

IMPROVING RENAL OUTCOMES COLLABORATIVE (IROC)

Design and Development of a Network Based Learning Health System for Children with a Kidney Transplant

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A. Introduction

Children with a kidney transplant and chronic kidney disease have a complex condition with implications that affect every facet of their lives. The current system of kidney transplant care is failing to deliver results at a suitable pace or impact. A constellation of systemic interventions is required to deliver both immediate and long-term impact that improves the lives of those with a kidney transplant.

This short report describes the design of the Improving Renal Outcome Collaborative (IROC), a network-based Learning Health System (LHS) for children with a kidney transplant involving fifteen kidney transplant centers in the United States. IROC is a quality improvement and research network dedicated to **partnering with patients who have kidney disease and their families to achieve health, longevity and quality of life equivalent to the general population.**

To achieve this bold goal, **IROC is tapping into the inherent motivation and expertise of patients and caregivers, health care providers, researchers and community partners to simultaneously improve care, spawn innovation and conduct research that improves health and outcomes.** Using Quality Improvement Science methodology, IROC centers and their patients and families will test change in clinical practices, and identify and implement best standards of care across the country.

IROC is built around a set of key components that are summarized below:

1. Focus on improving outcomes of kidney transplant recipients as the foremost purpose through discovery and reliable implementation of the best care
2. Engagement of all stakeholders working together:
 - a. Patients and families involved in all aspects of the network, including governance, improvement and research;
 - b. Clinical experts in kidney transplant and their care teams;
 - c. Experts in quality improvement;
 - d. Researchers;
 - e. Network staff with expertise in managing collaborative networks, IT, data management, quality improvement training, and managing innovation and research.
 - f. Payors and representatives from pharma and industry
 - g. community partners
3. Culture of transparency, and policies that promote sharing and collaboration to accelerate dissemination and implementation of ideas that work
4. Effective use of technology, including:
 - a. A standards-based, interoperable “data-in-once” registry to support chronic care management, performance measurement for quality improvement and comparative effectiveness research
 - b. A variety of tools and methods for data acquisition/aggregation to minimize the work for centers to collect and share data in the network

- c. A system for aggregating, connecting, accessing, presenting/visualizing, analyzing and interpreting longitudinal data about the experience of care, the process of care and patient outcomes.
 - d. Pre/post-visit planning, population management, performance measurement and other tools to report on and visualize data for chronic illness care
 - e. Analytics, simulation and other predictive technologies to safely accelerate hypothesis testing, experimentation and discovery of novel therapies and methods.
5. Core Resources to train, mentor, and support centers in local quality improvement efforts and to facilitate the sharing and spread of ideas that work. The development of other resources including:
- a. Business development and monetization resources to secure ongoing funding for the network through a combination of philanthropic capital from healthcare donors as well as revenue from centers and other partners that value the data and insights derived from the network
 - b. Resources to test and scale programs to attract users and patients to engage with the network and share data and insights. We will also seek opportunities to derive economies of scale by coordinating across networks whenever possible
 - c. Strategic partnering resources to identify and form partnerships with vendors that can help accelerate the network's ability to achieve its aims. Examples include data, technology and patient engagement partners, some of whom might also become funding sources.

This report summarizes the design process that took place August 1, 2015 through June 30, 2016. Through this process we identified how IROC key components should work together yield a system capable of transforming chronic illness care for pediatric kidney transplant recipients across the country. During the Design Phase, specific attention was given to identifying outcome and process measures, developing registry requirements, and brainstorming about new ways to delivering care that meet patients, families, clinicians and researchers' needs.

All relevant source documents, reference materials, resources, tools and intervention designs, developed during the design process will be accessible to all IROC teams on a member-only website.

IROC seeks to capitalize on the current changes in health care, including:

1- A policy environment that is moving toward value-based payment models. The increased emphasis on performance-based licensure and maintenance of physician specialty certification, as well as the move by payers to adopt value-based payment models, will accelerate pressure to optimize chronic care using advanced registries. In this context, clinical sites in other disease areas have been willing to pay to participate in networks that support the imperative of improving outcomes. There is also an opportunity to align the system with the efforts of major professional organizations (e.g., Children's Hospital Association, the American Board of Pediatrics, the American Academy of Pediatrics, the Association of Medical School Pediatric Department Chairs) who are interested in collaborative networks. Furthermore there is now

significant investment in large-scale transformation efforts (e.g., Center for Medicare and Medicaid Innovation (CMMI) practice transformation networks).

2- *An increasing emphasis on patient-centered outcomes research.* IROC can align its efforts with ongoing federal investment to reduce the costs of research, including significant investment by the Patient Centered Outcomes Research Institute, the National Center for Advancing Translational Science, and the Precision Medicine Initiative.

Based on the above, we found a deep level of motivation among all stakeholders to transform the current state of care and interest in a profound and robust set of ideas, which if combined into a singular large-scale system with a centralized Registry, offers significant potential for achieving breakthrough impacts on health, care delivery and research for people affected by kidney disease.

The project's aim was to design an integrated clinical care and research system in Kidney Transplant that would support patients, caregivers, health care providers, researchers, and organizations (e.g., health systems, clinics, industry) and allow them to work together to improve care, spawn innovation, accelerate research and improve health outcomes. We used a structured process of complex system design aimed at producing a network-based Learning Health System. The design builds on past successful design efforts for various Anderson Center led networks.

We applied the Collaborative Chronic Care Network (C3N) framework, which is based on an organizational approach called commons-based peer production that increases the capacity of large complex systems. Commons-based peer production is a new model of socioeconomic production in which large numbers of people work cooperatively to meet the needs of all participants and enable new levels of co-production of health care services.

Commons-based peer production begins with a small group of individuals who are highly committed to a common purpose, norms, and culture of contribution and collaboration. We engaged a diverse group over 126 patients, families, clinicians and researchers to participate in the design process, with a core group of 50 regular contributors. The expertise of the team included clinical care and research, design, informatics, data management, software engineering, education, and business. This group formed the Design Team that led and participated in design activities. These activities included an assessment of the current kidney transplant environment and the system of care for kidney transplant, broad environmental scanning and searches of the medical literature for innovative approaches, an ethnography to identify the needs of all participants in the system, and multiple participatory design sessions.

B. Methodology

1- Project Aim & Requirements

This project took place between August 1, 2015 and June 30, 2016 and took advantage of a structured process of complex system design.⁶ The Idealized Design White Paper (see Appendix

A) by Associates in Process Improvement served as the basis of the design process. The design began with the development of a charter that described the aim of the project, goals, and preliminary measures, and system requirements (See Appendix B: Charter)

The **Project Aim** was to design the system that would enable IROC to accomplish its vision to partner with patients with a kidney transplant and their families to achieve health, longevity and quality of life equivalent to the general population. To support the aim, **preliminary measures** and **goals** were set. Participating centers identified 20 possible outcome measures and ranked them on a grid according to feasibility and impact (see appendix C). Three “High Impact” and feasibility outcome measures that aligned with IROC’s vision emerged as the initial focus for IROC over the first 3-5 years. They include:

1. Controlling blood pressure
2. Decreasing acute rejection
3. Improving quality of life for patients and families

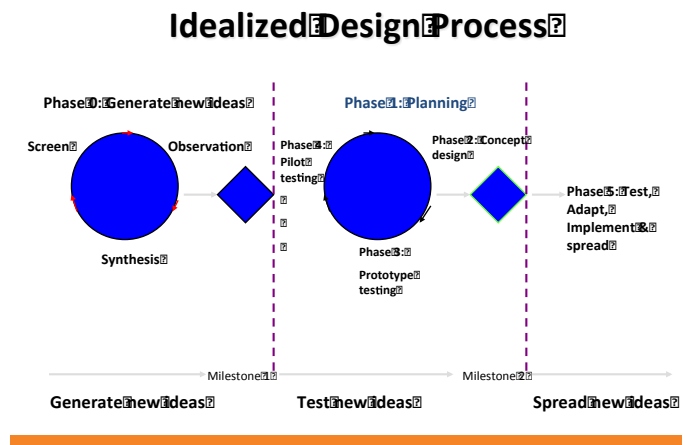
An initial set of system requirements was developed by the design team and presented at a meeting in San Diego during the Kidney Week in November 2015. They provided an initial description of the attributes the new system would need to have to be attractive to the multiple users.

2. Overview of the Idealized Design Process

The Idealized Design process is a 6-phase process to create and implement new ideas. The Kidney Transplant Design project included Phases 0 to 2. Phases 3-6 will be implemented during the launch phase.

Phase 0: Generate New Ideas

The focus of Phase 0 is on generating new ideas that will lead to a fundamental redesign to better meet the needs of users of the system. Understanding the needs of the user is the critical starting point.



