

Iraqi Renal Transplant Registry (IRTR)

Preliminary report - October 2018

This report is written by the Ministry of Health Oversight Committee established by the Ministerial Order number 3432 in 20/3/2017.

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INTRODUCTION

The Iraqi Renal Transplant Registry (IRTR) officially started in October 2015 thanks to a research grant by the pharmaceutical company Novartis. The IRTR software development, launch at participating centers, implementation management, technical support, and analytics were contracted to the research group Partners in Wellness and Research (PWR).

The enthusiastic support of the board members of the Iraqi Society of Nephrology during the initial phase of IRTR implementation, supplemented by effective regulatory support by the Commission of Medical Tertiary of the Iraqi MOH, proved to be instrumental in its successful launch in April 2017.

The report will place high emphasis on the methods section, and present some results from the demographic profile of maintenance kidney transplant patients (MKTP) in Iraq.

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IRTR- STRUCTURE AND IMPLEMENTATION

The IRTR – Structure

The IRTR represents an internet-based electronic medical record (EMR) for kidney transplant patients in Iraq. The database captures clinical activities linked to care of a chronic renal failure (CRF) patient prior to transplant surgery, organ procurement, transplant surgery, and post-surgery clinical management.

The IRTR pre-surgery clinical information modules were structured to capture a summary of patient information during the CRF progression or during conduct of dialysis prior to qualification for transplant surgery. In two forms: renal failure or chronic dialysis management. These modules provide a template that can potentially link to EMR for those phases of CRF

progression and management.

In preparation for transplant surgery, the IRTR allows capture of recipient and donors assessment for organ procurement, matching criteria, and surgery parameters.

Finally, the IRTR documents post-surgery clinical information (immunosuppressant, acute and chronic rejection monitor, complications, and outcome parameters).

Functionally, the IRTR database is structured into three segments:

1. Fixed patient data (contact, demographics, risk factors, and medical history) which can be completed by a clerical person.
2. Baseline clinical data and measurements which can be completed by an assistant medical professional

- Clinical data of follow up visits pre- or post-surgery, medications, co-morbidities, and outcome measures to be entered by the physician or special trained medical personnel.

The IRTR: Implementation and Current Status

Implementation of the IRTR was carried out by a very capable field team of four medical professionals who were thoroughly trained by PWR, managing the Baghdad, Central, South, and North regions. Their effort was supported by the prompt regulatory action of the Commission of Medical Tertiary of the MOH, and a number of workshops organized by members of the Iraqi Society of Nephrology.

After a slow start in adoption of the electronic forms in the first four months, PWR changed the registry approach to involve the pharmacy which dispenses immunosuppressant medications supplied by the MOH. Patients were required to complete a paper "Patient Form" structured to match the exact content and sequence of the first two database modules.

The registry was re-launched in August 2017 using the new approach and paper patient forms were subsequently entered into the database to create patient records. The re-launch was a great success. Currently, as of September 1, 2018; there were 2210 patient records in the IRTR (Figure 1).

The total number of CRF patients living with a kidney transplant in Iraq is estimated to be approximately 4856 patients, which means that after about 14 months of active enrollment, approximately 46% of Iraq's kidney transplant patients have IRTR records (71% of patients outside the Kurdistan Region).

Two situations are worthy of noting:

- The Nephrology group in Mosul, only four months after the city liberation from ISIS, was fully engaged in entering their patients into the registry, and is currently at 100% entry.
- The unusual security and economic conditions in the Kurdistan Region has hampered the efforts of their hospitals to actively engage in the IRTR. These obstacles are currently being addressed, and PWR will continue to provide resources and support to achieve such engagement of the region's hospitals.

