Name of the study: INDIAN PEDIATRIC CHRONIC KIDNEY DISEASE REGISTRY

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1) **Background:**

Chronic kidney disease (CKD) refers to a condition related to irreversible kidney damage that can further progress to end-stage renal disease (ESRD). CKD is a major public health problem worldwide. In contrast to adult wherein extensive epidemiological research is available, little is known about the epidemiology of CKD in the pediatric population. A better understanding of the epidemiology of CKD in children is essential in order to make a precise and early diagnosis, identify preventable or reversible causes of progression, predict prognosis, counseling of the children and their families as well as for proper advocacy regarding need for governmental / society focus on this condition.

True prevalence of pediatric CKD is difficult to estimate, as often CKD in children is often left unnoticed, and is only diagnosed in advanced stages [1]. Thus most population-based estimates represent moderate-severe pediatric CKD / ESRD.

- **Most comprehensive report on Pediatric CKD from Italy, Italkid project, included all Italian children with creatinine clearance less than 75 ml/min/1.73m$^2$ between 1990 and 2000** [2]. They found the mean yearly incidence and prevalence to be 12.1 and 74.7 cases per million children and adolescents below the age 20 years.

- **Other reports on children with GFR<30ml/min/1.73m$^2$ or those with ESRD includes:**
  - **Sweden [3]:**
    - Survey from 1986-1994
    - Incidence and Prevalence 7.7 and 21 per million children between 6 months to 16 years of age
  - **Chile [4]:**
    - Survey done in 1996
    - Incidence and Prevalence 5.7 and 42.5 per million children below the age 18 years
  - **USA [5]:** In 2012, the incidence of ESRD was found to be 13.1 per million population adjusted for age, sex and race.
Etiology:

Congenital causes account for more than 60% of cases of chronic kidney disease in children. Table 1 shows the salient distribution of etiologies of causes of CKD according to NAPRTCS, Italkid and United States Renal Data System (US RDS) data.

Table 1: Etiology of Pediatric CKD

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<td>• Congenital anomalies 57%; most common being obstructive uropathy 21%; and hypodysplasia 18%</td>
<td>• Renal hypo-dysplasia with/without urinary tract anomaly 54% and 14% respectively</td>
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<td>• Non glomerular causes 78% (n=457), with the most common being obstructive uropathy (n=118).</td>
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<td>• Glomerular causes 17%</td>
<td>• Glomerular causes 7%</td>
<td>• Cystic, hereditary and congenital disorders 38.3%</td>
<td>• Glomerular disease 22% with FSGS being the most common cause (n=42).</td>
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<tr>
<td>• Others 25%; within which diagnosis could not be established in 15%</td>
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<td>• Glomerular disorders 23%</td>
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There is data on pediatric CKD from other countries as well including France, Sweden and Kuwait [8-10].
**Data from India**: An initial Indian Pediatric CKD Registry data was presented at the Indian Society of Pediatric Nephrology meeting in 2010. Children with GFR<60 ml/min/1.73m$^2$ were included in the registry. Out of 949 patients, 32% were stage-5 CKD. The most common etiology was obstructive uropathy 24% followed by others and reflux nephropathy. The Pediatric CKD registry is an ongoing effort to collect more epidemiological data for these children in India.

A comprehensive national registry of paediatric CKD is essential as there are no national or regional reports on incidence or prevalence of either CKD or end-stage renal disease (ESRD) among children in India. The true burden of this disease in our country is unknown due to lack of a common definition and absence of nationalized data collecting system. There is a need for a centralized registry to understand the epidemiology of CKD more accurately.

The Indian Pediatric CKD Registry has been set up on behalf of the Indian Society of Pediatric Nephrology with the aim to serve as a comprehensive nationwide data warehouse for studying various aspects of Pediatric CKD. Such an effort would be of value not only for characterization and documentation of the disease and practice patterns, but also for identifying special characteristics in any geographic or demographic group(s), so that tailored prevention or management strategies that appropriately target these groups can be developed. The purpose of the registry is to produce cumulative, chronologically oriented records about children with CKD for epidemiologic and other research purposes. The key to the success of the registry will not lie in technical and statistical details alone, but in an essential spirit of cooperation and commitment among all participating centers.

2) **Aim and Objectives of the registry**

**Aim**

- To collect cross sectional data on paediatric chronic kidney disease (CKD) across India.

**Objectives**

- To encourage reporting of children with CKD across India and maintain a validated robust electronic database.
- To increase the accuracy of estimates of the incidence / prevalence of paediatric CKD in India.
- To improve our understanding of their time and modes of presentation to medical services
- To assess current pattern of care and clinical practices
- To identify any socio-economic, cultural or demographic barrier in their receiving optimum treatment.
- To advocate for equity of access and of optimum quality of care for children with CKD across India
- To support any quality improvement initiative locally / nationally by appropriate use of data collected in the registry. Collaborate with other agencies to develop quality improvement initiatives and ensure best use of data.
- Encourage research by providing aggregate, de-identified data to research entities

3) **Role of participating centers:**

Participating centers shall be enrolled from all over India from members of ISPN, and they shall be requested to submit participating patient’s data on a regular basis. Data shall be submitted to the online CKD Registry.

4) **Benefits of participation for the participating centers**

Center’s contributions of patient data to the CKDRegistry database will benefit all other registry participants, since data are pooled to study spectrum, trends or address specific questions.

The Registry will allow individual centers to:
- Access their own data
- Obtain descriptive summaries/reports of individual center/ pooled data
- It is also planned to generate specific reports (eg: trends, dialysis related analysis etc)
- Research and publications based on registry data will be actively encouraged albeit prior permission from the CKD registry core committee is mandatory.
5) Confidentiality

All patient and physician information submitted to the CKD Registry shall be maintained as confidential.

- Patients will be referenced by Registry ID number only
- No site-to-site data comparisons will be made
- Members of ISPN will be able to see only their own centre’s data. Only the secretariat shall be able to see the whole registry data.

6) Definition of CKD

CKD will be defined as per KDIGO definition by a presence of kidney damage (for example, any structural or functional abnormality involving pathological, laboratory or imaging findings) for ≥ 3 months or a GFR < 60 ml/min/1.73 m² for ≥ 3 months. It is to be noted that the classification does not apply to children under 2 years of age as GFR increases from birth and reaches normal adult values by 2 years of age. Furthermore, children born with major structural anomalies will be considered to have CKD before waiting 3 months for such a diagnosis.

7) Ethical clearance

Although all data submitted will be anonymous participants are encouraged to discuss with their institutional ethical body regarding need for ethical clearance and get appropriate clearance if required

8) Registry Secretariat

Pediatric Nephrology, Kidney Institute, Medanta, The Medicity, Gurgaon

9) Collaborators

All the interested centers shall be enrolled in the study from across India, and shall be asked to fill the online forms. Hard copy options for submitting data are also available for centers opting for it.

8) Funding
The registry is currently funded as a grant from ISPN.

References: