

**OPTN/UNOS Ethics Committee  
Meeting Minutes  
March 1, 2019  
Teleconference**

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**Introduction**

The OPTN/UNOS Ethics Committee met via Citrix GoToTraining on 03/01/2018 to discuss the following agenda items:

1. Spring 2018 Public Comment

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

**1. Spring 2018 Public Comment Review**

The Committee reviewed selected proposals out for public comment and provided feedback to the sponsoring committees.

Summary of discussion:

The Executive Committee presented the following proposals to the Committee for feedback. The discussion of this proposal took place over the entire meeting on 03/01/2018. The Ethics Committee then synthesized these discussions into feedback:

- a. Concept Paper on Improving the OPTN/UNOS Committee Structure

The Ethics Committee recognizes that OPTN/UNOS's goals to foster greater engagement in UNOS deliberations and policy making by the public and the transplant community are laudable. Greater engagement may foster broader understanding about policy proposals and accommodate multiple perspectives with the goal of producing more effective policies.

The Ethics Committee also recognizes that the OPTN/UNOS proposal to restructure committees presents significant problems, as currently proposed, both substantive and logistic, and is unlikely to achieve the important objective it has articulated. Our take home message is this: This proposal is unlikely to achieve the goal of expanding public engagement in UNOS policy-making and further risks losing independent ethical direction and guidance for the transplant system, reducing public trust in the transplant system, and eliminating a voice for the most vulnerable. Though the goals are important, the solutions will not achieve them and are likely to set the community back. In the spirit of collegiality, the Ethics Committee proposes some potential solutions, including to: (a) Retain the current UNOS Committee structure including the capacity for all current Committees to sponsor public comment and Board proposals; (b) Decline the OPTN/UNOS proposal to re-categorize the Ethics Committee into an 'Expert Council'; (c) Decline the OPTN/UNOS proposal to have members of the Ethics Committee serve on Subject Committees; and (d) Enhance opportunities for public participation and engagement by partnering with patient organizations, advocates, and others with an interest in the transplant community. Accordingly, the Ethics Committee believes that our proposed restructure alternative will better accommodate OPTN/UNOS's goals and

address the concerns by the Ethics Committee, and most, if not all, other Committees. Below, we articulate these problems and solutions in detail.

## PROBLEMS

### Substantive Problems

The transition from Committee to 'Council' would entail a pivotal change in the scope of the Ethics Committee's (and other Committees proposed to become a Council) role. Traditionally, the Ethics Committee developed numerous white papers, guidance documents, and reviewed policy proposals developed by other committees to ensure that proposals were ethically sound. The OPTN/UNOS proposal removes the ability of the Ethics Committee to "Sponsor public comment and Board proposals" to instead, "Provide perspectives on public comment and Board proposals". Constraining the Ethics Committee's ability to comment only on existing policies or matters raised by other Committees will jeopardize the Ethics Committee's ability to effectively serve the OPTN/UNOS because it removes the only committee independently tasked with identifying and advising on ethical concerns related to transplantation. Limiting the Ethics Committee's ability to identify and address new and important ethical considerations independently will diminish the quality and import of the Ethics Committee's contributions. Further, the OPTN/UNOS's proposed changes will jeopardize Ethics Committee members' morale or willingness to participate, and the perceived value of their input, which may inevitably reduce Committee member engagement, which is precisely the opposite of the proposal's intended effect. It may be difficult to find and retain ethicists to serve in these roles if they are perceived as merely a "rubber stamp" on Subject committees. Moreover, removing the Ethics Committee's ability to sponsor public comment and Board proposals would only serve to reduce engagement by the Ethics Committee with the broader transplant community, contrary to the proposal's goals. Finally, the Ethics committee serves as a venue for the public and vulnerable stakeholders to direct their concerns if they believe that ethical issues are not currently being considered but should be.

The Ethics Committee must retain its ability to sponsor public comment and Board proposals along with writing guidance documents, for several reasons:

#### 1. Historical Perspective: UNOS's loss in oversight of ethical issues

Ethics has been fundamental to the growth and maturation of human transplantation from its inception, and remains equally important today. The need for equity in the provision of renal replacement therapy drove the U.S. Congress in 1971 to pass the ESRD entitlements to prevent nephrologists from selecting patients for dialysis based on social worth criteria. Ethical deliberation, particularly in the context of the organ shortage, is key to ongoing promotion of equitable organ allocation. The Final Rule codifies the need for policies that establish equitable organ allocation [§121.4(a)(1); and §121.8 (a)], and thereby positions ethics central to policies regarding organ allocation. The Ethics Committee is responsible for reviewing UNOS policy proposals and generating guidance documents that support the Final Rule in its requirement to support equity in transplantation. No other UNOS Committee focuses exclusively on this issue without conflicts of interest or competing commitments to other areas (e.g., specific organs, an OPO, etc.). Removing the Ethics Committee's responsibility for providing important guidance to the transplant community by sponsoring public comment and Board proposals including will jeopardize the equitable foundation of transplant policies and

