

Appendix III

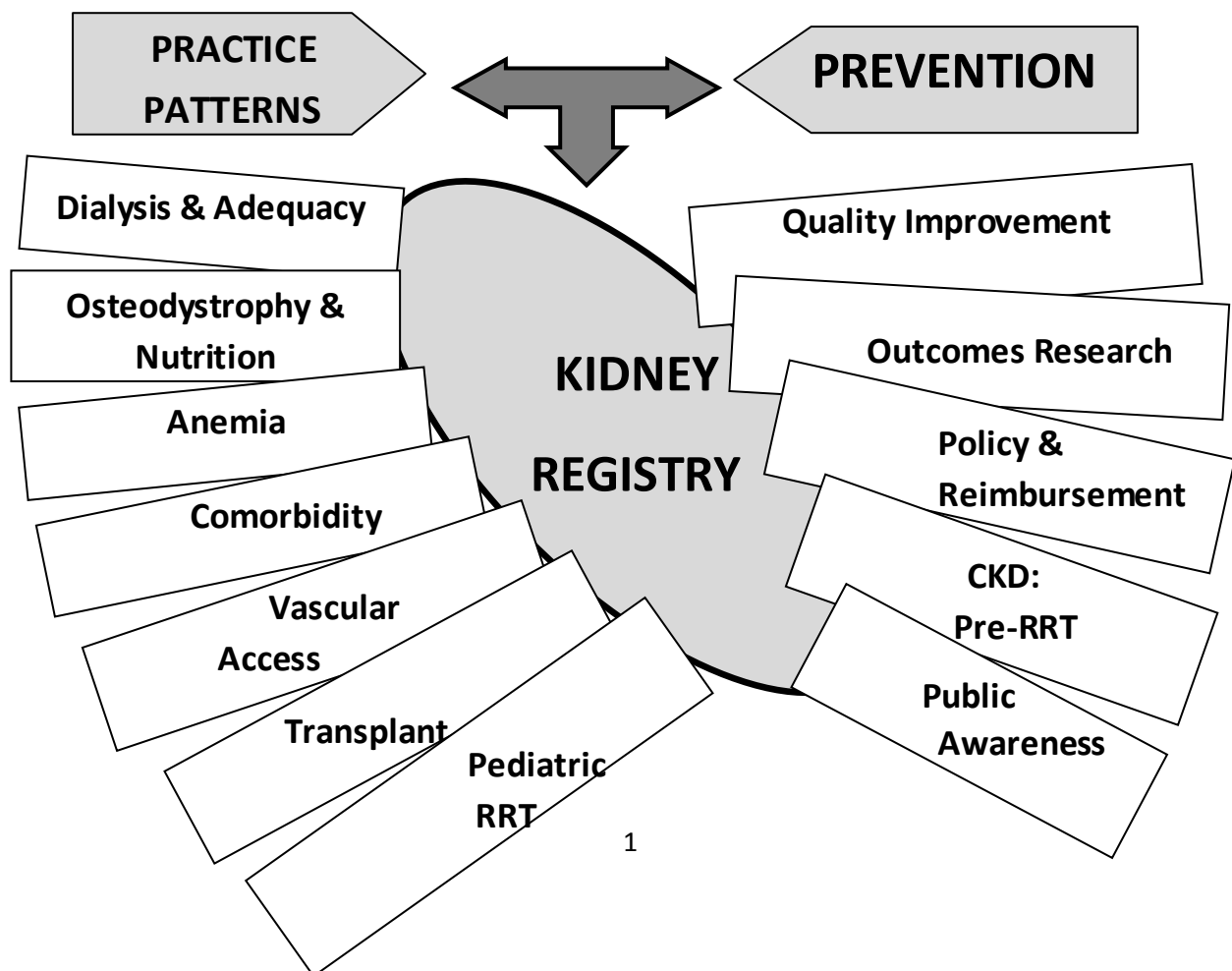
Research Program: Overview

The NKR provides an excellent foundation to foster a comprehensive research program in clinical nephrology. Practicing physicians, medical trainees (interns, residents, and fellows) and graduate students in medical specialties (nurses, dietitians, biological sciences and technicians) are beneficiaries of such research potential. When the program is well established, it would be governed by:

1. The scientific committee which serves as a scientific board for the program, with representation of the 7 medical schools in Lebanon.
2. Similar to the NKR, the LSNH executive committee provides operational oversight.