METHODS

a. Database Specifications

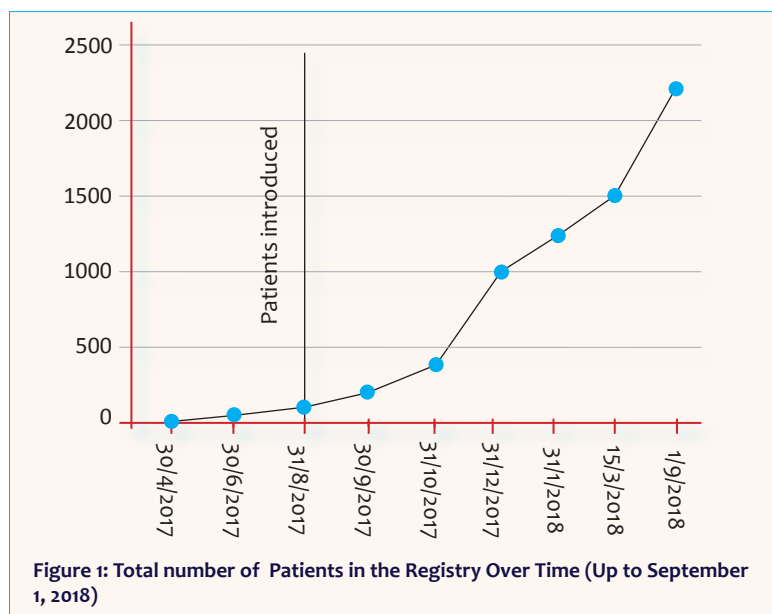
The IRTR database was custom-constructed to match the administrative practices, demographic construct, and clinical management practices of kidney transplant patients in Iraq. The database is web-based and all data are stored on a limited access server space which is backed up daily.

Individual centres access the database following a login process on the internet web address: <http://www.renalregistryiraq.com/>. Each hospital has its own username and passwords defined by staff members who have access privileges as determined by the physician designated as site administrator.

The software core code was written as a web-based application using Java programming language structured in a MS-SQL database template. The registry website was constructed using the Dual content management platform. Both the website and database were customized to run on all browsers including the mobile platform.

b. Implementation Process

The country was divided into four regions



(North, Central including Baghdad, Middle Euphrates, and South). Each region is covered by a field manager who contacts, trains, and provides technical support to hospitals that provide transplant surgery or patient follow up services in the region.

The field team in Iraq was first trained during a two-day workshop in Baghdad in March 2016, followed by ongoing communications in weekly meetings using the Zoom teleconferencing service. Following training, the field team started contacting hospitals in their regions, introducing them to the registry concept, assess existing computer and personnel skills at each hospital, and communicate evolving aspects of registry implementation as they relate to MOH regulatory instructions to official local health departments in each Province.

Each hospital has complete password protected control of its web space. However, due to the fluid nature of the patient population (pre-surgery, surgery, and post-surgery may occur at different providers), a subset of patient contact and demographic parameters are open across the database and can be accessed by physicians throughout Iraq who have access privilege to the registry database.

Such user-wide access occurs only with patient permission, and entering either his/her registry unique registry identifier or personal telephone number. This information is printed on a registry card given to the patient upon completion of the patient form at the institution of first encounter, and is handed directly by the patient to the physician at the next institution to pull-out his/her registry record.

Physicians will not be able to access other physicians' follow up visit entries in the registry unless permission for such access is given by the physician-owner. Such permission can be initiated through an intra-mail process built into the registry which sends a request to the physician-owner's email. A positive response will trigger the process of opening these visit records to the requesting physician only and none other. A denial response will keep these visit records locked for the physician-owner access only.

Such access flexibility facilitates sharing of patient information across physicians contingent on patient's request and physicians granting share permission to their colleagues. This

will also help eliminate duplication of patient records as they seek service at different hospitals.

c. Estimates of Patient Numbers Prior to Launch

Prior to start of data entry of patient records, the field team obtained estimates of the number of patients who receive the MOH-provided immunosuppressant medications at each hospital. Such overall estimate theoretically reflects the projected number of living maintenance kidney transplant patient (MKTP) post-surgery follow-ups in the country.

These estimates have two main shortfalls that are hard to resolve at this point: security and displaced refugees, in addition to a third serious issue: weak documentation of records for medication distribution both at the institutional receiving end and at the source at the MOH.

The security issue influences three key Province: Diyala, Salahuddine, and Kirkuk and continues to be the case today. Until November of 2017, Nineveh was also on that list, but is recovering fast after its liberation from ISIS in July 2017.

The displaced refugees came from the same Province that had security issues. Many of their MKTP were receiving medications from distribution institutions at the areas they were displaced into.

The record keeping issue made it difficult to distinguish medication recipients who were native residents of the Province or refugees displaced to it.

Some "sorting out" is possible to be partially achieved by cross-matching the place of birth, place of last residence, and location of medication receipt. PWR chose not to undergo this tedious cross-matching process for the purpose of this preliminary report especially that the issue of refugees have started to get resolved, such as in Nineveh.

d. Operational Methods

An administrative statistical summary run of a copy of the registry data file, is performed weekly using Power-BI software. The summary is generated for all-Iraq data (accessed by Director and Statistician only), by region, and by in-

dividual hospitals in each region. Regional field managers are provided by summaries of hospitals in their region only.

