

Chapter 3 - Patient Population, Enrollment & Registry Evolution

تطور السجل الوطني، تعداد وتسجيل المرضى

Patient Population

Kidney transplants in Iraq can only be performed at a few large governmental medical centers and private hospitals located in main cities. However, patient follow-up care is done mostly at the main governmental hospital in each province where the transplanted patient resides, and in which government-funded immunosuppressive medications are supplied to patients every month. The vast majority of transplanted patients benefit from this government offering, while a small fraction may purchase those medications privately.

Monthly disbursements of medications to patients are operationally separated from routine clinical patient follow up which occur on an outpatient basis, with frequencies varying by province. Clinical follow-up visits take place mostly at the nephrology division of the provincial hospital, but may also take place in nephrologists private offices.

Since government-funded immunosuppressive drugs are dispensed at provincial hospitals, accounts of patients receiving that service include the vast majority of transplant patients, regardless of whether their follow up occurs at the same hospital or private hospitals or clinics.

New transplants have to be authorized by the MOH based on pre-defined regulatory parameters, including organ-matching criteria, surgeon name, and the hospital where the surgery will be performed.

However, records for matching and surgery parameters remain mostly physician-kept. Such information is minimal or non-existent in the patient chart, or paper records for these procedures may have been "thinned-out" into storage boxes after 6-12 months post-surgery.

Enrollment in the Registry

Given realities on the ground, PWR designed the software application such that most "fixed data" (personal, demographics, medical histo-

ry, risk factors, and existing comorbidity and medications) could be collected by non-medical professional site coordinators. Capture rates of “minimum” patient data varied from center to center, and required involved locations where transplant patients picked-up their monthly medication (i.e, hospital pharmacy, nephrology clinic). Occasionally, patients were contacted by telephone to obtain that information.

Phases of Registry Enrollment

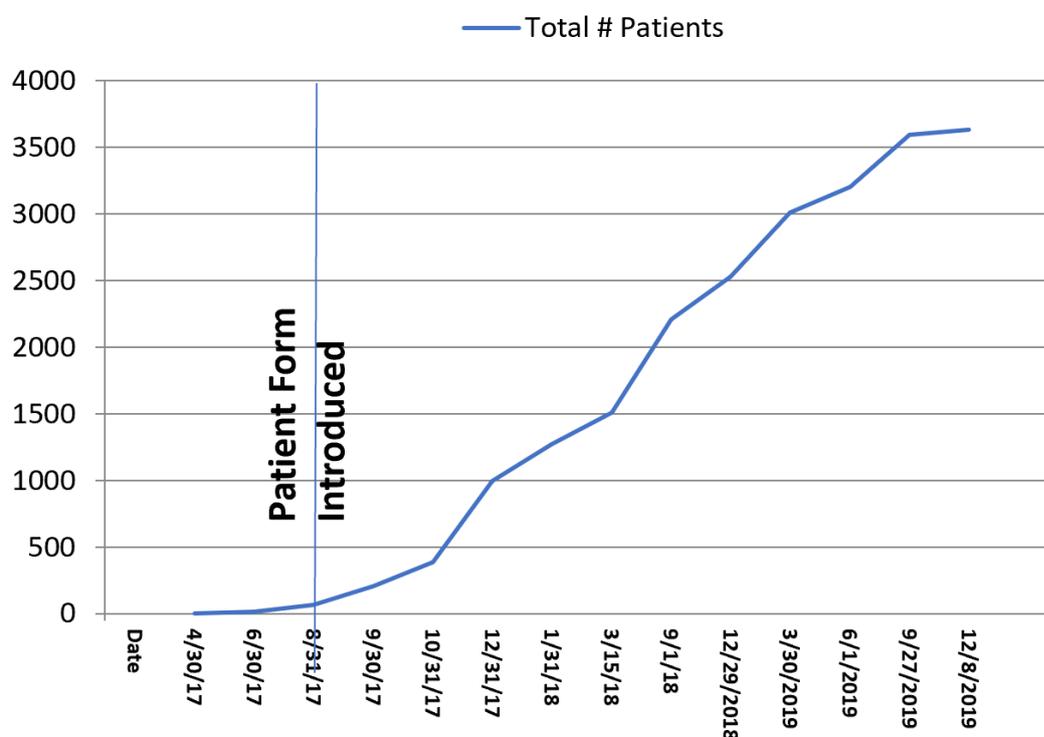
In order to establish a reference point for enrollment progress, we asked each center to estimate the number of patients who receive immunosuppressive medications. Transplant patients from populations displaced from various areas (Nineveh, Salahuddin, Diyala, and Kirkuk provinces) were obtaining their medications at the locations where they sought temporary refuge throughout the rest of the country.

