Chapter 2 - Methods
آليات العمل

The IRTR was established through a collaborative process with stakeholders involved in Iraqi kidney transplant and renal care. Stakeholders from partnering organizations identified the goal of developing, managing, and maintaining a national kidney transplant registry for Iraq. Stakeholders also identified other noteworthy objectives:

- Enroll 65% of kidney transplant patients in Iraq
- Obtain accurate data on transplant patients
- Develop national dataset useable for research
- Enroll at least 18 transplant centers
- Produce an annual report presenting registry data

Overview

The IRTR database was custom-designed to match the administrative practices, demographics, and clinical management practices of renal care in Iraq. All data on the online database is stored on a limited access server that is backed up daily. A team of field managers provided technical training and support for staff at participating kidney transplant centers to utilize the registry portal. Trained staff entered data for transplant recipients receiving care at their location.

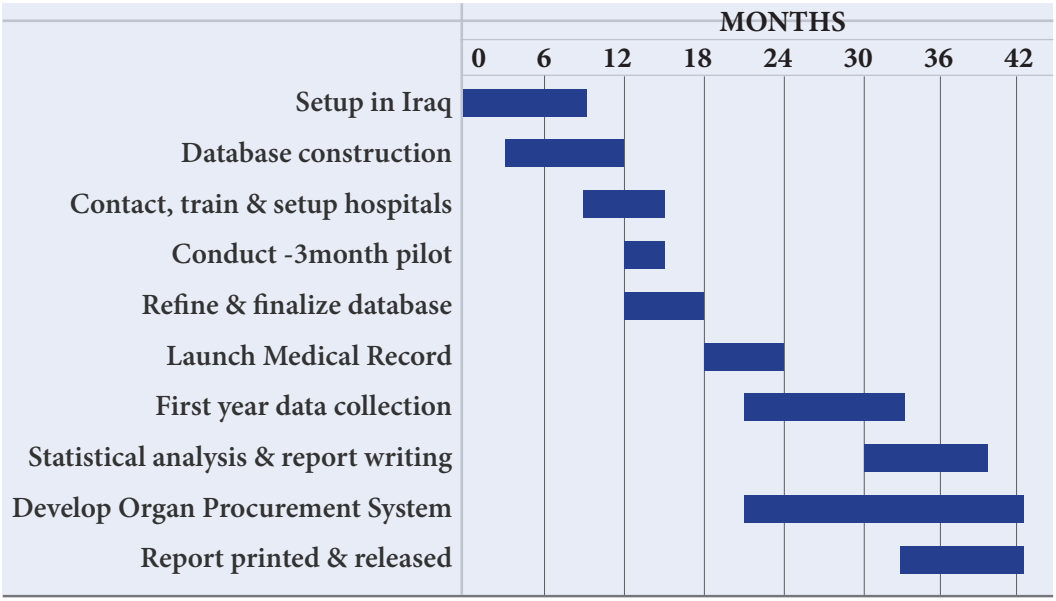
Implementation Process

The IRTR management team led a national implementation strategy with a dedicated field manager assigned to coordinate registry activities in each of four designated regions in Iraq (North, Baghdad, Central, and South). The field team activities were coordinated by Partners in Wellness and Research (PWR) Director who trained the managers during a two -day workshop in Baghdad in March 2016 and provided supplemental support through weekly teleconference meetings.

Following their initial training, each field manager initiated contact with hospitals in their regions, introducing them to the registry concept, as-

sessing existing computer and personnel skills at each hospital, and communicating the regulatory aspects of registry implementation to official health departments in their region. As hospitals began engaging with the registry, field managers maintained ongoing communication, providing technical advising and support to ensure compliance. Figure 2 highlights the initial project milestones and timelines proposed by the IRTR implementation team.

Figure 2. Project milestones and timelines.



On occasion, PWR had to authorize contracting with outside personnel to assist in data collection and entry at staff-depleted centers after the physician's approval. Staff were also authorized to conduct telephone interviews with patients to collect demographic and health history information, especially during a period when MOH supplied immunosuppressive drugs were unavailable for several months and patients were not coming to hospitals for follow-up.

Data entry and management

A designated staff person was responsible for entering data for patients receiving care at their facilities. Both this designated staff person and physicians could enter and access patient data through the portal, according to a well-designed access privilege system.

> Record migration protocols were in place to assure patient privacy while facilitating improved follow-up care when patients transferred centers.

A limited subset of patient data, such as contact and demographic parameters, were accessible to all physicians with access privilege to the database. This data was made available only with patients' permission and required the registry user to enter the patient's 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 where they first receive care. To transfer access to their records, patients share the card with the physician at the new institution where they are receiving care.

Physicians are unable 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. 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, is contingent on patient's request and physicians granting share permission to their colleagues.

Record continuity protocols were in place to assure patient privacy while facilitating improved follow-up care when patients transfer across different physicians and centers at various phases of their disease. These systems help eliminate the duplication of patient records as they seek service at different hospitals. Incidents of patient record migration were quite common due to a number of factors, including population displacement and the fluid nature of kidney transplant care, whereby patients often received transplants at different hospitals than pre- and post-operative care.

Database technology

Physicians and staff at each transplant center have accesses to the

database through a unique account managed by a site coordinator who was trained by the IRTR field team. The database 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 mobile platforms.

Limitations to the national technological infrastructure also posed a challenge. Database access required an internet connection, which was not always available on site. The field team adopted several measures to overcome this barrier, supplying mobile modems and laptops on loan to centers. Centers without reliable internet connections would document data entry on paper forms, to be entered electronically at a later time.