This process allows ongoing monitoring of patient enrollment, and of missing data to be addressed in direct communication between the field manager and respective sites. Compared to the estimated follow up patients at that institution, it was possible to monitor the completeness of record entry at each hospital.

For new patients who are currently having their transplant surgery, the institution where the surgery was performed will initiate the entry of the patient record, regardless whether the patient will be followed up at the same hospital or in a different one.

The majority of patient records currently captured in the registry will be for maintenance patients who have completed their surgery recently or in the past. As the registry matures, the proportion of incident patients who just underwent kidney transplant surgery will grow higher.

e. Prevalence Calculations

The prevalence of MKTP in each Province was calculated using the estimates of the number of patients receiving immunosuppressant medications standardized to 100,000 population of that Province.

It was not possible to calculate the prevalence for all Iraq because estimates for hospitals located in Provinces that are out or reach for security reason were missing.

f. Other Calculations

Incidence rates are difficult to report at this point due to the situation in Kurdistan where about 65% of new kidney transplant surgeries in Iraq are performed. Some of these patients are captured after they return to their Province of residence and become a MKTP receiving MOH sponsored medications.

The number of missing patient entries for various parameters was reported to bring the issue of reporting accuracy and completeness into the attention of participating institutions.

Table 1: IRT: Actual Registry Patient Entries by Hospital as of 1 September, 2018 compared to expected number receiving immunosuppressive medication

Region	Hospital	Projected No. of Patients	No. of Actual Entries (%)
Central Iraq	Hospital of Specialized Surgeries	750	581 (77.5)
	Baghdad Teaching Hospital		
	Nursing Home Hospital		
Middle Euphrates	Al-Karama Hospital	585	546 (93.3)
	Central Hospital for Children		
	Al Sader Hospital (Najaf)	181	137 (75.7)
	Diwaneya Hospital (Diwaneya)	59	59 (100)
	Merjan Hospital (Babil)	261	118 (45.2)
	Al-Husseiny Hospital (Karbala)	191	67 (28.8)
Southern Iraq	Al-Batool Hosp (Wassit)	130	130 (100)
	Basra Teaching Hospital (Basra)	80	73 (91.2)
	Al-Jamhoury Hospital (Basra)	150	102 (63.3)
	Al-Sader Hospital (Missan)	90	57 (63.3)
	Imam Hussein Hospital (Thiqar)	103	6 (5.7)
	Al-Hussein Hospital (Al-Muthamma)	64	0 (0)
(Iraq – excluding North)		2644	1876 (70.9)
Northern Iraq	Mosul Hospital	204	204 (100)
	Al-Jumhory Hospital (Erbil)	695	130 (18.7)
	Razkari Hospital (Erbil)	39	0 (0)
	Shar Hospital (Sulaymaneya)	813	0 (0)
	Duhok Hospital (Duhok)	461	0 (0)
IRAQ TOTAL		4856	2210 (45.5)
Diyala hospital, Salaheddeen Hospital and Kirkuk Hospital are not shown in this table because they are new, and we do not have their figures at the time of writing this report			

In this preliminary report, only key demographic information will be reported. More complete results will be included in the inaugural annual report expected to be published in October 2019.

KEY DEMOGRAPHICS OF THE MAINTENANCE KIDNEY TRANSPLANT PATIENT POPULATION IN IRAQ

Data cutoff date: September 1, 2018

Analysis: Summary distribution of demographic parameters

Analytic software: Microsoft Power BI

Table 2: IRTR - Prevalence of Maintenance Kidney Transplant Patients by Province As of September 1, 2018 (USA Prevalence approx. 65.6/100,000)

Province	Projected Patients †	Registered Patients in IRTR (%)	Registered Female Patients (%)	Provinces Estimated Population ‡	Projected Patients per 100000 Population
Baghdad	1335	1127 (84.4)	334 (29.6)	8318000	16.04
Diyala*	?	0	?	1660000	NA
Najaf	181	137 (75.7)	35 (25.5)	1500000	12.07
Diwaneya	59	59 (100)	18 (30.5)	1311000	4.50
Babil	261	118 (45.2)	15 (12.7)	2093000	12.47
Karbala	191	67 (28.8)	17 (25.4)	1241000	14.39
Wassit	130	130 (100)	33 (25.4)	1401000	9.28
Basra	230	175 (76.1)	37 (22.0)	2972000	7.74
Missan	90	57 (63.3)	13 (22.8)	1134000	7.94
Thiqar	103	6 (5.7)	1 (16.7)	2132000	4.83
Almuthanna	64	0	0	824000	7.77
Iraq without North	2644	1876 (71.0)	499 (26.8)	22926000	11.53
Nineweh	204	204 (100)	52 (25.5)	3793000	5.38
Erbil	695	130 (18.7)	44 (33.8)	1896000	36.66
Sulaymaneya	750	0	?	2212000	33.91
Duhok	418	0	?	1318000	31.71
Salaheddeen*	?	0	?	1615000	NA
Kirkuk*	?	0	?	1626000	NA
Iraq Total	4856	2210 (45.5)	?	NA	Cannot be Calculated

* Data about projected and registered patients are not available at time of preparation.

