OPTN Data Advisory Committee
Holistic Data Review Workgroup
Meeting Summary
June 23, 2023
Conference Call

Sumit Mohan, MD, Chair
Jesse Schold, MD, Vice Chair

Introduction

The Data Advisory Committee Holistic Data Review Workgroup (the Workgroup) met via GoTo teleconference on 06/23/2023 to discuss the following agenda items:

1. Data Definition Update
2. Clinical Data Standards Project Update

The following is a summary of the Workgroup's discussions.

1. Data Definition Update

Data definitions were discussed on the following topics: insulin patients, primary insurance, and between listing and transplant.

Summary of discussion:

Patients on insulin
Staff presented data collection fields related to insulin treatment regimen. It was noted these fields had been discussed in a previous work group meeting, where feedback was gathered to report to the Pancreas Committee. Staff provided data collection fields and clarified that they could be found on the kidney and pancreas Transplant Candidate Registration (TCR), Transplant Recipient Registration (TRR), and Transplant Recipient Follow-up (TRF) forms.

A member noted transplant programs usually entered an approximate date for reporting, with the options of selecting between 1 and 5 years, 10 years, or 15 years. Other members recommended having a minimum age or year identified, stating that obtaining an age from the patient would likely be easier and more accurate.

Staff proposed updating the definition to state that the transplant program may enter the approximate date for when the patient began insulin therapy or the patient's age when the therapy began. Members agreed with this suggestion and emphasized the need for accurate data and better instructions.

Staff noted the challenges in calculating an accurate average due to variations in long and short-acting insulin and different dosing methods, such as using insulin pumps. A member expressed the difficulty in obtaining accurate data.

Staff acknowledged the challenges and suggested that the feedback primarily targeted short-acting insulin, even though the field did not specify it. Members agreed that the integer limit for dosage reporting should be increased for more accurate data collection.

Members discussed the forms that referenced the insulin data collection fields, clarifying the reporting period variations between different forms. A member brought up the TRR and TRF form, which dealt with the duration of insulin use and the definition of pancreas failure.

Staff proposed changing the data collection label to "average total short-acting insulin dosage per day" to better clarify the type of insulin being reported. Members agreed to update the definition accordingly and review the forms that referenced this data collection.

Primary insurance
Staff reviewed the topics discussed in the previous meeting, including the identification of inconsistencies in existing definitions and addressing member queries about reporting data. Staff introduced the planned revisions which primarily focused on updating the valid value list for primary insurance options.

Staff introduced modifying the private insurance options to provide more clarity. Changing the options to private insurance, commercial health insurance, public insurance, Medicare, and self-pay were brought up. Additionally, the inclusion of Medicare Part C or Medicare Advantage was suggested.

Revisions to the definitions were also proposed, i.e., updating the definition of public insurance to encompass Medicare C or Medicare Advantage for better clarity. "Welfare Trust" was suggested to be used an example of a funding source for private insurance. "Affordable Care Act" was suggested to be used in place of “Obama-Care”. The term "Public Insurance-Other Government” was suggested to be removed, considering its infrequent usage and potential for inaccuracies. These changes were agreed upon by members.

Between listing and transplant
Staff addressed feedback on clarifying clinical events occurring between listing and transplant. The input received from the OPTN Heart Transplantation Committee on proposed changes and additional feedback from the OPTN Heart Transplantation Committee was presented for review.

A member supported the feedback, except for a repetition in the third bullet regarding pulmonary embolism. Staff confirmed the repeated information would be removed. Another member suggested further clarification of the point on infection requiring IV therapy within 14 days prior to the date of transplant. Staff confirmed this was a transcription error and would be resolved before sending information for review.

Next steps:

Staff planned to review and follow up with the OPTN Kidney and Pancreas Transplantation Committees for approval and feedback on the recommended data collection changes. The OPTN Heart Transplantation Committee may also be making updates that would impact the data definitions, in which case this would be discussed in a future meeting.

2. Clinical Data Standards Project Update

Details about the implementation strategy and timeline for the Clinical Data Standards Project were discussed.

Summary of discussion:

Staff updated committee members about their meetings with various external stakeholders to understand the potential impact of adopting data standards on the community. They met with organizations like organ procurements organizations (OPOs), electronic donor record vendors, transplant programs, electronic medical record vendors, and histocompatibility laboratories.

Findings include:

- OPOs were still in the early stages of adopting data standards, despite external push from the Centers for Medicaid and Medicare Services (CMS) and limited support in informatics.
- Electronic donor records had either no or low adoption of standards.
- Hospitals and healthcare centers showed a high level of maturity in the standard space, largely due to compliance with Office of National Coordinators' requirements.
- Some academic centers had separate processes for pulling OTN data to support local analytics and research projects.
- Although registry APIs are growing, electronic medical records (EMRs) need more time to fully support data sharing using standardized health data exchange.
- Histocompatibility laboratories are fully integrated with standards and can share histocompatibility data.

Staff also discussed the vendor assessment for solutions that provide terminology, features, and configuration capabilities. They evaluated aspects like cybersecurity compliance, integration with existing software, and pricing models. They also shared the pilot project evaluation criteria, which included data mappable to standards, community readiness for adoption, system design, API, and research/analytics.

Support staff shared that the second half of the assessment project would focus on the implementation strategy and timeline. This information will be shared with the Workgroup at an upcoming meeting. The Workgroup's activity to document a comprehensive data review plan will likely extend into October or November to allow for revisions and input from stakeholders.

Next Steps:

The comprehensive plan for data standard adoption will be developed once the assessment phase of the project is completed.

Upcoming Meeting

- August 25, 2023 (teleconference)

Attendance

- **Sub-Committee Members**
  - Rebecca Baranoff
  - Karl Neumann
  - Ashley Cardenas
- **HRSA Representatives**
  - Adriana Martinez
  - Ajay Israni
- **SRTR Staff**
  - Jon Snyder
- **UNOS Staff**
  - Eric Messick
  - Elena Liberatore
  - Kimberly Uccellini
  - Lauren Mooney
  - Nadine Hoffman
  - Sevgin Hunt
  - Jonathan Chiep
  - Brooke Chenault
  - Divya Yalgoori