Research areas correspond to the specialty areas involved in clinical management of HD patients as shown in the diagram below. Clinical studies of epidemiological profile, practice patterns, interventions to improve outcomes, compliance or efficiencies, outcomes research and pharmacoconomics are main areas of possible research. The generated information and learning can prove instrumental in the development of prevention planning, practice guidelines and scientific guidance for health planning, policy and accreditation.

Two demonstration research projects are in progress with Two members of the scientific committee served as principle investigators. Eighteen dialysis units and 25 Nephrologists participated, and over 600 patients were enrolled. Both studies received one-year funding from the Lebanese National Council for Scientific Research.



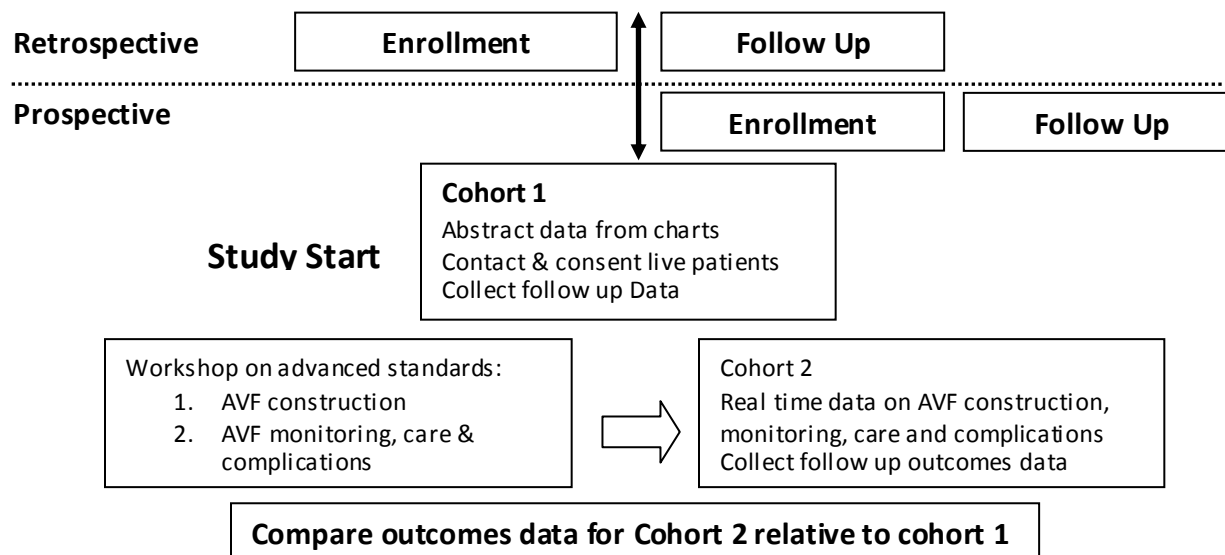
First Study

Title: Minimizing Failures in Arteriovenous Fistula (AVF) in Hemodialysis (HD) patients in Lebanon

Principle Investigator : Salim Kabalan, MD – Professor of Medicine / Lebanese University

Co-Investigators : The Vascular Access Study Group in Lebanon (List on page 81).

STUDY SCHEMA



FIRST-YEAR PROGRESS REPORT

General

- The study was contracted to Partners in Wellness & Research (PWR).
- Launched in the second half of April 2012.
- Fourteen centers were approached and eight agreed to participate.

Study Launch

- I. Study launch and training workshop for co-investigators and their staff was held on April 21, 2012
- II. Online space was allocated in the NKR website dedicated for the study. The online address:

<http://www.kidneyregistrylb.com/pages/research-program/research-projects/vascular-access-study/>

Operational Milestones and Timelines

- I. Participating centers were contacted in March and first half of April 2012.
- II. Physicians participating in the study: 19 Nephrologists & 15 vascular surgeons (List below).
- III. Participating centers were initiated between April 23 and June 30, 2012.
- IV. All participating centers obtained study-specific IRB or ethics committee approval, including agreement to abstract their study related sections of the NKR records.
- V. All patients enrolled in the study signed a study-specific consent form.
- VI. Study data obtained from two sources: 1) data recorded in the NKR and 2) additional data recorded on 3 study forms: study enrollment history, vascular access creation and repair information and diagram, and vascular access technical parameters and assessments.