† Projected Number of Kidney Transplanted Patients: Numbers provided by central hospital for patients receiving Immunosuppressant drugs through MOH

‡ Projected population – Generated by Iraqi Planning Ministry for 2018

1. Number of MKTPs (Table 1)

Two sets of patient numbers will be presented: expected numbers based on drug utilization estimates, and actual numbers based on patient records entered in the registry.

a. Expected Numbers

The number of maintenance follow up kidney transplant patients in the IRTR is expected to be 4856, whose distribution by region, “Province”, and individual medication-distributing hospitals within each Province, is reflected in **Table 1**.

These numbers represent a drug-utilization distribution source of information which in this case can be considered a reasonable estimate of the overall number of MKTPs in Iraq since it includes patients from both public and private hospitals receiving MOH distributed medications at designated government hospital(s) in the Province, usually in its capital.

These estimates will miss the small number

of patients who pay out-of-pocket for these medications, and may be biased by periods when these medications are out of supply at the MOH, which are not infrequent.

Patients whose records are captured at medications distributing hospitals in major cities such as the Hospital of the Surgical Specialties in Baghdad will include records for patients who were followed clinically by physicians at other public hospitals such as Baghdad Teaching Hospital and Nursing Home Hospital, as well as private hospitals in the area. These physicians will be able to access their patients’ records and update their clinical data from follow up visits after the baseline record have been established at the medication distributing hospital.

In hospitals where kidney transplant procedures are done but are not medication distributing locations, the expected and actual numbers should be identical, and the majority of these patients will have had a recent surgery there. More often, the maintenance follow up records for these patients will take place at a different hospital than the one where surgery was per-

Table 3: IRTR - Distribution of Maintenance Kidney Transplant Patients by Age In Iraq by Provinces of 1 September – 2018								
Region	Province	Patients in Registry	Age (Years)					Missing
			Mean (±SD)	<20	20-44	45-64	≥ 65	
Central	Baghdad	1127	42.58 (13.71)	58	541	453	75	0
Middle Euphrates	Najaf	137		4	73	55	5	0
	Diwaneya	59		3	36	19	1	0
	Babil	118		2	86	26	4	0
	Karbala	67		3	34	23	6	1
	Wassit	130		2	78	45	5	0
	All Middle Euphrates	511	39.7 (13.28)	14	307	168	21	1
South	Basra	175		9	108	50	7	1
	Missan	57		2	35	18	2	0
	Thiqr	6		1	3	2	0	0
	Almuthanna	0		0	0	0	0	0
	All South	238	39.4 (12.85)	12	146	70	9	1
North	Nineweh	204		10	113	66	14	1
	Erbil	130		12	75	34	8	1
	Sulaymaneya	0		0	0	0	0	0
	Duhok	0		0	0	0	0	0
	All North	334	40.0 (13.44)	22	188	100	22	2
Total Iraq		2210	41.18 (13.55)	106 (4.8%)	1182 (53.5%)	791 (35.8%)	127 (5.7%)	4

Table 4: IRTR: Distribution of Maintenance Kidney Transplant Patients by Education In Iraq by Provinces of 26 August – 2018							
Region	Province	Patients in Registry	Education Level				Missing
			Illiterate	Elementary School	Secondary School	College / Technical	
Central	Baghdad	1124	39	328	360	342	55
Middle Euphrates	Najaf	137	1	42	43	43	8
	Diwaneya	59	3	22	15	15	1
	Babil	118	4	55	36	22	1
	Karbala	67	7	28	15	12	5
	Wassit	130	10	38	42	39	1
	All Middle Euphrates	511	25	185	151	131	19
South	Basra	168	15	64	48	38	3
	Missan	57	10	24	13	9	1
	Thiqr	6	2	2	1	0	1
	Almuthanna	0	NA	NA	NA	NA	NA
	All South	231	27	90	62	47	5
North	Nineweh	204	42	68	44	36	14
	Erbil	130	20	59	28	21	2
	Sulaymaneya	0	NA	NA	NA	NA	NA
	Duhok	0	NA	NA	NA	NA	NA
	All North	334	62	127	72	57	16
All IRAQ		2200	153 (7%)	730 (33.2%)	645 (29.3%)	577 (26.2%)	95 (4.3%)

formed.

b. Actual Numbers

Up to September 1, 2018 which is the date of data cutoff for the purpose of this analysis, 2210 actual patient records were captured at 16 hospitals nationwide. The distribution of these patients by hospital is also shown in Table 1 and can be compared to the projected estimate in each geographic category.

