

At-a-Glance

Proposal to Notify Patients Having an Extended Inactive Status

- **Proposed Policy:** Policy 3.5.A (Patient Notification of Having an Extended Inactive Status)

- **Transplant Coordinators Committee**

The goal of this proposal is to promote effective and safe care for organ candidates by increasing awareness of their inactive waiting list status. Published literature suggest that the longer candidates wait for an organ while in an inactive status, the less likely they are to receive a transplant. In addition, the Committee is concerned that candidates are not consistently informed of their status nor do they understand what it means to have an inactive status.

The new policy will require transplant hospitals to provide written notification to candidates with an inactive waiting list status when the candidate has been inactive for:

- 90 consecutive days
- 365 consecutive days
- Annually, thereafter, for as long as the candidate remains inactive

The notification must include *all* of the following:

- The most recent date they became inactive,
- That the candidate cannot receive organ offers for transplant while inactive, and
- A telephone number at the candidate's transplant center to contact for more information

- **Affected Groups**

Transplant Coordinators
Data Coordinators
Transplant Administrators
Transplant Physicians/Surgeons
PR/Public Education Staff
Transplant Program Directors
Transplant Social Workers
Organ Candidates

- **Number of Potential Candidates Affected**

This policy has the potential to affect any candidate waiting for an organ in an inactive status for 90 consecutive days and also those in an inactive status for one consecutive year or longer. As of December 27, 2013, 26,407 registrations were waiting with an inactive status for one year or longer without interruption, of which 87% were kidney registrations.

- **Compliance with OPTN Strategic Plan and Final Rule**

This new policy addresses the OPTN Strategic Plan's Key Goal of increasing access to transplant by informing candidates on the waiting list with an inactive status that they are not eligible to receive an organ offer. This also meets the OPTN Strategic Plan's Vision by promoting effective and safe care for persons with organ failure.

Proposal to Notify Patients Having an Extended Inactive Status

Proposed Policy: Policy 3.5.A (Patient Notification of Having an Extended Inactive Status)

Transplant Coordinators Committee

Public comment response period: March 14, 2014 – June 13, 2014

Short Description of Policy Proposal

The goal of this proposal is to promote effective and safe care for organ candidates by increasing awareness of their inactive waiting list status. Published literature suggest that the longer candidates wait for an organ while in an inactive status, the less likely they are to receive a transplant. In addition, the Committee is concerned that candidates are not consistently informed of their status nor do they understand what it means to have an inactive status.

The new policy will require transplant hospitals to provide written notification to candidates with an inactive waiting list status when the candidate has been inactive for:

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The notification must include *all* of the following:

- The most recent date they became inactive,
- That the candidate cannot receive organ offers for transplant while inactive, and
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Background and Significance of the Proposal

Data and literature show the prevalence of inactive candidates on the waiting list has increased over the last decade. It is important for candidates to be aware of whether they are active or inactive on the waiting list and to understand that they are only eligible to receive an organ for transplant while in an active status. This proposal will improve communication between transplant hospitals and their candidates regarding their waiting list status and the implications of being inactive. Although this new requirement would create additional work for transplant coordinators, in particular, the Committee is confident that this proposal will promote effective and safe care for persons with organ failure by increasing candidates' awareness of their inactive waiting list status and providing them with the information required to be proactive in their reactivation. The intent of these notifications is to prevent candidates from being inactive for unnecessary extended period of times.

In November 2003, UNOS implemented a policy change to allow the accrual of waiting time for candidates awaiting kidney and pancreas transplants while in an inactive status. Prior to the policy change, 12% of kidney candidates were on the waiting list with an inactive status, 11% were listed with an inactive status, and 13% had an inactive status within the first three months of listing. By

2006, 29% of candidates had an inactive status, and 44% of those candidates were newly listed as inactive.¹

A study of kidney transplant candidates listed between 2000 and 2011 collected information on initial waiting list status, conversion from inactive to active status, and associations of inactive status with waiting list survival and eventual transplantation. The study concluded that the percentage of inactive candidates on the waiting list increased from 2.3% pre-policy to 31.4% in 2011, and that an inactive status was associated with lower rates of transplantation.²

In 2009, the Transplant Coordinators Committee (TCC) distributed a survey to transplant hospitals to study professional practices, timing, and communication related to listing and managing candidates with an inactive waiting list status to determine if effective practices exist. The survey sought clarification on how candidates, their physicians, and dialysis centers are informed of status changes, and how the inactive waiting list is overseen by staff. Surveys were sent to 800 programs at 251 hospitals, and 555 (69%) responses were received, representing 476 programs at 198 hospitals.