Intervention

Cohort-1: Existing practices during the historical enrollment period

Cohort-2: Observed practices in conjunction with recommended best practice conveyed through:

1. A training workshop on vascular access construction, maintenance and repair
2. International K-DIGO and Fistula First guidelines easily accessible on study website
3. Standardized data collection forms that promote and record best practice information

Study Conduct

The study milestone details and their timelines are:

- I. Study initiation workshop was held on Saturday April 21, 2012. The workshop was attended by 12 nephrologists, 9 vascular surgeons and 26 staff members of the participating sites. The workshop consisted of 6 presentations, each followed by a discussion and suggestions session. The presentations were placed online in the study website space.
- II. Enrollment of historical cohort-1 (N=160): Patients who started HD at the 8 sites between June 1, 2011 and June 3, 2012. NKR records were completed for all patients by September 2012.
- III. One-year follow up for cohort-1 patients completes Friday June 7, 2013. Investigators are given one month after the end of a patient's one year follow up to ensure NKR records are complete.
- IV. Enrollment into the prospective cohort-2 (N = 78 as of May 3, 2013) started on June 4, 2012 and continues through September 30, 2013. Patients who start HD during that period are identified as soon as their record is entered into the NKR as a new patient at the participating sites.
- V. One-year follow up for cohort-2 patients have started for those enrolled up to date and will continue up to October 3, 2014 for patients enrolled on September 30, 2013.

Results

1. Outcomes:

Three preliminary outcomes can be reported at this point of the study:

- i. Of the 242 patients enrolled into both study cohorts as of May 24, 2013, 39 patients have passed away. This is within the expected rate of 26% mortality during first year after start of HD, observed in the NKR in Lebanon.
- ii. Five patients transferred into non-participating sites
- iii. The demographics of the recruited sample at baseline are presented in **table 1**.

2. Demographics (Table-1):

The demographics for cohort-1 and cohort-2 are quite similar. No comparisons between the two cohorts are possible at this point of the study as there are 4 more months of enrollment into prospective cohort-2. However, few key preliminary observations can be made about the overall study sample in comparison with the Lebanon-wide data:

- i. Mean age at start of HD was 60.3 years (median = 63) compared to 60.9 years (median = 63) among incident patients Lebanon-wide
- ii. Patients who died were 10 years older at start of HD compared to those alive
- iii. Females were 41.7% of the study sample (43% Lebanon-wide)
- iv. Married patients were 76.4% (73.5% Lebanon-wide)
- v. Low education (illiterate or elementary) were 65.7% compared to 65.4% Lebanon-wide
- vi. Working patients were 24% (23.6% Lebanon-wide)
- vii. Insurance coverage: 52.1% were MOPH, 22.3% were NSSF and 9.5% were Army, compared to 55.9%, 24.9% and 8.6% respectively Lebanon-wide.

The study sample enrolled so far (N=242) appears to be a sound demographic representation of the HD patient population in Lebanon (approximately 3100 patients).

Table-1 Demographics of AVF study sample by patient cohort

{Frequency shown as # (%)}

Parameter	Detail	Patient Category				
		Overall	Cohort-1		Cohort-2*	
Sample Size	N	242	160		82*	
Age at Start of Dialysis	Mean		60.2		60.5	
	SD		16		18.1	
	Minimum		15		9	
	50 th Percentile (Median)		63		66	
	Maximum		87		89	
Age at Start of Dialysis by Living Status	Status		Alive	Dead	Alive	Dead
	N		130	30	73	9
	Mean		58.4	68	59.2	70.8
	SD		16	13.5	18.7	6.8
	Minimum		15	16	9	54
	50 th Percentile (Median)		61	71	63.5	72
	Maximum		86	87	89	77
Gender	Female	101 (41.7)	71 (44.4)		30 (36.6)	
	Male	141 (58.3)	89 (55.6)		52 (63.4)	
Education	Illiterate	51 (21.1)	39 (24.4)		12 (14.6)	
	Read & Write / Elementary	108 (44.6)	67 (41.9)		41 (50)	
	Intermediate / Vocational	36 (14.8)	23 (14.4)		13 (15.9)	
	Secondary	27 (11.2)	19 (11.9)		8 (9.8)	
	University / Post-graduate	20 (8.3)	12 (7.5)		8 (9.8)	
Living Situation	With Others	237 (97.9)	157 (98.1)		80 (97.6)	
	Alone	5 (2.1)	3 (1.9)		2 (2.4)	
Marital Status	Married	185 (76.4)	122 (76.3)		63 (76.8)	
	Single	37 (15.3)	26 (16.3)		11 (13.4)	
	Widowed	16 (6.6)	10 (6.3)		6 (7.3)	
	Divorced / Separated / Other	4 (1.6)	2 (1.2)		2 (2.4)	
Working Status	Working	58 (24)	37 (23.1)		21 (25.6)	
	Not Working	132 (54.5)	85 (53.1)		47 (57.3)	
	Housewife	42 (17.4)	31 (19.4)		11 (13.4)	
	Student	7 (2.9)	6 (3.8)		1 (1.2)	
	Other	3 (1.2)	1 (0.6)		2 (2.4)	
Insurance Coverage	MOPH	126 (52.1)	90 (56.3)		36 (43.9)	
	NSSF	54 (22.3)	39 (24.4)		15 (18.3)	
	Army	23 (9.5)	11 (6.9)		12 (14.6)	
	Employees Mutuality	16 (6.6)	7 (4.4)		9 (11)	
	Internal Security Force	8 (3.3)	4 (2.5)		4 (4.9)	
	Private / Self / Other	15 (6.2)	9 (5.6)		6 (7.3)	

