Chapter 2

Methods

Introduction
This chapter describes the methodology of the NKR setup, maintenance and data analysis. The NKR contains patient level data captured on site at the HD unit, which is exported into a national-level data file after stripping patient personal and contact information. Patients and centres in the analysis data file are numerically coded. The database contains adult HD patient's fixed data and monthly updates on dialysis, laboratory, clinical and outcomes parameters grouped into 9 functional modules: demographics, dialysis initiation, dialysis parameters and vascular access, dialysis adequacy, anemia, osteodystrophy and mineral balance, vital signs and anthropometrics, medications and complications and outcomes. Each of the nine modules is saved into an analytic view of the national data containing parameters of that module. A few parameters are used as grouping variables: patient type (incident / prevalent), geographic region, gender, diabetic status and their subset receiving insulin.

Setting
The NKR is a program of the Society of Nephrology and Hypertension, supervised by a scientific committee consisting of nephrologists representing the LSNH (two: President + designated principle investigator), MOPH (1), representative from each medical school in Lebanon (7), representative of the pan-Arab pediatric nephrology association in Lebanon (PAPNA-Lebanon), and the general director of Partners in Wellness and Research (PWR).

The management of the registry is contracted to PWR which employs a research team for that purpose. PWR represent a neutral entity that conducts all contacts with hospitals and nephrologists, database maintenance, updates and quality assurance, data analysis and publication of annual reports.

This format was approved by the LSNH cabinet of 2008-9 when the registry was in development, and reaffirmed by the 2010-2011 cabinet when the registry was launched. The current LSNH cabinet continues to provide topline supervision of the registry conduct with input from the scientific committee. Regulatory and logistical support was provided by the MOPH and the Syndicate of Private Hospitals. Funding has been kindly provided by a number of pharmaceutical companies.

Enrollment of Dialysis Centers
The registry setup at each hospital was coordinated with the main nephrologist and the hospital administration. A package containing copies of the MOPH, LSNH and Hospitals Syndicate letters and the registry concept document were presented to the hospital as a basis to approve registry participation. After institutional approval, internet access was secured at the dialysis unit and database training conducted. HD patients consent to include their data in the registry was requested and the Arabic and English consent forms were placed on the registry website.

All hospitals containing a dialysis unit in Lebanon were approached for inclusion in the registry. Enrollment of institutions and patients started in the last week of March 2011. Most hospitals were contacted, trained and initiated in the registry by the end of June 2011. Currently, 64 of the 66 HD units in Lebanon have a registry account with various degrees of compliance (**Table 3.1**). The HD units at the Military Hospital in Beirut and at the Palestinian Red Crescent Hamshari Hospital in Saida are being processed for inclusion as well.

Enrollment of Patients

All HD patients undergoing maintenance HD for at least 3 weeks were eligible for inclusion. Pediatric patients dialyzed at these adult HD unit were included in the registry and their data analyzed if age > 10 years. Once enrolled, a patient record remains in the registry even after termination of HD (death, transplant, loss to follow or cessation of dialysis). If a patient transferred to a different HD unit, their registry record was switched to the new HD unit account after careful verification and consent by the patient for the transfer of record. Data entered during HD at the old hospital was saved and available for view as "read only" by professional staff of the new HD unit.

Quality Control (QC) and Quality Assurance (QA)

The NKR database was constructed with built-in backup, export and QC / QA processes consisting of two levels:

1. <u>Real-time summary of activity</u>: Provides immediate update of data entry activity summary at each institution: number of patients entered and their status, if dialysis initiation module was completed, total number of monthly updates and average per patient and count and ID numbers of patients reported dead. Also, parameter-by-parameter completion count for the demographic and dialysis initiation modules and a list of IDs of patients with missing data for each parameter.

2. <u>Periodic activity update</u>: Provides an encrypted excel file for each institution generated from a standard analytic view of the exported backup file. The file contains four worksheets:
   a. Complete demographic data – one record per patient, with missing data highlighted
   b. Complete dialysis initiation data – one record per patient & highlight missing data
   c. List of IDs of patients who have no monthly updates
   d. List by month of IDs of patients who have missing updates for that month

The first analysis data file was generated in early June 2012. Preliminary statistics were done to uncover data errors. Missing or erroneous data, extreme values and unit discrepancies in lab parameters were identified and queries generated. Research coordinators worked with the HD units to correct data at the origin. This process was completed end of October 2012.

