3.9 RESEARCH PROGRAMME FOR CHRONIC KIDNEY DISEASE OF UNKNOWN AETIOLOGY IN SRI LANKA

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Research Programme for Chronic Kidney Disease of Unknown Aetiology in Sri Lanka

Chronic Kidney Disease (CKD) is often combined with poor health outcomes and high economical cost. As discussed in the previous issue, it is now emerging as a global health problem. Sri Lanka is no exception to this trend. The aetiology of CKD varies between countries, but diabetes and hypertension are usually the leading factors, followed by glomerular and vascular causes. However, for a significant proportion of CKD cases reported from some parts of Sri Lanka, especially in North Central, North Western, Uva and Eastern Provinces, aetiology of the disease remains a mystery (CKD of Unknown Aetiology - CKDu).

To resolve this public health issue, the Government of Sri Lanka in collaboration with the World Health Organization has initiated a multisectoral and multidisciplinary research effort built upon on existing information. This coordinated series of research activities is designed to generate conclusive evidence regarding the aetiology within a specified time period to make prevention an option.

National Coordination Mechanism for CKDu Research

To ensure smooth functioning of the research programme, it is of vital importance to outline the functions and responsibilities of different stakeholders. In order to achieve this, three committees have been constituted at different levels namely the National Steering Committee, Management Committee and Scientific Committee with clearly defined terms of reference. In addition to these committees, there is a panel of International Experts providing technical inputs for the conduct of research. They also help in ensuring quality and ethical standards of research together with peer reviewing of protocols, reports and publications. The Epidemiology Unit, Ministry of Health has been given the responsibility of overall coordination.

CKDu - Case Definition

Adoption of a consistent case definition of CKDu will facilitate collaboration of study groups and, sharing and adoption research findings more readily. It is also essential for following trends over time and for cross region comparison. The following case definition has been agreed upon by the Scientific Committee of the National Research Programme. Accordingly, it will be used in future studies on CKD:

A case of CKDu should satisfy all the criteria stated below:

1. No past history of or current treatment for diabetes mellitus or chronic and/or severe hypertension, snake bite, urological disease of known aetiology or glomerulonephritis
2. Normal HbA1C (< 6.5%)
3. BP < 160/100 mmHg untreated or < 140/90 on up to two antihypertensive agents

The staging (Grade 1-4) of CKD will be based on the classification system recommended by the National Kidney Disease Outcomes Quality Initiative but modified for logistic and financial reasons.

A circular has been issued by the Ministry of Health with regard to the definition of CKDu (Circular No. Epid/392/2008/25 dated February 10th, 2009).

CKDu Study Groups

The National Research Programme for CKDu consists of a series of coordinated studies, each of which will potentially contribute to elucidating key determinants of CKDu. However, due to limited resources it is not possible to carry out all the studies listed in the study protocol simultaneously. Hence, the studies were consid-

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ered in order of priority and five studies have been commenced. An update on these studies is given below:

Population Prevalence study

The main purpose of this cross-sectional study is to identify the prevalence of CKDu in selected areas of Sri Lanka. This study is currently being conducted in Anuradhapura, Polonnaruwa and Badulla Districts. A total of 6698 subjects aged between 15 to 70 years (both inclusive) from 22 GN divisions were found to be eligible for this study according to the selection criteria. Representativeness of the study population was assured by strictly adhering to the scientifically sound methodology including sampling procedure. At the beginning of the study, all the selected households were mapped using the global positioning system (GPS). The field assistants were able to interview 6132 subjects (92% of the eligible). Early morning urine samples for albumin creatinine ratio (ACR) were obtained from 4941 subjects (74% of eligible). Those who found to be having urine ACR of equal or more than 30 mg/g were subjected to anthropometric measures, blood pressure measurement and biochemical investigations (serum creatinine and glycosylated haemoglobin).

All the field activities related to this research component have been completed and now we are in the process of identifying subjects with chronic kidney disease of unknown aetiology (CKDu) according to the case definition agreed upon. By identifying the prevalence of CKDu in different areas, this study will help to get an estimate of the diseases burden in the country. Further, the 'cases' identified from this study will be used for a case control study planned for this year and the serum specimens of the subjects currently stored at -70°C at the Epidemiology Unit will be subjected to further biochemical analysis (levels of cadmium, aluminium, lead. fluoride etc).

Hospital Based CKD Registry

The objectives of this registry are to characterize CKD/CKDu populations; to estimate prevalence and incidence of CKD/CKDu based on hospital data; to enable geographic mapping of CKD patients; to help in identifying new areas for special renal studies and to support investigator-initiated research. It has been established in four hospitals in the North-Central Province namely TH Anuradhapura, DGH Polonnaruwa, BH Medirigriya and DH Medawachchiya. At present the registry is having the details of 1997 patients. For each patient in the registry, the database includes information on basic socio-demographics, primary medical diagnosis that led to CKD and treatment details.