Ideas for Phase 0 are generated using observation as the primary method to understand patient and customer needs and ideas to meet those needs.⁷ What are their likes and dislikes? What are their latent needs not addressed by current products or services? Such observations, obtained by “walking in the shoes” of the patient/customer, require an approach that integrates “doing, thinking, feeling, and being” by the observer. This combination reduces the chasm between the observer and the consumer, leading to the experience of the observer being closer to the reality of the consumer. This facilitates neutrality of observations. Innovations emerge from the inferences drawn from these observations.

Key steps of Phase 0 are summarized in the Deployment Flow Chart in Appendix D, including drafting the charter, and completing an environmental scan. The environmental scan used a broad set of tools to catalogue what already existed in the environment. Using literature review, Internet searches, group discussions on web-based platforms like Batterii, and ethnographic studies, designers documented how the system currently operates and addressed what worked and what did not work for current users. Centers assessed their current ability to provide chronic illness care, using the Assessment of Chronic Illness Care 3.5. This is a survey developed and validated in multiple chronic illness settings to assess implementation of the Chronic Care Model in practice. See appendix E for survey results.

IROC used the Batterii platform (<http://batterii.com/>) to solicit ideas from its broad range of stakeholders, organize them in a user-friendly way, and allow discussion and comments to take place over the course of six months. IROC also set up an organizational structure around workgroups, with weekly meetings to encourage live conversations on targeted topics, and to complement the Batterii on-going cataloguing of ideas (See Appendix B for the IROC Organizational Structure).

Ethnography is a particularly important tool during Phase 0. It is a qualitative form of research that relies on in-depth observation and interviews of a group of users to identify unmet needs. It leads to the creation of personas that represent groups of users with similar goals and desires. The IROC personas were developed by Seek Inc, and are available in Appendix F. As personas emerged, the design team began to develop persona-based scenarios that described ideas to meet the persona's needs.

Personas also provided a way to filter or triage the ideas that the broad IROC community shared on Batterii and at the 1st design meeting, in March 2016. At that time, using hands-on exercises, teams contributed to the generation of over 1,400 new ideas that were transcribed into Batterii and served as a fertile ground for web-based exercises, including commenting, and polling. More specifically, through Batterii, all stakeholders were asked to refine their posts and vote according to the relevance of the idea in light of IROC goals and personas. The pre-selected ideas were grouped into 46 design concepts or interventions as the refinement process proceeded. These design concepts are available in Appendix G.

The process of prioritizing and developing new ideas began next. During Phase 1 of Design, the team reviewed the interventions that emerged from Phase 0 and revised the charter and plans. During Phase 2, the 46 interventions were reviewed and prioritized at a second design meeting that took place in June 2016. The goals of the second design meeting were to: 1) converge towards a core group of impactful and feasible interventions to test in IROC centers as individual QI activities, and as part of a larger package of interventions, 2) create consensus around key driver diagrams and measures for IROC key outcomes (blood pressure control, acute rejection, and quality of Life); and 3) develop the infrastructure to officially launch the network.

C. Recommended actions

With Phase 2 of the Design process ending on June 30, the Core team gathered enough evidence and support from its stakeholders to support the following actions:

1. Implement IROC as a network-based learning health system where quality improvement and research work simultaneously to change outcomes for children with kidney transplant. Primary focus will be on improving blood pressure control, reducing acute allograft rejection, and improving quality of life for patients and care givers.

To support advancement in each outcome measure, IROC will rely on three outcome measure subcommittees with the following committed members. These subcommittees will join QI workgroup meetings as needed to share with the larger group the results of their efforts.

- *Blood Pressure Control*: Stanford, Emory, Colorado, Boston
- *Reduction of acute allograft rejection*: CCHMC, Seattle, Colorado, Iowa, UAB, CHOP
- *Quality of Life*: University of Michigan, Nationwide, CHOP, CCHMC, Children Mercy