As displaced populations started returning to their homes, the estimates of patients who benefited from medications was reduced in the refugee-host areas, while some of those areas (Nineveh and Diyala) re-opened their hospital facilities and were promptly enrolled in the registry. The provinces of Salahuddin and Kirkuk continue to be high risk areas, even though their provincial hospitals are open.

As patient enrollment in the registry progressed towards completion (which was achieved at thirteen centers) the actual number of patients in the registry became the de-facto total for that center, and any changes in the number of patients at the center, became a reflection of either newly transplanted patients who started receiving their medications there (increase), or patients who were deceased or moved to a different province (decrease). In other words, the original estimate of total patients at that center became irrelevant. As a result, the numbers of total patients at various centers were different in December 2019 compared to November 2017 estimates (see Table-1 on page 16).

In order to ensure the highest possible number of patients have a record in the registry, emphasis was placed on having a basic record for patients containing the “fixed” data. As most sites were slow to adopt direct electronic entry of patient records, PWR devised a paper form that contains the fixed data, and mimicked the same sequence as in the electronic modules. This process provided the flexibility to separate data acquisition from data entry into the database application.

Figure 4. Total # Patients in the registry over time (through Dec. 8, 2019)



The adjustment of adopting a paper patient form to capture the fixed data made a large difference in the rate of patient enrollment (Figure 4), which picked up steeply as a result. This also provided flexibility to utilize contracted outside help for data entry when the need arose. Once the patient basic record was in the registry, this made it easier for physicians to complete and update the file if they chose to. PWR put special emphasis on completion and accuracy of that fixed data component through an ongoing process of data quality assurance and real-time monitoring that was shared by the project director with the field team in weekly meetings and one-on-one follow up if necessary.

Registry Contribution to the Accuracy of Patient Numbers

The conflict-caused population movements were a major factor influencing the difference in the total number of transplant patients in a province in December 2019, compared to the original estimates of November 2017. However, a number of other factors contributed to that difference between the starting-point list of patients receiving medications and the actual list at the end of

2019:

- Names of deceased patients still on the list were removed.
- Duplicates records of patients who moved to a different province (hence their names appeared on two lists) were removed.
- Newly transplanted patients were added (surgery may have occurred in a different province).
- Over 40 duplicate patient records were removed.
- Even though new transplants occurring in the Kurdistan Region were largely unrecorded in the registry, some of these transplant recipients may appear in the registry after obtaining their medications at another regional hospital.
- Special emphasis was put on identifying patients who were newly transplanted in 2018 and 2019 to constitute incident cohorts for those years. Incident cohorts were confirmed with high certainty in 9 provinces.

Table 1 (page 16) offers an account of patient enrollment in the registry updated through December 28, 2019. We would like to highlight few observations from that table:

1. The total number of kidney transplant patients who benefit from the MOH offering of monthly supply of immunosuppressive medications as of December 2019 is 5,090 patients. Of those, 3668 (72.0%) have verified unique records in the registry. We estimate that there are additional few hundred patients that were not accounted for in the provinces of Kirkuk and Salahuddin (about 400) and those who are not using the MOH offering.
2. The total number of patients in December 2019 is few hundred less than the projected estimate in November 2017. We suspect the difference is due to elimination of duplication of names in multiple provinces, removal of deceased patients' names, and uncertainty about numbers of patients displaced from areas affected by the ISIS insurgency.