Environmental Study

Details of 606 CKDu patients identified from the hospital-based registry were shared with the Environmental Study Group by the Epidemiology Unit of the Ministry of Health. Fifty patients from this list were randomly selected and their houses were visited for sample collection. From each household, 15 - 20 different types of samples were collected (e.g. soil, water, rice, pulses, vegetables, tobacco, fish, milk etc). They were analysed for Cadmium, Lead and Iron using internationally accepted, standard pre-preparation and analysing methods. A total of 670 samples were collected from above households and the analysis was done at the Department of Chemistry, University of Kelaniya. GPS coordinates of the selected households were obtained. Entire dermal, dental and other variations among the patients were recorded and other information such as food habits and water usage were collected.

Pilot Analytical Study (Post-mortem Study)

As the metal analysis is very expensive, this component of the research programme will be conducted initially as a pilot study. The postmortem study is expected to give the direction for future studies on which particular element/s will be focused. Postmortem specimens (kidney cortex, liver and bone) are currently being collected from the following: CKD patients who had dialysis and were residents of Colombo, CKD patients who had dialysis and were residents of North Central Province, healthy adults aged between 40 and 60 years killed in accidents and were residents of North Central Province and healthy adults aged between 40 and 60 years killed in accidents and were residents of Colombo.

The specimens collected will be subjected to trace metal analysis at an international reference laboratory located at the University of Antwerp, Belgium. The "Collaboration and Material Transfer Agreement" between the Ministry of Health and the reference laboratory in Belgium has been already signed. The collected specimens are currently stored at -70°C at the Epidemiology Unit.

Sociology Study

The Disaster Management Centre (DMC) and United Nations Development Programme (UNDP) have supported a sociology study on behavioural patterns of CKD patients..This study also analysed the patterns of water and food consumption, consumption of liquor, smoking and chewing betel, and agricultural practices. Addressing the social and mental wellbeing of CKD patients and their families, improving patients' capacity to seek treatment and looking for practical alternatives for safe agricultural practices were some of the recommendations highlighted in this study.

Fund Mobilization for the National Research Programme

The collaborative national research effort is expected to cost around USD 1 million. To raise the necessary funds, two donor forums were organized by the World Health Organization with the participation of national and international donor agencies. These forums were chaired by the Hon. Minister of Healthcare & Nutrition. As the Ministry of health deemed this issue as a public health priority, the WHO Country Office has managed to raise USD 75,000 by re-programming some of the funded activities. In addition, WHO - SEARO (South East Asia Region) has contributed USD 240,000 up to December 2009. A proposal had been submitted to the Department of National Planning of the General Treasury through the National Science Foundation, which has a mandate to carry out research and development for socio economic development of Sri Lanka for further funding. This effort was successful in securing USD 700,000 for research activities in 2010.

Compiled by Dr. N. Janakan (Epidemiology Unit), Dr. Lanka Jayasuriya Dissanayake (Country Office, WHO) and Sumudu Hewawasam (Field Programme Officer, CKD Research)

Table 1: Vaccine-preventable Diseases & AFP

21st - 27th November 2009 (48thWeek)

Disease	No. of Cases by Province									Number of cases during current week in 2009	Number of cases during same week in 2008	Total number of cases to date in 2009	Total number of cases to date in 2008	Difference between the number of cases to date in 2009 & 2008
	W	C	S	N	E	NW	NC	U	Sab					
Acute Flaccid Paralysis	01	00	00	00	01	00	00	00	00	02	02	68	91	-25.2%
Diphtheria	00	00	00	00	00	00	00	00	00	00	00	00	01	-
Measles	00	01	00	01	00	00	00	01	00	03	00	165	108	+52.8%
Tetanus	00	00	00	00	00	00	00	00	00	00	00	27	36	-25.0%
Whooping Cough	00	00	00	00	00	00	00	00	00	00	01	61	48	+27.1%
Tuberculosis	203	03	64	32	22	39	00	16	57	436	160	9771	7735	+26.3%

Table 2: Newly Introduced Notifiable Disease

21st - 27th November 2009 (48thWeek)

Disease	No. of Cases by Province									Number of cases during current week in 2009	Number of cases during same week in 2008	Total number of cases to date in 2009	Total number of cases to date in 2008	Difference between the number of cases to date in 2009 & 2008
	W	C	S	N	E	NW	NC	U	Sab					
Chickenpox	14	04	09	04	06	13	03	01	03	57	87	14036	5075	+176.6%
Meningitis	08 CB=5 KT=3	01 KN=1	05 GL=2 MT=2 HB=1	00	03 TR=3	08 KR=4 PU=4	00	01 BD=1	06 RP=2 KG=4	32	17	1546	1219	+26.8%
Mumps	06	00	05	01	01	01	00	01	06	21	39	1640	2729	-39.9%
Leishmaniasis	00	00	04	00	00	00	00	00	00	04	Not available*	636	Not available*	-

Key to Table 1 & 2

Provinces: **W**: Western, **C**: Central, **S**: Southern, **N**: North, **E**: East, **NC**: North Central, **NW**: North Western, **U**: Uva, **Sab**: Sabaragamuwa.