- Study sample of cohort-2 through May 24, 2013. Enrollment continues prospectively through September 30, 2013

Table-2 List of Participating Sites, Nephrologists and Vascular Surgeons

Hospital	Physician	Name
Centre Hoptalier de Nord (CHN) Zgharta	Nephro	Dr. George Dahdah
		Dr. Balsam Elghoul
		Dr. Sola Bahouth
	Surgeon	Dr. Talal Kassar
		Dr. Mehrez douaihi
Saydet Zgharta Hospital	Nephro	Dr. Walid Mahfoud
	Surgeon	Dr. Nadim Chakess
		Dr. Jamil Akkari
Ain Wazein Hospital Chouf	Nephro	Dr. Zuheir El Imad
		Dr. Ammar SAYRAWAN
	Surgeon	Dr. Bechara El-HAJJAR
		Dr. Omar ABDEL SAMAD
Hammoud University Hospital Saida	Nephro	Dr. Kassem HAMADEH
		Dr. Khalil JABER
		Dr. Hilal ABOUZEINAB
		Dr. Hani CHAABAN
	Surgeon	Dr. Mohammad Wehbeh
Rafic Hariri University Hospital (RHUH) Beirut	Nephro	Dr. Salim Kabalan
		Dr. Khalil Taki
		Dr. Antoine Barbari
		Dr. Abdalla Zein
	Surgeon	Dr. Fadi Tannouri
		Dr. Fathallah Fattouh
		Dr. Fayez Abou Jaoudeh
University Medical Center – Rizk Hospital (UMCRH) - Beirut	Nephro	Dr. Antoine Stephan
		Dr. Albert Karam
		Dr. Sola Bahous
		Dr. Hala Kilani
	Surgeon	Dr. Elias Arbid (Chair)
		Dr. Fadi Hayek
		Dr. Joseph Naoom
Riyak Hospital Beqaa	Nephro	Dr. Ali Hazimeh
	Surgeon	Dr. Walid Ghantous
ElYoussef Hospital Akkar	Nephro	Dr. Amer Mehrez Atiya
	Surgeon	Dr. Jamil Akkari

Second Study

Title: Management of mineral and bone disorder (CKD-MBD) among Hemodialysis (HD) Patients in Lebanon: Impacting Clinical, Quality of Life (QOL) and Cost Outcomes.

Principle Investigator: Dr Saadé Abboud - Instructor in Faculté de Médecine / USEK

Co-Investigators: Mirey Karavetian, LD, PhD (C) Maastricht University and the NEMO trial group

Goal

Determine impact of a dedicated dietitian in the HD unit on patient clinical outcomes in Lebanon.

Objectives

The aim of the study was to assess the effect of implementing Self-Management Dietary Counseling (SMDC) on improved compliance of HD patients and achieving related mineral bone disorder (CKD-MBD) management. The SMDC was administered by a dedicated dietitian (full intervention) or study-trained hospital dietitian (partial intervention) and compared to existing practice by hospital dietitian (control).

This was done through an integrated two-prong research study:

1. Patient-directed track: Effect of optimal nutritional awareness in HD patients through specialized dietetic education programs conducted by trained professionals, on improving adherence to therapy and thus clinical, quality of life and cost outcomes.
2. Health care staff-directed track: Effect of training key health care professionals (especially dietitians) in hospitals on management of CKD-MBD.