practice, and may undermine public trust cultivated by the Ethics Committee and UNOS for over twenty years. OPTN/UNOS policy proposals must strive to ensure racial and ethnic diversity in organ distribution. Yet policy proposals can conflict with ethical principles of achieving maximal equity, utility, and efficiency. Such conflicts must be resolved through in-depth ethical deliberation about ethical principles to balance the interests of all constituents in a just way. The Ethics Committee's guidance has been critical in maintaining justice in UNOS policies.

## 2. Independent deliberation is essential to maintain integrity

By becoming an 'Expert Council', the ability to identify ethical issues warranting comment would be stripped from the experts, and instead, this responsibility would fall to members of the Board or Subject committees without ethics training and members who necessarily do not have ethics as the primary concern of their UNOS committee deliberations. Rather, members of proposed Subject Committees will continue to spearhead primarily, and rightly so, issues pertaining to their respective subject, rather than ethical issues. Thus, no one in the OPTN/UNOS proposed Committee structures will champion the inherent ethical issues in transplantation. Ethics 'Expert Council' would be beholden to the proposed Subject Committees to advocate for and address ethical issues. The Ethics 'Expert Council' would become a handmaiden to the other committees to uphold any concerns that the Ethics 'Expert Council' may have. Moreover, having Ethics Committee members comment on issues raised by the OPTN/UNOS proposed Subject Committees may miss key systemic ethical concerns that do not fit neatly into the purview of a single Subject Committee.

Even though the proposed 'Expert Councils' would have a representative on the Subject Committees, that one voice would carry less weight than the voice of Committees in their current form. Requiring a single representative from the proposed Ethics 'Expert Council' to be the lone voice on Subject committees to raise issues could raise similar challenges as being a "whistleblower" with little protection or guidance on how ethical feedback will be incorporated.

The OPTN/UNOS proposed 'Subject Committees' have vested interests in their area of work, and these interests may lead them to choose one side of an ethical issue to protect those interests without fully realizing the breadth of the issues. The Ethics Committee in its current form has members with expertise in ethics who have the necessary independence to make arguments, when necessary, some of which may be unpopular or contrary to current practice that may impact policy and organ committee sentiments. Therefore, maintaining the Ethics Committee's independent review process is critical for fostering the integrity of ethical oversight of OPTN/UNOS policies.

## 3. Vulnerable groups are not well represented in the proposed new structure

The Ethics Committee and other Committees (e.g., MAC, LD, Pediatric), currently give voice to vulnerable populations (e.g., under-represented groups, ethnic minorities, living donors, children). The proposed committee structure would diminish the influence of leaders whose primary responsibility is to advocate for vulnerable groups. Consequently, and contrary to the intended effect of the new policy, these groups may become even more vulnerable. Stakeholder groups for minorities, living donors, and children are likely to take notice and lose faith. The risk of erosion in public trust in UNOS and in transplantation is a genuine risk since there will no longer be a voice spearheading ethical concerns and protecting those most vulnerable in the transplant enterprise.

## Logistic Problems

Including representatives from the Ethics 'Expert Council' (and LD, MAC, Pediatric 'Councils') onto the OPTN/UNOS proposed 'Subject Committees' might help to infuse different perspectives into the proposed Subject Committees' deliberations. However, several logistical problems, in addition to the substantive problems noted above, could undermine the ability to achieve the proposed goal of broader engagement among the current committees and the OPTN/UNOS Board.

1. Transforming committee structure is not necessary to foster greater engagement  
There is no requisite need to transform Committees into the proposed 'Expert Councils' in order to infuse representation by the Ethics, LD, or MAC Committee on the proposed Subject Committees. There is no evidence indicating that the current overall Committee structure is not conducive to engagement.

The Ethics Committee does encourage collaboration and engagement by any committee with an ethical question. The Ethics Committee is amenable to having its members attend other committee's meetings on an ad-hoc basis by an appropriately experienced member with knowledge of the issue at question. The Ethics Committee has repeatedly demonstrated its ability to engage other committees in its development of Board-approved white papers to guide the transplant community. As an example, the OPTN/UNOS Board asked the Ethics Committee to work on delineating the ethical issues involved in multi-organ transplantation. Because the Ethics Committee is comprised of a diverse array of healthcare providers (of diverse clinical backgrounds), administrators, philosophers, clinical ethicists, researchers, and living donors, the Committee is highly adept at leveraging multiple perspectives to contribute to discussion of ethical issues. Thus, problems with engagement do not pertain to the Ethics Committee. Accordingly, it is worth noting that no other current committee would have the expertise to develop a white paper on the ethical principles that should guide multi-organ allocation. The Ethics Committee is uniquely qualified to address concerns of many different groups (e.g., patients, donor families or living donors). Formation of subcommittees has also been successful in bringing together expertise around emerging areas of interest.