The survey demonstrated that a consistent pattern of waiting list management practices among most programs does exist. A large percentage of transplant hospitals indicated that they inform their candidates of their inactive status either by phone, in person, or by letter, with a letter being the most common form of notification. However, the Committee still has concerns that candidates are on the waiting list with an inactive status for years because they are overlooked after extended inactive periods or the candidates are unaware of their status or what their status means. Data, show that 38-44% of inactive periods that are at least one month long and 44-50% of inactive periods that are at least two months long end up being inactive a year or longer.

Currently, there are no national policies requiring patient notification for candidates with an inactive status *for patient-specific* reasons or after an extended period of inactive time. This proposed requirement will begin to create consistency among all transplant hospitals for informing candidates, who are unable to receive organ offers, about their inactive waiting list status. In turn, candidates will become more educated about their listing status and the necessary steps to take to be eligible to receive an organ for transplant.

Centers for Medicare and Medicaid Services (CMS) and Organ Procurement and Transplantation Network / United Network for Organ Sharing (OPTN/UNOS) have other patient notification requirements currently in place as outlined below:

¹ Shafi S, Zimmerman B, Kalil R. Temporary Inactive Status on Renal Transplant Waiting List: Causes, Risk Factors, and Outcomes. *Transplantation Proceedings*, 2012; 44: 1236-1240.

² Grams ME, Massie AB, Schold JD, Chen BP, Segev DL. Trends in the Inactive Kidney Transplant Waitlist and Implications for Candidate Survival. *American Journal of Transplantation*, 2013; 13: 1012-1018.

CMS Requirement in CoP 482.94	OPTN Policy 3.5								
<p>(c) Standard: Patient records.</p> <p>Transplant centers must maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a center's waitlist and who is admitted for organ transplantation. This includes notification to patient (and patient's usual dialysis facility if patient is a kidney patient) of:</p> <ul style="list-style-type: none"> • Patient's placement on the center's waitlist; the center's decision not to place the patient on the waitlist; or the center's inability to make a determination regarding the patient's placement on its waitlist because further clinical testing or documentation is needed. • Removal from waitlist for reasons other than transplantation or death within 10 days. • Patient records must contain documentation of: • Multidisciplinary patient care planning during the pre-transplant period. • Multidisciplinary discharge planning for post-transplant care. 	<p>Policy 3.5: Patient Notification.</p> <p>Transplant programs must notify patients in writing:</p> <p>(i) within ten business days</p> <p>(a) of the patient's being placed on the waiting list including the date the patient was listed, or</p> <p>(b) of completion of the patient's evaluation as a candidate for transplantation, that the evaluation has been completed and that the patient will not be placed on the waiting list at this time, whichever is applicable; and</p> <p>(ii) within ten business days of removal from the waiting list as a transplant candidate for reasons other than transplantation or death that the patient has been removed from the waiting list.</p> <p>Transplant hospitals must notify patients in writing according to <i>Table 3-2</i> below:</p> <p>Table 3-2: Transplant Hospital Patient Notification Requirements</p> <table border="1" data-bbox="841 961 1531 1633"> <thead> <tr> <th data-bbox="841 961 1187 1178">When:</th> <th data-bbox="1187 961 1531 1178">The transplant hospital must send a notification within 10 business days with the following information:</th> </tr> </thead> <tbody> <tr> <td data-bbox="841 1178 1187 1262">The patient is registered on the waiting list</td> <td data-bbox="1187 1178 1531 1262">The date the patient was registered.</td> </tr> <tr> <td data-bbox="841 1262 1187 1478">The patient's evaluation for transplant is complete and the patient is <i>not</i> registered on the waiting list</td> <td data-bbox="1187 1262 1531 1478">That the patient's evaluation has been completed and the patient will not be registered on the waiting list at this time.</td> </tr> <tr> <td data-bbox="841 1478 1187 1633">The patient is removed from the waiting list for reasons <i>other than</i> transplant or death</td> <td data-bbox="1187 1478 1531 1633">That the patient has been removed from the waiting list.</td> </tr> </tbody> </table> <p>Each written patient notification required in <i>Table 3-2</i> must also include and refer to the <i>OPTN Contractor's Patient Information Letter</i>, which provides the number for the toll-free Patient Services Line. The transplant hospital must document these notifications.</p>	When:	The transplant hospital must send a notification within 10 business days with the following information:	The patient is registered on the waiting list	The date the patient was registered.	The patient's evaluation for transplant is complete and the patient is <i>not</i> registered on the waiting list	That the patient's evaluation has been completed and the patient will not be registered on the waiting list at this time.	The patient is removed from the waiting list for reasons <i>other than</i> transplant or death	That the patient has been removed from the waiting list.
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The only other OPTN patient notification requirements are outlined in OPTN Bylaws Appendix D and K. Appendix D requires that *all* patients are notified at a program that they will be inactivated due to functional inactivity defined as either the inability to serve potential candidates, candidates, recipients, potential living donors, or living donors for a period of 15 or more consecutive days or the failure to perform a transplant for a specified amount of time that is organ-specific.

