patients, who undergo treatment, as well as the collection of specimens from the postmortems.
  - b) A circular should be issued indicating the mechanism.
2. Increase the resources available at the hospitals in the area to hold post mortems.
3. Further develop the capacity of the medical officers of the area to carry out post mortems.
4. Facilitate the process of giving consent by the relatives by educating the public on benefits of post mortems for planning of interventions.

*We hope this proposal would create a good platform for brainstorming, planning, implementation and periodic reviews in order to address CKDue better.*

## **Proposal 6**

### **Improving the resources available for laboratory diagnosis for evidence gathering on CKD**

#### ***Background:***

Laboratory diagnosis includes rational usage of hematological, biochemical, radiological or histopathological investigations. Efficient utilization of these investigations include a chain of events commencing from the correct decision to investigate, correct collection techniques, correct storage of specimens, correct transport of specimens, standardized analysis of the specimens and timely report generation.

#### ***Hence we suggest to:***

1. Establish guidelines for investigation of suspected chronic kidney disease patients under the chain of events mentioned above.
2. Establish a mechanism to collaborate the College of Pathologists, College of Forensic pathologists and other relevant professional organizations to strengthen the laboratory diagnosis.
3. Allocate resources for Medical Research Institute (MRI) and related laboratories (eg: Industrial Technology Institute – ITI, Government Analyst Department) for investigations of those samples
4. Improve laboratory procedures for CKD reporting as part of the surveillance system.

*We hope this proposal would create a good platform for brainstorming, planning, implementation and periodic reviews in order to address CKD better.*

## **Proposal 7**

### **Redefining safety regulatory guidelines for water, food etc., in relation to dissolved materials**

#### ***Background:***

The maximum concentration limits of dissolved materials in water and food must be revisited and redefined according to the context. In demarcating most of those cut-offs, Sri Lanka depends on the global literature rather than on local literature. For the safety of the public, the specimen collection instruments and necessary facilities must be available adequately to conduct investigations.

#### ***Hence we suggest to:***

1. Establish Sri Lanka specific tolerance levels for metal concentrations in relation to water, food etc.
  - a. The Ministry of Health should take the initiative in preparing the specific tolerance levels.
  - b. These tolerance levels should be decided with consultation of all relevant professional organizations.
  - c. These tolerance levels should be published in the Ministry of Health website.
2. Improve facilities for analysis of water, food and agrochemical samples
3. Redefine the legislations related to the handling of water, food and agrochemicals and for a mechanism of certifying organic food products.

*We hope this proposal would create a good platform for brainstorming, planning, implementation and periodic reviews in order to address CKD better.*

## **Proposal 8**

### **Establish a CKDue advocacy initiative through the Health Education Bureau to facilitate health promotion initiatives**

#### ***Background:***

Advocacy initiatives have to be developed to engage the relevant policymakers and to sustain such engagement. It is critical to identify relevant policymakers and stakeholders who have responsibility for CKDue management; to communicate strategies for CKD prevention and control and to align CKDue programme with their objectives; and to develop sustained relationships. Considering the multifactorial determinants of CKDue it is imperative to engage relevant sectors to create an environment conducive to promote health.

Health promotion means “enabling people to improve and take control over their own health”. This goes beyond “absence of disease”. Health promotion would include building healthy public policy, environmental facilitation, capacity development, resource mobilization and re-orientation of health services. Messages and materials for health promotion of the public play a crucial role in the success of interventions in public health problems. New methods are practiced currently, aiming for behavioral change, not only limiting to delivery of health messages, like Behavioral Change Communication (BCC) and Communication for Behavioral Impact (COMBI) methods. However, empowerment of people to make necessary behavioral changes can only happen in an enabling environment which can be created with correct advocacy, as mentioned above.