Compared to the OPTN/UNOS proposed 'Subject Committees', the proposed 'Expert Councils' would be nebulous in terms of charter, character, and composition. Members of the public or other scholars would likely have little motivation to join the proposed 'Expert Councils' given that their involvement would remain peripheral to the decision-making authority retained by core committee members. Accordingly, such 'Expert Councils' would be difficult to establish and sustain over time.

2. Precedent for engagement

Historically, members of the Ethics Committee have effectively collaborated with other Committees members in specialized workgroups on white papers (e.g., pediatric ethics, living VCA donor evaluation, manipulation of waitlist priority). The Policy Oversight Committee already fosters engagement upstream in the project development and policy-making process. Thus, precedent has already been established for such desired engagement. There is no evidence indicating that these processes are not conducive to engagement.

### 3. Crowding out

The voices of Ethics 'Expert Council' representatives will likely be crowded out by the clinical focus of proposed Subject Committees. As an analogy, in the context of IRB Committee deliberations, community members rarely speak up because as nonscientists they feel inhibited from contributing. The concern is that one or two representatives' voices may be too few to be truly heard because the proposed Subject Committees are focused on their specific subject matter rather than on topical issues of ethical issues, minority, and pediatric perspectives. There is concern that proposed Subject Committees may simply pay lip service to the representatives of the proposed Expert Councils. Moreover, placing Ethics 'Council' representatives on proposed Subject Committees may result in less engagement than in current practice (whereby committees must seek stakeholders through the POC process or create cross-committee workgroups, etc.). Any given proposed Subject Committee will address few areas that require ethical attention, resulting in a lot of wasted time by Ethics 'Council' representatives. The deliberation over ethical issues with only one or two representatives on a proposed Subject Committee would lack the rigor of ethical deliberation, which is at the core of our Ethics Committee's analytic approach.

### 4. Oversized councils may become unwieldy

OPTN/UNOS' rationale of transforming Committees into Expert Councils is to foster greater engagement by the public in UNOS's deliberations. Increasing the number of people involved in proposed Expert Council deliberations is logistically unrealistic and unwieldy. Current Committees include about 18 members, and any more members would be too difficult to partake in a group discussion. There is simply not enough time in a 1-hour meeting for every member of a proposed Council to express themselves. Unrealistically large memberships will exacerbate opportunities for groupthink, power dynamics, and gender dynamics, all of which will undermine the ability of proposed Expert Council members to be engaged. Opening the Expert Council to a larger community of general members also opens the door to lobbying-type efforts rather than genuine public comment and debate. The OPTN/UNOS's proposal has not resolved these issues, which makes the proposal untenable.

### 5. Problems with engagement

The OPTN/UNOS' proposed 'Expert Councils' would no longer hold in-person meetings, which jeopardizes relationship building necessary for engagement. In-person, face-to-face meetings are essential for the Ethics Committee to effectively deliberate on controversial topics, and this cannot be replaced by webinars or teleconference calls. There is also a concern that members of the proposed Expert Councils will not be engaged because they will not be formally recognized as a member of a Committee. Accordingly, their involvement may be sporadic and unreliable. While this proposal admirably seeks to increase public engagement, it does not clarify how it will achieve this and does not set forth resources necessary to achieve this goal.

### 6. Regional representatives on the Ethics Committee represent diverse ethical perspectives

Ethical issues can vary by geographic region. As the liver redistricting effort showed, some regions' populations can be more vulnerable than other populations to the point of jeopardizing geographic equity in organ allocation. Thus, it is critical for the Ethics Committee to include regional representative members who have the ability to provide insight into the specific needs of their constituents in order to inform ethical deliberation.

Removing regional representation from the Ethics Committee (and on other committees) holds great potential for enabling powerful groups to consolidate power that may overlook the interests and concerns of weaker groups or regions. Regional representatives serve a valuable purpose of providing checks and balances in the transplant policy-making process.

An issue exists with the current process of selecting regional representatives because the Ethics Committee has not been traditionally involved. Consequently, regions have come to select some regional representatives who lack the ethics expertise to engage effectively in ethical deliberation. Thus, the Ethics Committee recommends that representatives be nominated by regions and be approved by both the Committee in addition to UNOS/OPTN Board Leadership.