Appendix K of the OPTN Bylaws defines transplant program inactivity, withdrawal, and termination ultimately resulting in the inactivation of *all* patients at a program.

The The Joint Commission does not have a requirement that addresses patient notification.

Collaboration

In August 2013, the project proposal was presented to the Policy Oversight Committee (POC), where the POC suggested that candidates placed in an inactive status be notified of the status change prior to one year of consecutive inactivity. Due to this suggestion, data were gathered to determine if there was a time interval that would best address an earlier notification knowing that a candidate's inactive status may fluctuate due to infection, insurance issues, the need for additional testing, etc. The goal of the proposed policy is not to capture short-term inactivity, but to capture long-term inactivity.

Concerns about the project proposal were also brought forth by the Executive Committee in September 2013. The Executive Committee was concerned that UNOS does not have an easy process in place for transplant programs to be able to track their candidates who have been waiting in an inactive status for one consecutive year or longer. However, current UNetSM programming has the ability to capture these candidates using the "Create a Custom Report" tool through the UNetSM Waitlist Portal. All listing transplant programs have access to this tool. Education for the use of this tool could be achieved through UNetSM tutorials or educational programs. More information demonstrating how to use this tool is located under the expected implementation plan section of this proposal.

The Committee also sought input from the Patient Affairs, Transplant Administrators, Minority Affairs, and Ethics Committees on this issue prior to the development of the public comment document. Members of the Patient Affairs Committee (PAC) were in support of this proposal and agree that patients may not be aware of their inactive status or what inactive status means. The PAC believes that patients waiting longer than six months without receiving some type of communication from their transplant hospital begin to get nervous about whether they will ever be transplanted.

Members of the Transplant Administrators Committee (TAC) were concerned with the additional requirement and added burden this policy could create for transplant hospitals. An estimate of what that burden may have been for programs required to have sent at least one letter, had this policy been in place during 2012 is shown in figures 4-11 at the end of this document. The estimate is 3 letters for heart-lung and intestine programs, 5 letters for heart programs, 6 letters for kidney-pancreas, pancreas, and lung programs, 16 letters for liver programs, and 110 letters for kidney programs. Members of the TAC also expressed a desire that CMS and OPTN requirements be aligned.

The TCC is aware that this policy could impact programs due to an increase in mailing expenses. It may also cause an increase in coordinator workload hours, based on staffing models, to address candidate questions and to ensure the notification letters are sent out in a timely manner. A

possible outcome of this policy is that the inactive list should decrease over time as patients become more aware of their status and some patients are reactivated or removed from the list. The new Kidney Allocation System (KAS) may also have an impact on the inactive waitlist, thus relieving some of the initial burden of the policy proposal.