#### ***Hence we suggest to:***

1. Establish a core group for advocacy initiative
2. Development of new Health Promotion material, based on evidence
3. Formation of a systematic strategy to disseminate health promotion information to the public.
4. Utilization of new developments like Behavior Change Communication (BCC) and Communication for Behavioral Impact (COMBI) in health promotion

*We hope this proposal would create a good platform for brainstorming, planning, implementation and periodic reviews in order to address CKDue better.*



## **Proposal 9**

### **Program to look after the children who lost their parents due to CKD**

#### ***Background:***

CKD has given rise to many social problems where children of the affected families also suffer.

The morbidity and death of parents or elderly family members and neighbors is a traumatic experience for children and youth. This is frightening even for adults, and the devastation to the familiar environment (i.e., home and community) can be long lasting and distressing. While coping with challenges, due to issues associated with CKD and its outcome, some children have been relocated to safer places away from their families.

These factors present a variety of unique issues and coping challenges like death of a parent or close relation, economic pressure especially when there is a patient at home who needs medical attention, which children can't manage by themselves, and need help with a multi-sectoral professional approach. A social intervention is advocated in collaboration with the government stakeholders in social service provision.

#### ***Hence we suggest to:***

1. Establish a professional support center with experts in relevant fields to support these affected children.
  - a. Collection of data regarding affected children by relevant local authorities to identify their potential needs.
  - b. The support center should be able to address the physical, psychological, educational, financial and other relevant needs of the affected children.
  - c. Ensure a safe environment for children.
2. This professional support center should develop a mechanism to encourage guided donations.
3. Functions of this Centre should be closely monitored by local health and related professionals, such as Paediatricians, Psychiatrists etc.,

*We hope this proposal would create a good platform for brainstorming, planning, implementation and periodic reviews in order to address CKD better.*

## **Proposal 10**

### **Building the capacity of the Ministry of Health to adequately contribute to other health related sectors in order to safeguard health concerns of the public**

#### ***Background:***

Healthy public policy is characterized by “an explicit concern for health and equity in all areas of policy and by accountability for health impact.” CKD management is linked with several governmental and non-governmental institutions.

Government sector institutions concerned with agriculture, trade and industry need to take into account health as an essential factor when formulating policy. These sectors should be accountable for the health consequences of their policy decisions. They should pay as much attention to health as to economic considerations.

#### ***Hence we suggest to:***

1. Review the legal framework to ensure healthy public policies in relation to CKD, within other sectors, to make them equally responsive to the CKD management.
2. Representatives of the Ministry of Health who participate in forums organized by other ministries/organizations should have the necessary technical expertise to effectively contribute to the process.

*We hope this proposal would create a good platform for brainstorming, planning, implementation and periodic reviews in order to address CKD better.*

## **Proposal 11**

### **Appointing clinicians with expertise in toxicology to support the CKDue public health programme**

#### ***Background:***

Currently the Post Graduate Institute of Medicine conducts a Masters Degree course in Toxicology. As many toxins have been implicated as possible aetiological agents these experts can contribute to the CKDue management framework.

#### ***Hence we suggest to:***

1. Appoint clinicians with expertise in toxicology to support the CKDue public health programme, so that their expertise can be utilized to combat CKDue.

*We hope this proposal would create a good platform for brainstorming, planning, implementation and periodic reviews in order to address CKDue better.*

## **Proposal 12**

### **Enhancement of the Curative Settings in the local level**

#### ***Background:***

Although local hospitals have been improved to accommodate the growing number of CKD patients, there still remains a considerable demand over supply in delivery of healthcare in the affected regions. The local health infrastructure needs strengthening at all levels of care. Whilst enhancing the capacity of secondary and tertiary level institutions, the primary level also must be strengthened to provide continuous care close to home. These institutions must be equipped with adequate human and other physical resources.

#### ***Hence we suggest to:***

1. Clinic facilities should be improved with special emphasis on clinics at primary care institutions to provide individualized care.
  - a) Provide facilities for dialysis and transplant to meet the demands.
2. Ensure adequate and timely supply of quality drugs, medical equipment and other physical resources.
3. Provide adequate specialist medical care in local hospitals in Nephrology and related fields

*We hope this proposal would create a good platform for brainstorming, planning, implementation and periodic reviews in order to address CKD better.*

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