7. The OPTN/UNOS committees could achieve greater diversity.

A more 'diverse' conceptualization of 'diversity' is needed. The OPTN/UNOS's proposal aims to increase 'diversity' in terms of committee minority composition and in constituent groups (patients, donors, family members). The Ethics Committee strongly believes in the importance of diverse representation. Ethical analysis requires examination of issues from multiple perspectives to ensure that all principles, norms, and values are considered. There are different reasons for wanting to promote 'diversity'. For example, to ensure that all constituencies are represented; to ensure broadest representation possible; and to ensure that certain classes of people are not excluded who have traditionally been vulnerable and not heard.

Thus, the transplant community would be remiss if it disregarded inclusion of various other forms of identity that people hold (e.g., in terms of ethnicity, religion, sexual orientation, professional training, geography, etc.). Thus, by taking a broader, more inclusive conceptualization of 'diversity', the Ethics Committee's membership is already quite diverse, albeit could benefit from more. This diversity has served the Ethics Committee well. It is unclear why the OPTN/UNOS believes that 'Expert Councils' would achieve greater diversity. The Ethics Committee strives and will continue to strive to ensure diverse views and perspectives are represented. Moreover, the OPTN/UNOS has not articulated the benchmarks for determining when goals of diversity have been achieved.

## SOLUTIONS

The Ethics Committee proposes the following solutions:

(a) Retain the current UNOS Committee structure including the capacity for all Committees to sponsor public comment and Board proposals. The Ethics Committee contends that it must retain its ability to sponsor white papers, guidance documents, policy proposals, etc. Retaining this capacity will in no way undermine public engagement; rather, it will foster public buy-in and engagement because members of the public will recognize that the Ethics Committee will retain its capacity to guide policy.

(b) Decline the proposal to re-categorize Committees. The Ethics Committee recommends that all Committees remain as Committees. Any Committee that is in consideration of transitioning to an Expert Council would need to provide strong justification that the Council model will enhance and better achieve OPTN/UNOS's goals and serve OPTN/UNOS in its fullest capacity.

(c) Decline the OPTN/UNOS proposal to have representative members of proposed 'Expert Councils' to serve on proposed Subject Committees for the substantive and logistical concerns outlined above. The Ethics Committee will continue to support and partake in the formation of subcommittees as needed to foster greater engagement by the transplant community and the public. There are more effective ways to foster greater engagement by the transplant community and the public.

(d) Enable all Committees (including the proposed 'Expert Councils') to be directly engaged in the process of selecting members and/or regional representatives to ensure that members have expertise necessary for participating in Committee deliberations. There should be some safeguards set up to prevent selecting too many members from the same institution or geographic region.

(e) Involve members of the public in all Committees (not just in proposed 'Expert Councils'), and improve transparency and accessibility of UNOS meetings to include the public.

(f) Be flexible with how members of the public may be engaged in Committees, dependent on the goals and mission of each respective committee.

Recommendations for increasing public engagement:

(1) Maintain a list of ad hoc experts who have registered with UNOS their interest in contributing their time and expertise to Committee work. As each Committee begins work on a new project, the Committee may review the list of ad hoc experts to solicit their involvement.

(2) Develop a system of recognition to retain engagement. Currently, white papers, and other guidance documents specify the originating committee, but do not list members contributing to guidance development. Continued engagement can be further fostered by giving credit to all individuals involved in the workgroup including ad hoc experts involved in a specific guidance document.

(3) Welcome all listed ad hoc experts and other members of the public to attend in-person Committee meetings (albeit travel will not be compensated), during which time there will be a protected time on the agenda (e.g., 30 minutes) for the public members to provide their input in 2-3 minute statements.

(4) Welcome all listed ad hoc experts and other members of the public to listen to Committee teleconference call meetings and provide written feedback to the Committee.

(5) Other options include: Web-streaming of meetings; increasing efforts to increase engagement at regional meetings; having a "public conference" to generate new ideas about ethical concerns in transplant; a "Listening tour" with various stakeholders.

(6) Adding additional members to each Committee who will represent patient, donor, and family perspectives and represent diverse perspectives may be the simplest answer to the proposal's desired objective.

(7) OPTN/UNOS should revise its approach to outreach and dissemination including its public comment process. Information should be disseminated to patient advocacy groups, such as via WebEx presentations or recorded presentations maintained on the OPTN/UNOS website so that patients may listen at their own convenience. The minutes of committee meetings should be made publically available on the OPTN/UNOS website.

The Ethics Committee would feel more confident in the proposal to modify the current committee structure and public engagement if UNOS could provide evidence of cases where it works. In sum, the Ethics Committee believes that our proposed restructure will accommodate UNOS's goals and address the concerns by the Ethics Committee, and most, if not all, other Committees.