Members of the Minority Affairs Committee were in support of this policy and would like to even further extend it to require that not only the patient, but their primary care physician and dialysis unit, receive notification about their inactive status as well. Results from the 2009 TCC survey showed that a large percentage of transplant hospitals already inform the candidate's referring physician and dialysis center of their inactive status within 30 days of inactivation.

Lastly, members of the Ethics Committee commented that there was not an automatic notification in UNetSM to alert hospitals when their patients had been waiting a year, and to find this information would create more work for transplant hospital staff. UNOS staff have developed a Microsoft Excel macro that, in conjunction with the "create a custom report" tool in the UNetSM Waitlist application, will help transplant hospitals with this. The additional work would be the responsibility of the transplant coordinator, and since hospitals are required to have protocols in place for Policy 3.5, the transplant coordinators on the Committee believe that adding one more notification to their existing protocol would not be a burden when thinking about what is best for their patients.

Collaboration efforts with The North American Transplant Coordinators Organization (NATCO) included participation in the proposal development by the current president-elect, who is a member of the TCC. Information regarding the proposal was also posted to the organization's website or members to review and provide feedback.

Alternatives Considered

The Committee initially considered developing a proposed policy that would have required programming in UNetSM to notify programs when they had a patient listed as inactive for one consecutive year or longer; however, since Policy 3.5 requires similar notification, the Committee determined that programs should be responsible for this additional notification, not the OPTN.

Early feedback from other OPTN/UNOS committees suggested notifying patients of their inactive status at each time they were made inactive; however, the Committee felt that the unintended consequences of that requirement were too severe. The purpose of the inactive status is for a temporary period of inactivation, and the Committee had concerns that requiring a written patient notification at each use would deter programs from using the inactive status for short periods of time, causing match runs to be unnecessarily lengthy, leading to inefficiencies in organ allocation. In addition, any offers made for those candidates that should have been inactive will be refused, therefore causing refusal rates to increase for the transplant hospital.

The Committee also considered only pursuing an educational effort for transplant programs through presentations and webinars; however, they were not confident that this would guarantee communication between the program and the patient unless programs were required by policy to do so.

Strengths and Weaknesses

This requirement will begin to create consistency among all transplant hospitals for informing candidates, who are unable to receive organ offers, about their inactive waiting list status. In turn, candidates will become more educated about their listing status and the necessary steps to take to be eligible to receive an organ for transplant.

Requiring an additional notification will initially create an increased burden to the transplant hospital of having to determine which of their candidates have been waiting in an inactive status for 90 consecutive days and one consecutive year or longer, generating letters for these candidates, and maintaining documentation of this notification. However, the Committee believes the long term results will improve patient access to transplantation and more effective care.

Description of intended and unintended consequences

This proposal could persuade centers to not inactivate patients for temporary periods of inaccessibility. This, in turn, could result in more organ offer refusals, increasing the time it takes to make successful organ offers. The Committee was aware of this possibility and therefore did not propose a requirement to notify patients upon inactivation but instead is proposing a notification be sent after 90 consecutive days of inactivation. This would allow centers to inactivate patients for temporary reasons without the need to send the patient notification letter.

If the proposed policy is approved, candidates waiting in an inactive status for 90 consecutive days and those waiting one consecutive year or longer will be informed and educated about their status, have access to the reason why they were inactivated, and, in turn, be able to receive information on the necessary steps to become reactivated.

Supporting Evidence and/or Modeling

Documented literature found throughout the proposal support the necessity for this proposal. Although some literature focuses on the numbers of inactive candidates on the waiting list, other literature focuses on the impact to the candidate. It is important for candidates to be aware of whether they are active or inactive on the waiting list and to understand that they are only eligible to receive an organ for transplant while in an active status. This proposal will improve communication between transplant hospitals and their candidates regarding their waiting list status and what that means for them.

One single-center study suggests that effective strategies for monitoring candidates on the inactive list should be developed.¹ Of the 436 candidates in their study, 322 were never inactive and 114 were inactive at least once during the study. Eighty-three percent of candidates that had never been inactive received a transplant compared to only 24% of candidates that had been inactive at least once. Placing candidates in an inactive status creates challenges for programs, which must monitor workup results and decide whether to reactivate or delist a candidate. There are questions about how inactivation is defined from program to program and how candidates are reactivated. This policy would make it clear to candidates that they are inactive, give them access to why they were inactivated, and tell them what steps are necessary for them to become reactivated.