2. Develop tools and resources to help care centers transform care in the network. We developed three types of resources that are needed to enable care centers to participate successfully in a learning network: 1) system level, clinic level, and outcome level key driver diagrams (Appendix H), 2) measures to monitor progress and establish the learning system (Appendix I), and 3) a set of specific, evidence-based changes that if implemented will result in improved outcomes (ex: Pre-Visit Planning, Population Management, Self – Management, etc.) (Appendix J – Change Packages).
3. Develop an Enhanced Registry Platform that, **with time**, has the capability to: receive data from electronic health records and webforms; integrate device data and patient-generated data; provide patient access to their own data; integrate care management reports into the electronic health record; facilitate use of data for research, identifying cohorts, supporting comparative effectiveness research, and linking to biorepositories and genomic data in the future (Appendix K).
4. Develop a knowledge exchange (“commons”) where resources, knowledge and knowhow can be shared on a member-only website.
5. Develop and test potentially transformative innovations at care centers. In addition to the evidence-based changes referenced above, we developed high-impact ideas that could be prototyped or pilot tested as part of the collaborative network. Using a scoring scale from 1-5 with 5 the best score, attendees at the design meeting ranked the 46 design concepts that were pre-voted on Batterii, according to two criteria: 1) feasibility (or know-how) and 2) impact on IROC’s outcomes. Appendix L shows how the 46 design concepts were individually ranked on Batterii and then at the Design meeting. The results are displayed in a plotted chart with the top right quadrant indicating the ideas with the highest scores on both criteria.

Later in the meeting, the same attendees conducted a series of hands-on exercise to assess the extent to which the ideas, if combined with other ideas, could have increased impact or feasibility, therefore making the “package” more powerful on the lives of the patients, families, clinicians and researchers. Following the similar scoring system, the packages were ranked. Appendix M that shows the corresponding plotted chart and quadrants.

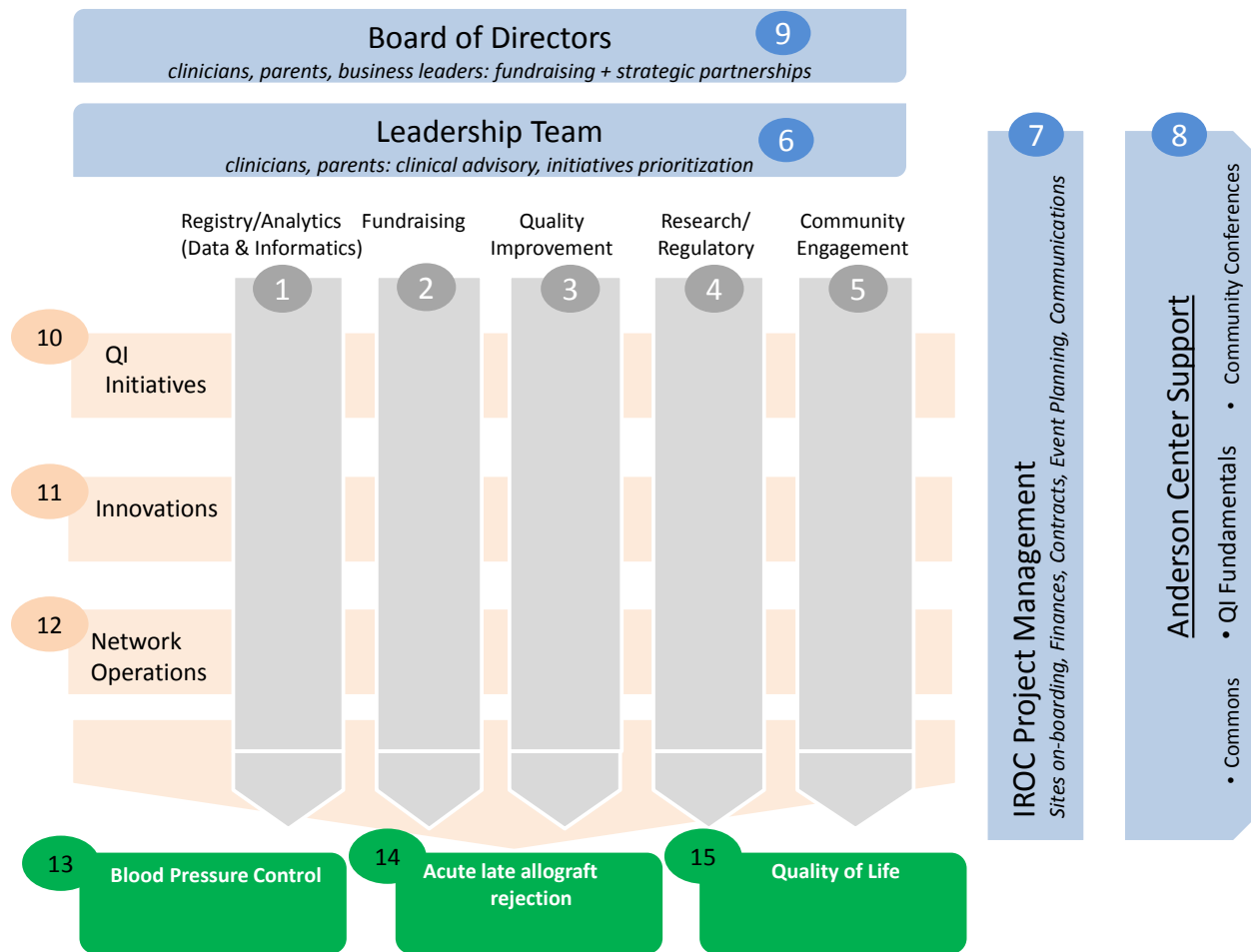
The analysis of the plotted charts revealed what package of interventions carried most promises. These packages are described in the IROC Interventions Packages Report. Many of them are aspirational in nature as they will require additional funds for proper development and testing in clinics. However, a quick analysis of these packages also shows that top ranked packages shared common design concepts. This implied that such concepts were foundational and needed to be tested and implemented *first* to secure the success of future QI network interventions.