Sample selection

- **HD units:** Participating HD units were randomly selected from the national sample and assigned into two groups: group 1(6 hospitals, 370 patients): divided into a) “Dedicated Dietitian Group” and b) “Existing practice group” as per the HD shift (to prevent contamination of information from one group to another) , and group 2 (6 hospitals, 370 patients): “Hospital Dietitians Group”.
- **Patients:** Stable (free of acute diseases) HD patients ≥ 18 years, able to comprehend the study and sign a consent form were included to the study.

Staff Training





Eleven dietitians were trained by the study co-investigator on KDOQI nutrition standards for HD patients. Five of these dietitians were externally recruited and the other 6 were hospital dietitians responsible for managing HD patients. Dietitians received a certificate of course completion.

Patient Education Material Development:

Patient education material was developed on the basis of the Trans Theoretical Model (TTM) and aimed to increase knowledge and self management skills of patients on phosphorus (P) restricted diet, and emphasize the importance of balancing low P with adequate protein intake to prevent malnutrition.

Conduct of study and data collection / Study groups:

- Dedicated Dietitian Group: Each patient in this group received an individualized twice per week 15 minutes education, by the trained research dietitian, for 6 months, a total of 12 hours of education, in accordance to ADA-EAL (2010).

1) RECIPES	2) BOOK OF ALTERNATIVES	3) POSTERS	4) EDUCATIONAL HANDOUTS
			

- **Trained Hospital Dietitian Group:** Patients were educated by the trained hospital dietitian. The dietitian was not given educational material or any protocol to follow for patient care.
- **Existing Practice Group:** Considered as control, where patients received education from hospital dietitians as per existing practice, who were blinded the study.

Study phases:

The study had 3 stages: baseline (t0), intervention (t1), follow-up (t2). Also, data was collected for the 6 pre-baseline months. During the follow up period the research team had no contact with participants.

Data collection

From the medical chart: demographics and serum phosphorus. Moreover, 2 questionnaires were used in this study: 1) **Knowledge questionnaire (KnQ)** to assess knowledge about kidney disease, renal diet, phosphate binders, vitamin D therapy. Score of less than 60 % indicated insufficient knowledge; 2) **Malnutrition Inflammation Score (MIS):** to assess malnutrition inflammation, and anemia. The score ranged from 0 (normal) to 30 (severely abnormal).

Data collection times: Baseline (t₁: average of 6 months preceding the education), post-intervention (t₂: average of 5 months during the education and 1 month immediately after the education,) and follow up (t₃: average of 6 months after the education).

Results

The results of serum P, patients’ knowledge and MIS at t0, t1 and t2 are shown in tables 1, 2 and 3 respectively. The Dietitian Dedicated group was the only one that showed significant improvement in all 3 parameters indicating superiority of this model over the other two. In this group, serum P dropped significantly from t0 – t1, but increased again at t2 (Table 1). Patients’ knowledge significantly increased to 60% and above at post intervention and stayed unchanged at t2. As for MIS, all groups experienced significant increase in MIS from t0 to t2, but this was not clinically significant since an MIS score of 0-10 indicates adequate nutritional status.

The “Trained Hospital Dietitian” group received the same specialty training as the dedicated dietitians. Their knowledge of renal dietetics showed significant improvement but did not reflect in their patient’s serum P or knowledge improvement results. This demonstrated the lack of time that dietitians have in hospitals and lack of supportive policies to facilitate patient education.

Table 1: Effect of NEMO Trial on Serum P

	Dietitian Dedicated group (n=88)	EP group (n=96)	Trained Hospital Dietitian group (n=210)
t0	5.55 ± 1.57 ^a	5.35 ± 1.48	5.18 ± 1.49
t1	5.11 ± 1.43 ^b	5.30 ± 1.56	5.05 ± 1.49
t2	5.29 ± 1.67 ^{ab}	5.64 ± 2.03	5.13 ± 1.51

- Values are shown in mean ±SD; *p* value in the table indicates significance as per GLM-Repeated Measure ANOVA.
- Different superscripts indicate statistical difference between each pair as per posthoc Bonferoni test *p*<0.05.

Table 2: Effect of NEMO Trial on Knowledge (%)

	Dietitian Dedicated group (n=88)	EP group (n=96)	Trained Hospital Dietitian group (n=210)
t0	40.31 ^a ± 13.00	38.73 ^a ± 11.94	39.43 ^a ± 12.91
t1	63.97 ^b ± 9.14	30.11 ^b ± 20.79	39.95 ^a ± 19.15
t2	62.94 ^{ab} ± 16.89	51.22 ^c ± 21.04	55.26 ^b ± 20.79

- Values are shown in mean ±SD, *p* value in the table indicates significance as per GLM-Repeated Measure ANOVA.
- Different superscripts indicate statistical difference between each pair as per posthoc Bonferoni test *p*<0.05.