In a single-center survey of dialysis patients, 18 of 34 patients undergoing a workup were unaware of their listing status, and most mistakenly believed they were wait-listed when they were not. This

survey suggests a lack of communication and a potential barrier to transplantation.³ This policy addresses the necessity for more communication between the hospitals and their patients in the overall transplant process.

An analysis of deaths among candidates waiting for a kidney transplant concluded that candidates do not benefit from prolonged periods of inactivity. Data indicate that the percentage of inactive candidates that died on the waiting list increased from 31% in 2003 to 52% in 2007. Of those that died in 2007, 53% were inactive for more than one year over the entire course of their time waiting, and 47% were not listed in an active status consecutively for more than a year before their death.⁴

Data presented to the Committee in June of 2012 showed that the majority of inactive non-renal registrations removed from the waiting list due to death or being too sick were removed after being most recently inactive for less than 6 months, while approximately half of inactive kidney, pancreas, and kidney-pancreas registrations removed from the waiting list for death or too sick were removed after being most recently inactive for less than a year. The sentiment within the OPTN Transplant Coordinators Committee was that inactive registrants who die on the waiting list after being inactive for a year or more may have had access to a transplant had they been more informed of their status and the actions they could have taken for reactivation. After seeing the data related to candidates dying on the waiting list or becoming too sick to transplant while waiting in an inactive status, the Committee felt that one year after becoming inactive was an appropriate timeframe for notifying candidates of their status.

Figure 1 shows the number of inactive registrations removed from the waiting list only for reasons of death or for the candidate being too sick to transplant during 2007-2011, by waiting list organ and removal type. These data were presented to the Committee in June of 2012. The vast majority of registrations were removed after having been inactive for one year or less.

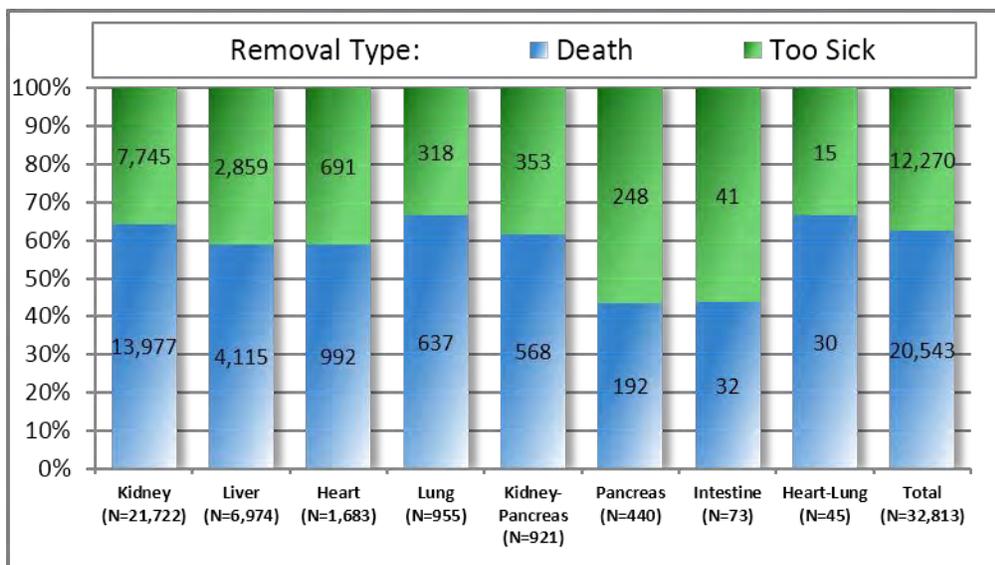


Figure 1. Inactive registrations removed from the WL for death/too sick during 2007-2011

³ Gillespie A, Hammer H, Lee J, Nnewihe C, Gordon J, Silva P. Lack of Listing Status Awareness: Results of a Single-Center Survey of Hemodialysis Patients. *American Journal of Transplantation*, 2011; 11: 1522-1526.