3. The number of verified newly transplanted patients in 12 provinces during 2018-19 is 407 patients. This number accounts for those patients who started using the MOH medication offerings at their provincial hospital, which will include a segment of patients who might have performed their surgeries at private hospitals or in the Kurdistan Region.
4. In Baghdad, all patients transplanted at Al-Karama hospital during 2018-19 (124 patients) have records in the registry initiated at the hospital. In contrast, at the Specialty Surgery hospital, only patients who are followed at the hospital were entered into the registry (26 patients), while many of the remaining newly transplanted patients at the hospital during that period (182 patients) had their records initiated at the provincial hospital where they receive medications.
5. We expect the actual total number of newly transplanted patients during 2018-2019 to exceed twice that number when patients in the remaining 7 provinces, especially in the Kurdistan Region, are accounted for.

Table 1 - IRTR: Historical Data of Patient Estimates and Current Enrollment

Region	Province / Hospital	Projected No. of Patients		No. of Incident Patients 2018-19	No. of Actual Entries (%) Nov. 2019
		Nov. 2017	Dec. 2019		
Baghdad	Baghdad – Rasafa Specialist Hospital of Surgery [§] + Baghdad Hosp. [◊] + Al-Tamreed Hosp. [◊]	899	746	26	746 (100) +147
	Baghdad – Karkh Al-Karama Hosp. [◊] + Central Hosp. of Children [◊]	767	673	124	673 (100) + 99
	Diyala / Ibn Sina Med. Ctr.	(---)	168	38	153 (91.1) +146
Central Iraq	Najaf / Al Sader Hosp. [§] ◊	181	231	20	231 (100) +74
	Dewanieh [◊]	59	65	5	65 (100) +6
	Hillah / Merjan Hosp. [◊]	261	262	69	262 (100) +142
	Karbala / Al-Husseiny Hosp. [◊]	191	176	24	176 (100) +16
	Kout / Al-Batool Hosp. [◊]	119	131	3	131 (100) +1
Southern Iraq	Basra - Teaching Hosp. [§] ◊	96	108	40	108 (100) +23
	Basra - Jamhoury Hosp. [◊]	403	186	4	186 (100) +73
	Imara / Al-Sader Hosp. [◊]	90	103	8	103 (100) +46
	Nasriyeh / Imam Hussein Hosp.	103	103	-	15 (14.6) +9
	Simawa / Al-Hussein Hosp. [◊]	64	78	8	78 (100) +27
(Iraq – excluding North) SUBTOTAL		3,233	3,030	331	2,927 (96.6) +812
Northern Iraq	Mosul Hosp. [◊]	190	260	22	260 (100) +53
	Erbil / Al-Jumhory Hosp.	695	695	3	180 (25.9) +40
	Erbil / Razkari Hosp. [§]	39	39	-	0 (0)
	Sulimaniah / Shar Hosp. [§]	813	605	-	0 (0)
	Duhok Hosp. [§]	461	461	13	301 (65.3) +301
	Tikrit Hosp. [⊘]	(---)	(---)	-	0 (0)
	Karkouk Hosp. [⊘]	(---)	(---)	-	
IRAQ TOTAL		5,431	5,090	407	3,668 (72.0) +1216

Table Key

[§] Hospital that performs transplant surgeries

[◊] Hospital with complete enrollment

[⊘] Hospitals inaccessible to registry due to security conditions. Will enroll when secure.

+X Number of new patients added to the registry since Jan. 5, 2019

Projected No. of Patients: Estimates of patient numbers based on immunosuppressive drug use.

Incident Patients: Patients who were verified to have kidney transplant in 2018 or 2019.