These four design concepts are described below. For each we have assigned a dedicated workgroup with committed centers, who will work on initiatives to develop the ideas into prototypes and pilots, before they are implemented as new standards throughout the network.

- *Pre-visit Planning*: The ability by clinical teams to conduct effective Pre-Visit Planning is perceived as a major driver to improving IROC outcomes, and therefore is an initiative considered a top priority by the network. CCHMC, Nationwide, Riley, University of Michigan and Emory will work together to create a PVP report and will collaborate with the bio-informatics team to make the functionality available in the registry.
- *Mentoring*: The availability of a patient and parent mentoring program at each center and at a network level is another critical intervention to support improvement in IROC three outcome measures. IROC will leverage initiatives currently in place at Boston Children’s, and will partner with the National Kidney Foundation to offer a state of the art mentoring program to IROC patients and families.
- *Virtual Roadmap*: A clear documented roadmap that families can use to navigate the complexity of the kidney transplant journey will help centers achieve health outcomes faster. Iowa Children’s and University of Michigan have developed local programs that IROC will improve upon and make available to the entire network.
- *IROC Exchange*: A user friendly platform where IROC materials, knowledge, commons and tools can be easily shared across all centers will help support faster learning and improvement, in our three focus areas. CCHMC and Iowa will lead the way.

7. Figure 1 below summarizes how the foundational initiatives will collaborate with IROC functional teams, to support the three IROC health outcomes.

Figure 1: IROC Organizational Structure



Legend

Functional Teams:

Registry/Analytics; Fundraising, QI, Research/Regulatory, Community Engagement

Domain Workgroups:

QI Initiatives (Pre-Visit Planning); Innovations (Mentoring, Virtual Roadmap);
Network Operations (IROC Exchange)

Support Groups:

Board of Directors, Leadership, Project Management, Anderson Center

Outcomes:

Blood Pressure, Acute late Allograft Rejections, Quality of Life

D. Next Steps: From Design to Pilot

IROC is proceeding with launching a network of 15-20 centers using structured systems improvement methods to develop a new system of care for kidney transplant patients. These methods will support the process of testing and adaptation, and avoid the risk of disrupting the current system.

The objectives of the next phase of development will be to:

1. Develop an enduring quality improvement network that fully integrates Quality Improvement and Research
2. Create an IROC Enhanced Registry to support a Learning Health System and provides data for clinical decision support, quality improvement and research
3. Develop a knowledge-sharing commons
4. Build capacity for co-production by expanding the scope of the Community Integration Group and integrating patients and families in centers' local QI efforts
5. Develop and prototype four transformative initiatives at one or more sites with potential for spread (PVP, mentoring, Virtual Roadmap, and an IROC Exchange)
6. Develop the research infrastructure (e.g., streamlined Institutional Review Board, authorship and publication rules)

E. Conclusion

The Launch of IROC will be primarily focused on setting up the infrastructure for the centers to start sharing data and receive the QI reports to assess performance and track improvement. QI tools such as Pre-Visit Planning and Population Management will be developed within months of launching the network. Semi-annual learning sessions will enable centers to share ideas and techniques for improving key processes and outcomes. Centers will also receive formal QI training.

F. Acknowledgment

The IROC Leadership team and Coordinating Center would like to thank all the 15 IROC centers for their commitment to the success of the Design Phase. Their generous financial and time contributions, along with their continuous sharing of ideas were critical in getting IROC where it stands now.