DPDHS Divisions: **CB**: Colombo, **GM**: Gampaha, **KL**: Kalutara, **KD**: Kandy, **ML**: Matale, **NE**: Nuwara Eliya, **GL**: Galle, **HB**: Hambantota, **MT**: Matara, **JF**: Jaffna, **KN**: Killinochchi, **MN**: Mannar, **VA**: Vavuniya, **MU**: Mullaitivu, **BT**: Batticaloa, **AM**: Ampara, **TR**: Trincomalee, **KM**: Kalmunai, **KR**: Kurunegala, **PU**: Puttalam, **AP**: Anuradhapura, **PO**: Polonnaruwa, **BD**: Badulla, **MO**: Moneragala, **RP**: Ratnapura, **KG**: Kegalle.

Data Sources:

Weekly Return of Communicable Diseases: Diphtheria, **Measles**, Tetanus, Whooping Cough, Chickenpox, Meningitis, Mumps.

Table 4: Surveillance of Communicable diseases among

21st - 27th November 2009 (48thWeek)

Area \ Disease	Dysentery	Enteric fever	Viral Hepatitis	Chicken Pox	Watery Diarrhoea
Vavunia	10	5	1	4	0
Chendikulam	4	1	0	25	80
Total	**14**	**06**	**01**	**29**	**80**

Table 4: Selected notifiable diseases reported by Medical Officers of Health

21st - 27th November 2009 (48thWeek)

DPDHS Division	Dengue Fever / DHF*		Dysentery		Encephalitis		Enteric Fever		Food Poisoning		Leptospirosis		Typhus Fever		Viral Hepatitis		Human Rabies		Returns Received Timely**
	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	%
Colombo	38	4144	6	234	0	13	3	220	0	90	12	1114	0	6	4	149	0	6	77
Gampaha	34	4147	1	159	0	22	2	48	0	38	10	459	0	9	1	252	0	6	53
Kalutara	8	1479	3	346	0	14	1	61	3	47	9	546	0	1	2	88	0	3	75
Kandy	24	3992	3	301	0	8	0	30	0	61	1	218	3	162	2	136	0	0	44
Matale	17	1873	4	142	0	4	0	32	0	39	1	324	0	5	2	90	0	2	83
Nuwara	8	257	3	399	0	2	3	180	0	803	0	44	1	75	4	95	0	0	92
Galle	11	609	6	243	0	10	0	4	0	111	48	225	0	15	1	33	0	6	100
Hambantota	20	928	1	92	0	8	0	8	1	16	2	92	1	84	0	52	0	0	64
Matara	7	1126	2	260	0	8	0	9	1	27	11	239	0	145	0	66	0	1	88
Jaffna	1	61	1	129	0	3	0	296	0	30	0	0	0	125	0	193	0	4	13
Kilinochchi	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Mannar	0	6	10	110	0	1	2	119	0	23	0	0	0	1	6	75	0	0	100
Vavuniya	49	327	12	1647	0	25	6	698	2	5	0	7	1	6	3	3773	0	0	50
Mullaitivu	0	0	0	2	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Batticaloa	1	565	4	298	0	14	3	22	0	56	0	10	0	5	0	24	0	5	55
Ampara	12	241	3	112	0	1	0	12	0	8	0	14	0	2	2	93	0	0	43
Trincomalee	0	330	10	177	0	4	0	18	0	5	0	20	0	19	0	61	0	1	50
Kurunegala	23	2790	7	267	0	13	0	82	0	15	3	150	1	93	2	168	0	4	75
Puttalam	5	632	2	169	0	7	1	76	00	11	1	93	0	31	0	44	0	1	89
Anuradhapu	0	547	3	136	0	7	0	8	0	42	0	92	0	30	0	197	0	4	47
Polonnaruw	4	191	2	127	0	4	0	21	0	10	0	65	0	9	1	94	0	0	71
Badulla	1	347	1	388	0	5	1	59	0	34	1	95	1	135	0	316	0	1	33
Monaragala	6	174	3	152	0	2	0	24	0	36	0	15	1	68	1	94	0	2	73
Ratnapura	7	2036	0	501	0	20	0	53	2	45	2	350	0	36	11	247	0	2	44
Kegalle	10	3737	0	185	0	9	0	55	0	7	5	313	0	38	7	271	0	1	73
Kalmunai	2	245	0	109	0	2	0	15	0	7	0	7	0	3	0	23	0	0	46
SRI LANKA	288	30784	87	6685	00	206	22	2151	09	1566	76	4492	09	1103	48	6634	00	49	62

Source: Weekly Returns of Communicable Diseases WRCD).

***Dengue Fever / DHF** refers to Dengue Fever / Dengue Haemorrhagic Fever.

****Timely** refers to returns received on or before 27th November, 2009 Total number of reporting units =311. Number of reporting units data provided for the current week: 194

A = Cases reported during the current week. **B** = Cumulative cases for the year.

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