OPTN/UNOS Operations and Safety Committee
Meeting Minutes
May 4, 2017
Conference Call

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Introduction

The Operations and Safety Committee met via Citrix GoToTraining on 05/04/2017 to discuss the following agenda items:

1. Introductions and Announcements
2. DonorNet Profiles: Pilot IT Project in Development
3. IT Follow-Up Discussion from April 6, 2017
4. Ethics White Paper on Terminally Ill Donors
5. Other Significant Items

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

1. Introductions and Announcements

After reviewing the agenda of the meeting, the committee liaison asked the committee to read the draft of an Ethics Committee white paper in order to provide feedback. The paper, which addresses a subset but different focus than the Imminent Death and Donation workgroup had tackled, is being prepared for potential public comment in the fall. The committee will discuss the paper in June. Imminent death donation issues, which have to do with potential donors who are able to make their own medical decisions, were discussed previously by the committee with that focus being on third party consent. It was decided to table those discussions due to the resulting controversy. The current white paper under discussion addresses fatally ill persons who would be able to make their own decisions.

2. DonorNet Profiles: Pilot IT Project in Development

A UNOS staff member from the UNOS Information Technology (IT) department, presented an overview and demo of a DonorNet project called Donor Profiles. The staff member is currently working with the business architect on this project, for which they are seeking feedback from various committees, including Operations and Safety.

Introduction

The goal of this project is to allow transplant hospitals to use criteria in combination to screen offers more precisely, with the ultimate goal being to increase the number of transplants by placing organs more rapidly. Donor Profiles hopes to reduce unwanted offers, decrease cold ischemic time, and increase organ acceptance, especially of hard-to-place organs.

The original idea came from a conversation with a UNOS/OPTN Board of Directors Past President and the UNOS Chief Technology Officer. The past president shared a tool his program uses to screen offers and asked if IT could create a tool to prevent unwanted offers up front and speed up organ allocation. Technical feasibility of a prototype was tested at a UNOS innovations day. After the successful test, IT worked with the Policy Department to form a working group to gather requirements. This working group is seeking broader input from various committees and work groups, including Kidney, Systems Optimization, IT Customer Council,

Organ Procurement Organization (OPO), and the Transplant Coordinators. The Donor Profiles working group currently has five members from three hospitals and two OPOs.

The project's key concepts include:

- Profiles will be set up at a program level, not at the individual candidate level. This streamlines the process by eliminating the need to set up individual profiles for each candidate.
- Tools will be provided to manage a large waitlist, including the ability to add and remove candidates in bulk.
- Individual candidate functionality would be limited, which reduces cost and provides better visibility at the program level.

Donor Profiles - Waitlist Screens Demo

A UNOS IT staff member presented a demo, which showed how transplant hospitals can add a profile, add and remove candidate associations, edit a profile, and remove a donor profile. The main page shows a list of all profiles, a description for each, and the total number of candidates associated with the profile.

The idea is to enter criteria to describe a donor from whom offers would be undesirable. Currently, the minimum acceptance criteria in Waitlist are inclusionary; Donor Profiles is designed to be exclusionary. The Add screen has ten donor criteria. Users must go through the following steps on the Add screen:

- Name the profile
- Specify donor type (brain death or donation after circulatory death (DCD))
- Specify offer type (pre-recovery or post-recovery). Depending on feedback received, the final product may include only post-recovery profiles, as that may be more useful than prerecovery.

Exclusionary criteria in the system include: maximum kidney donor profile index (KDPI), whether the donor is outside of your donation service area (DSA) or outside of your region, minimum and maximum ages, history of hypertension and/or diabetes, maximum cold and warm ischemic times, increased high risk, human leukocyte antigen (HLA) mismatch. A candidate panel reactive antibodies (CPRA) threshold has recently been added to allow users to adjust criteria as desired for highly sensitized candidates.

Regarding the "donor increased PHS high risk" category, the Committee Vice Chair suggested eliminating the word "high" and just using "increased risk." The term "donor PHS increased risk" was suggested. When the US Public Health Service (PHS) guidelines were revised in 2013 the terminology was changed from “high” to “increased” risk.

After creating a new profile, it will show up in the list of all profiles for that particular hospital. When a profile is first added, the total number of candidates associated is 0; candidates must be associated by the user. The user can search for a group of candidates by age, medical urgency status, waitlist add date, and other criteria. Entering the desired criteria generates a list of all candidates that meet these criteria. Candidates can be associated individually by entering their name, or they can be added in bulk from the group search. Profiles can also be deleted or edited.

On the DonorNet side, profiles would be applied at electronic organ offer time, not at match run time. Profiles would not be applied prior to match run, because information usually changes after match run. This allows for dynamic bypassing as information changes, which seems more useful.