The actual numbers of MKTPs are for those who have records in the registry. Their enrollment involved a two-step process: first, getting hold of the patient at the medication distributing hospital (usually at the pharmacy) or at the surgery-performing hospital, and completing a paper patient form; and second, the electronic entry of that information into the registry software.

A comparison of the actual to the expected numbers represents a rough measure of compliance by each medication distribution hospital in getting their patient data into the registry. That compliance was distributed as follows:

- Three institutions completed 100% entry of their patients: Mosul, Diwaneya, and Al-Batool hospital in Wassit.
- Two institutions are on the verge of complete entry: Al-Karama hospital in Baghdad-AlKarch, and Basra Teaching Hospital
- Four hospitals completed 60-80% record entry: Specialist Hospital of Surgery in Baghdad-AlRasafa, Al-Sader Hospital in Najaf, Basra Jam-hourly Hospital, and Al-Sader Hospital in Missan.
- The remaining hospitals completed less than 50% or had NO record entry.

2. Prevalence of MKTPs (Table 2)

There was a wide variation in the prevalence of MKTPs by Province

Table 5: IRTR: Distribution of Maintenance Kidney Transplant Patients by Marital Status In Iraq by Province, As of 1 September – 2018						
Region	Province	Patients in Registry	Marital Status			
			Single	Married	Other	Missing
Central	Baghdad	1127	228	819	27	53
Middle Euphrates	Najaf	137	25	108	0	4
	Diwaneya	59	19	39	0	1
	Babil	118	40	77	0	1
	Karbala	67	8	54	5	0
	Wassit	130	25	102	3	0
	All Middle Euphrates	511	117	380	8	6
South	Basra	175	34	132	2	7
	Missan	57	10	45	0	0
	Thiqar	6	0	5	0	1
	Almuthanna	0	0	0	0	0
	All South	238	44	182	4	8
North	Nineweh	204	36	153	5	10
	Erbil	130	29	96	4	1
	Sulaymaneya	0	0	0	0	0
	Duhok	0	0	0	0	0
	All North	334	65	249	9	11
	All IRAQ	2210	454 (20.5%)	1630 (73.8%)	48 (2.2%)	78 (3.5%)

that followed a specific pattern:

- Highest in the hospitals of Kurdistan region (31.7 to 36.7 per 100,000),
- Lowest in rural Provinces outside Kurdistan (4.5 to 9.3 per 100,000) in addition to Basra (7.7 per 100,000) and Mosul (5.4 per 100,000) which may be due the large number of displaced refugees from that city.
- Prevalence in main cities of Baghdad, Najaf, Babil, and Karbala was in the range 12.1 to 16.0 per 100,000 populations.
- The proportion of females in that patient

population was between 12.7% and 33.8%

For comparison purposes, the prevalence of these patients in the USA using numbers reported by the USRDS 2010 report was 65.6 per 100,000 populations.

3. Distribution by Age (Table 3)

The mean age of actual patient entries in the IRTR for all Iraq was 41.18 years $\pm$ 13.55 standard deviation (SD). Of these patients, only 106 (4.8%) were under age 20, and 127 (5.7%) were above age 65. The largest proportion of patients (53.5%) was in the 20-44 age range, and the remaining 35.8% were in the 45-64 years age range.

4. Distribution by Education (Table 4)

Only 7% of patients reported themselves as illiterate, and 4.3% had missing data. The remaining patients were distributed into 33.2% reporting elementary or less education, 29.3% had intermediate or high school education, and 26.2% had a college or technical education.

5. Distribution by Marital Status (Table 5)

Of the patients in the registry, 20.5% reported being single, 73.8% being married, and 2.2% reported "Other" (widowed, divorced, or separated), and 3.5% had missing data.



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This preliminary report had emphasis on presenting the database specifications, the implementation process and the various methods adopted in these processes.

The inaugural annual report expected to be published in October 2019 will have broader emphasis on results, reporting on a wide variety of parameters captured in the database.