Laboratory Data

During hospital setup, the way laboratory parameters were reported in the charts was observed. A hospital was assigned as "SI" if they used the International System of Units or "US" if they used the traditional method. Laboratory parameters in the modules were given units that corresponded to the hospital assigned system. We later discovered that such assignment worked well only in few hospitals (purely American-system and French-system hospitals). The remaining majority of hospitals used a mixture of both systems in various proportions. Also, a variety of methods or assays were available to measure certain parameters. It became clear that all possible methods were actually in use … a full-spectrum free market system. These issues will be addressed in the next database upgrade.

We performed comprehensive listings and summaries to uncover problem areas and attempted to correct at the origin. Then we performed conversions where it was obvious. Finally, we dropped extreme outliers and in some situations we applied bilateral data trimming that did not exceed 0.2% of the data to discard improbable extreme values.

Analytic Methods

1. <u>General considerations</u>: Patient data starting January 2011 were originally requested during center enrollment. However, patient records were minimal prior to June 2011 (< 300 patient-months). To perform a more robust analysis, only patient data spanning between

June 1, 2011 and June 2, 2012 were used for analysis to generate this inaugural 2012 report of the NKR.

A patient was included in the analysis if two or more valid monthly updates were entered. There were 1938 patients who met that condition for a total of 16797 patient-months, an average of 8.7 monthly updates per patient (Table 3.2). Geographic grouping was based on the city of location of the HD unit and analyzed based on the five main "Mohafaza" in Lebanon (Beirut, Beqaa, Mount Lebanon, North and South).

2. Patient status / type: Patients who started dialysis on or after November 1, 2010 were considered incident patients (recent starters), while those who started at an earlier date were considered prevalent (earlier starters). It will not be possible to obtain an accurate incidence rate in this inaugural year report, but can be computed starting next year's report.

3. Data transformations and truncations: After possible corrections of erroneous data at the HD unit origin were completed, some adjustments were necessary, especially in the laboratory and medications data. Ceilings and floors were set for parameters using acceptable values for the HD population. Data transformations were made for data with obvious context (ex. Monthly dose of IV iron, a value between 1 and 6 was multiplied by 100, assuming that the number of ampules was entered instead of their mg content). Below are key deletions or transformations that were applied to laboratory and dialysis data:

Table 2.1 Data deletions and transformations used in key parameters

Parameter	Lower Limit	Adjustment Applied	Upper Limit	Adjustment Applied
Pre-BUN	<5	Delete	>300	Delete
Post-BUN	<2	Delete	>100	Delete
Kt/V	2-5	Delete	>20	Delete
	>5	Divide by 10	<20	Divide by 10
IDWG (kg)	<0.5	Delete	>8	Delete
Hb	<5	Delete	>18	Delete
			>= 50	Divide by 10
Serum Iron	<5	Delete	5 - <15	Multiply by 5.6
TIBC	<25	Delete	>500	Delete
			25 - <60	Multiply by 5.6
Calcium	1.5 – 4	Multiply by 4	45 – 180	Divide by 10
Phosphorous	<0.8	Delete	>85	Delete
	0.8 – 2.5	Multiply by 3.1	25 – 85	Divide by 10
Potassium	<2.5	Delete	>=80	Delete
			25 - <80	Divide by 10
iPTH			>3000	Delete

As indicated earlier, deletion of values in any parameter did not exceed 0.2% of total patient-months measured. Transformations generally aimed to convert mmol/L or mEq/L values into mg/dl or in some cases conversion of mg/L into mg/dl. Module-specific adjustments will be described in the corresponding chapters.

4. <u>Duplicates</u>: Several analytic checks were made to detect duplicate records (name, telephone # and birthdate) prior to the generation of the encrypted analytic file.

5. <u>Missing Data</u>: Decisions for missing monthly update information were made on a parameter-by-parameter basis. Some parameters were captured every 3, 6 or even 12 months. Data for other parameters was entered on event occurrence only. Most missing data occurred in parameters that were captured either monthly or every dialysis session.

Data Confidentiality and Security
The NKR database recognized and instated confidential and secure access to patient information at the institutional space. Access to the backup and export files was restricted to only two people and protected by two levels of password protection. Analyses in this report used only encrypted data files and were performed on large patient groupings with the smallest being 143 patients (Table 3.2)

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A patient transferred into your dialysis unit from another hospital?

DO NOT START A NEW RECORD

Contact the registry staff to ensure transfer of the patient record. This prevents duplicate records and provides access to medical history of a patient who transferred to your unit on a "read only" basis