The vice chair notes, however, that factors like age and weight would not change, and wonders if allowing for a preliminary narrowing of the field earlier in the process would increase efficiency by avoiding a flood of notifications. The committee chair pointed out that you don't receive notifications automatically. Rather, because the system is dynamic, it allows any variables that have been entered to be applied when the OPO chooses to notify.

In response to this question, IT staff discussed how the system would look from the OPO side. Under the current system, the OPO clicks “Electronically Notify” after running a match. The new system would add an extra step for the OPO at this point, allowing them to edit or enter new data at this point in the process to ensure accuracy. When the user clicks “Next”, the system reviews every candidate on the list to see whether there are any profiles associated with that candidate. It matches the profile data with the donor data to determine if there are any exact matches. If there are, the system applies a bypass code for donor profiles. Under the new system, the starting sequence for sending electronic organ offers (EOOs) is often going to be further down a match.

After the first time a user goes in to run the notifications, the starting sequence would be further down the match run list.

Waitlist and DonorNet Pilots

During the pilot and initial rollout phases, the plan is to focus strictly on kidney candidates and donors.

The Waitlist pilot will be open only to a select group of transplant centers. After participating centers set up their profiles, UNOS will apply those profiles retrospectively to offers over a certain time frame (probably six months to a year). UNOS will then provide reports back to the pilot participants to allow them to review the criteria and refine as necessary. This pilot phase will involve at least two iterations.

Once participants in the pilot feel that the criteria are correct and that the profiles are working as intended and bypassing appropriately, the prospective DonorNet pilot would begin. At this stage, the profiles will be applied to live offers, but no bypassing will be performed. After the DonorNet pilot phase, bypassing would be introduced.

Feedback

The committee chair noted that the profile pop-up could become tedious from an OPO perspective, particularly post-recovery. It seems the new system is adding extra, unnecessary clicks. The chair thinks that once all the data is entered, there comes a point where it is unlikely to change. Maybe this extra work could be eliminated from the system once biopsy results have been entered and the OPO is trying to work through kidney allocation.

The vice chair thinks the new system would add a lot of useful information to DonorNet. Another committee member is also enthusiastic about the proposed system and asks how long before the project goes live. IT staff anticipates the first pilot will begin in the first quarter of next year, so it is hard to predict when it will go live--perhaps a year and a half or around that time frame. The committee member thinks that, when it goes live, it is going to be important to convince centers to actually use the system rather than just looking at all the offers.

The committee chair asks if criteria like minimum and maximum age will still exist in the new system, or whether it will force all users into viewing the profiles. IT staff says the development team is still working through that question. It seems likely that some of the minimum acceptance criteria might go away or change. The chair suggests it might be necessary to get rid of the minimum acceptance criteria because that would force people to use the profiles and to better define their acceptance criteria.

A committee member thinks it is important to give transplant centers a long lead time in order to give them a chance to update their minimum acceptance criteria. Not doing so could lead to centers getting bypassed for offers. It was also asked how conflicts between individual acceptance settings and Donor Profile settings would be handled. IT will research this question further.

The slides from the IT staff presentation will be posted on the SharePoint site for review by committee members. The links to the demos are in the slide deck and can be accessed by members.

3. IT Follow-Up Discussion from April 6, 2017

During the April 6th discussion with UNOS IT staff regarding TransNet and DonorNet verification, members were asked to go back and consult with their respective organizations. The committee chair asks if members have had a chance to do so or if anyone has additional thoughts on the previous discussion, to which there are no replies. The chair requests that the committee liaison pull this section from the minutes and forward it to members as a reminder. It is important that the committee help the Customer Advocacy Council determine a path forward.

A committee member noted that there was excitement about this topic at the Chicago meeting. He asks whether or not this feeling carried through to the April call, which he was unable to participate in. The chair believes everyone was still excited about it during the April call, at which time the committee hammered out a clear direction to head in. The idea was for members to further refine this direction between the April call and the current one.

4. Ethics White Paper on Terminally Ill Donors: Will Discuss on June 1, 2017

The Ethics Committee liaison will be sending out the draft white paper this week or next week so that members will be able to review it before June 1. There is an earlier draft, but the Living Donor Committee wanted to send a more recent version, which is why the Committee members have not yet received the document. The white paper will discuss current issues, including policy, that would need to be considered or revised to address proceeding with terminally ill living donors. A Living Donor Committee representative or the liaison will be available to discuss the paper on the June call.

5. Other Significant Items

The Chair of the Patient Safety Advisory Group noted that the work group has not decided on a topic for its next educational offering and asks the group for ideas. If anyone has an idea, please let the committee liaison know. They need to begin work on this within the next month or so in order to meet their timeline.

Upcoming Meetings

- June 1, 2017