Data collection

The data collected by the registry included patient demographics, health history, and pre- and post-operative data. The database was customized to blend in with patterns of service provision, with distinct modules based on patient provided information, nursing observations and notes, and physician modules. Patient records contained both fixed and follow-up data:

FIXED DATA

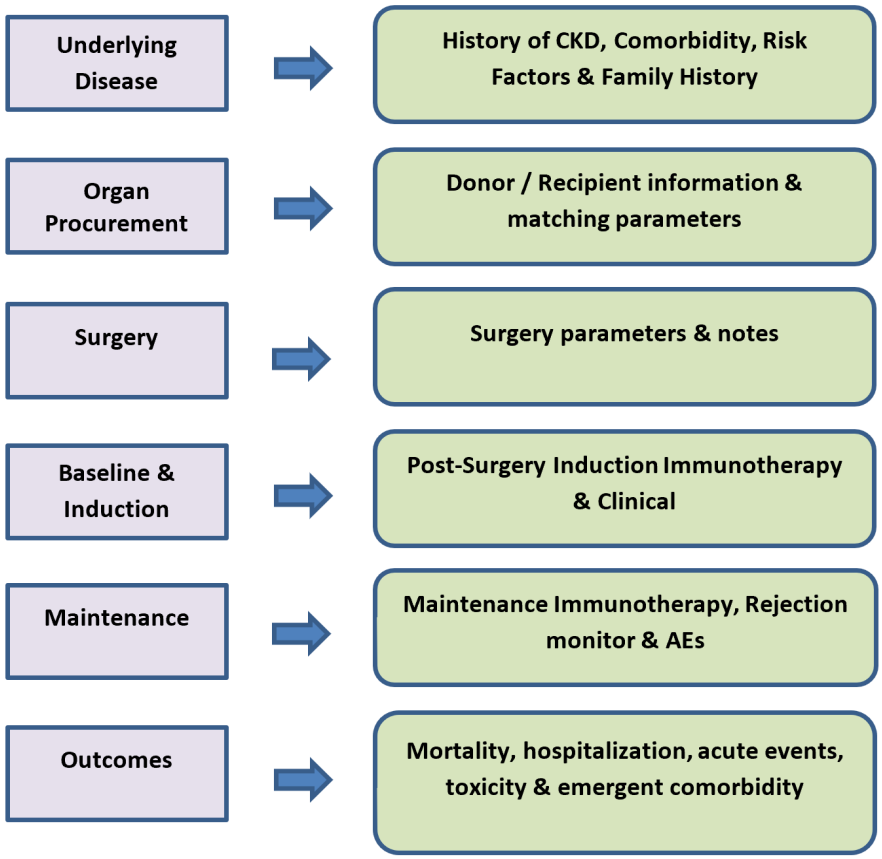
Collected during the initial intake, includes contact and demographic information; medical history; baseline clinical data; organ donor and recipient information; and first month of clinical data.

FOLLOW-UP DATA

Entered during follow-up visits or procedures, these data include patients' clinical profiles, orders, medications, diagnostics, and clinical outcomes.

A critical aspect of the registry was the types of measures and indicators captured, which were designed to mirror each phase of transplant care. Figure 3 illustrates the aspects of transplant care and corresponding data that was collected.

Figure 3. Data collected in each phase of transplant patient care.



Data analysis

The registry team was interested in exploring general features of the transplant patient population, including prevalence, incidence, and population characteristics. Prior to start of patient enrollment, the field team obtained estimates of the number of patients who receive the MOH-provided immunosuppressant medications at each hospital. These overall estimates theoretically reflect the projected number of living maintenance kidney transplant patients (MKTP) with post-surgery follow-ups in the country.

Efforts to estimate the total number of transplant recipients in Iraq were complicated by security issues that affected access to

some Iraqi provinces. Relatedly, population displacement as a result of conflict has created logistical challenges in tracking patients who have moved multiple times. These issues are slowly being resolved, as displaced Iraqis return to their homes.

Collected data is analyzed on a regular basis, with a weekly administrative statistical summary run on a copy of the registry data using Power-BI software. The summary is generated for all-Iraq data (accessed by the PWR Director and Statistician only), by region, and by individual hospitals in each region. Regional field managers are provided summaries of hospitals in their region, allowing ongoing monitoring of patient enrollment, and of missing or duplicate data to be addressed in direct communication between field managers and sites. Compared to the estimated follow up patients at that institution, it was possible to monitor the completeness of record entry at each hospital.

> While issues of domestic security are largely outside of the medical community's hands, the registry aims to address system error so as to improve documentation of patient data across the country.

For new patients who are currently having their transplant surgery, the institution where the surgery was performed will initiate the entry of the patient records, regardless of 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.

Incident transplant surgeries were possible to confirm in 12 of the 19 Iraqi provinces for the years 2018-19. As the registry matures, the proportion of incident patients who just underwent kidney transplant surgery will increase, and could be completed for the remaining seven provinces as the situation permits.

The prevalence of MKTP in each province was calculated using the estimates of the number of patients receiving immunosuppressant medications standardized to 1,000,000 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.

Demographic data were possible to verify with high certainty. Entry of disease baseline, clinical, surgery, organ matching, and post-surgery data was inconsistent and sporadic, which makes it impossible to analyze at this point, and would be targeted for improved compliance in the next phase of the registry, which can only happen if were required by targeted regulatory process that sets obligatory recording and reporting of that information, formulated into a set of performance measures.

This page intentionally left blank