Table 3: Effect of the study on MIS

	Dietitian Dedicated group (n=88)	EP group (n=96)	Trained Hospital Dietitian group (n=210)
t0	6.76±3.39*	6.44±2.93*	6.22±3.96*
t1	7.02±2.91*	7.70±3.84	7.46±3.18*
t2	8.37±3.65*	8.73±3.73*	8.87±3.67*

Values are expressed as mean ± SD, * indicates group significance at *p* < 0.05 based on GLM and Bonferoni's for post hoc test

The findings show that dietetic services in HD units in Lebanon are lagging although professionals involved do their best. Hospitals that operate a HD unit do not seem to equip their dietitians with sufficient time, training, or empowerment to follow KDOQI standards of care.

There is definite value in having a renal dietitian servicing HD units. The MOPH is encouraged to promote and support the integration of renal dietitians into HD units operation.

Participating Centers / Acknowledgements

Study data collection was done by 20 students from the Lebanese University, masters in nutrition program. The 5 externally recruited dietitians were from the nutrition department, master's program in nutrition and dietetics at USJ The list of nephrologists and dietitians at participating hospitals is presented in **table 4**.

Table-4 List of Participating Sites, Nephrologists and Dietitians

Hospital	Professional	Name
Bahman	Nephro	Drs Ali Jibai & Nina Haydar Mrad
	Dietitian	Carole Mounzer
	Research dietitian	Mona Wehbe (USJ)
Hopital Al-Koura	Nephro	Drs Tarek Sadek & Bashir Mouad
	Dietitian	Maryan al Chami
Centre Hospitalier Univ. Notre Dame de Secours	Nephro	Drs Saade Abboud & Norma Ghoson
	Dietitian	Layal Azzi & Cecile Obeid
Makassed University Hospital	Nephro	Drs Abed Al Rahman Itani & Jacque Karam
	Dietitian	Noura Tayara
	Research dietitian	Liliane Said (USJ)
Khoury General Hospital	Nephro	Drs Joseph Kassouf & Kamal Abou Chahine
	Dietitian	Raeda Sayed
Libano Canadien Hospital	Nephro	Drs Elias Abed El Nour & Moein Hneidi
	Dietitian	Crystel Cordahi
	Research dietitian	Fida Bechwaty (USJ)
Hopital Hayek	Nephro	Drs Eli Mbarak & Moen Hneidi
	Dietitian	NA*
	Research dietitian	Fida Bechwaty (USJ)
Al Hayat Hospital	Nephro	Dr Issam Cheahade
	Dietitian	NA*
	Research dietitian	Fida Bechwaty (USJ)
Middle East Institute of Health	Nephro	Drs Walid Abou Joude & Saade Abboud
	Dietitian	Murielle Abi Samra
Hammoud University Hospital Saida	Nephro	Drs. Kassem Hamadeh, Khalil Jaber, Hilal Abouzeinab, Hani Chaaban
	Dietitian	Aya Jammoul
	Research dietitian	Rim Jibai (USJ) & Sarah Haydar (USJ)
Rafic Hariri University Hospital (RHUH) Beirut	Nephro	Drs. Salim Kabalan, Khalil Taki, Antoine Barbari, Abdalla Zein
	Dietitian	Jaqueline Wassef & Marie Rose Samaha
	Research dietitian	Rim Jibai (USJ) & Sarah Haydar (USJ)
University Medical Center Rizk Hospital (UMCRH)	Nephro	Drs. Antoine Stephan, Albert Karam, Sola Bahous, Hala Kilani
	Dietitian	Sandra Rizk
Lebanese University Faculty of Sciences- Fanar Department of Professional Masters in Nutrition and Dietetics	Department Chair	Dr Bernadette Afifi Mounayar
	Research student involved in data collection	Sandy Merheb, Renne Abou Nader, Jessy Gedeon, Jesica Abi Chebel, Marie Stephan, Jiina Abs, Rim Abdul Kader, David Slim, Battoul Fouladkar, Maha Khoudor, Bayan Ahmad, Hanane Mahfouz, Zeina Aziz, Sandra Fatta, Sandra Nakhle, Naima Bawab, Raine Dagher, Simona Al Hosny, Josiane Ghazal, Mirna el Zein, Farah Sayah, Joyce Hayek

*NA indicates presence of a dietitian in the hospital that the research team was not able to meet with.

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