⁴ Delmonico FL, McBride MA. Analysis of the Wait List and Deaths Among Candidates Waiting for a Kidney Transplant. *Transplantation* 2008; 86 (12): 1678-1683.

Additionally, Figure 2 shows the number of inactive registrations removed from the waiting list only for reasons of death or for the candidate being too sick to transplant during 2007-2011 that had been inactive at least 5 years prior to removal, by removal type and organ. There were a total of 1,111 inactive registrations removed from the waiting list during 2007-2011 due to death or being too sick that had been *inactively* waiting for 5 years or more prior to removal. Of those 1,111 registrations, 811 (73%) were removed for death and 300 (27%) were removed for being too sick.

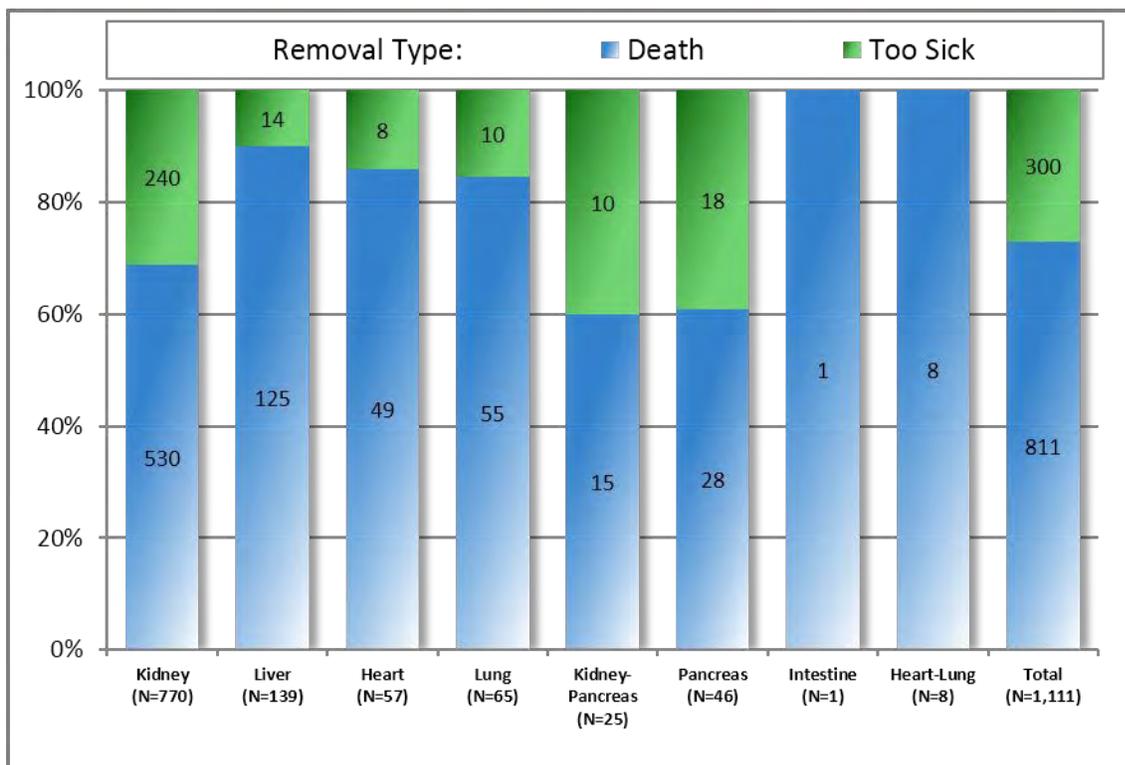


Figure 2. Inactive registrations removed from the WL for death/too sick during 2007-2011 that had been inactive at least 5 years

Figure 3 shows the number of inactive registrations removed from the waiting list only for reasons of death or for the candidate being too sick to transplant during 2007-2011 that had been inactive at least 10 years prior to removal, by removal type and organ. There were a total of 95 inactive registrations removed from the waiting list during 2007-2011 for death or too sick that had been inactively waiting for 10 years or more prior to removal. Of those 95 registrations, 78 (82%) were removed for death and 17 (18%) were removed for the candidate being too sick to transplant.

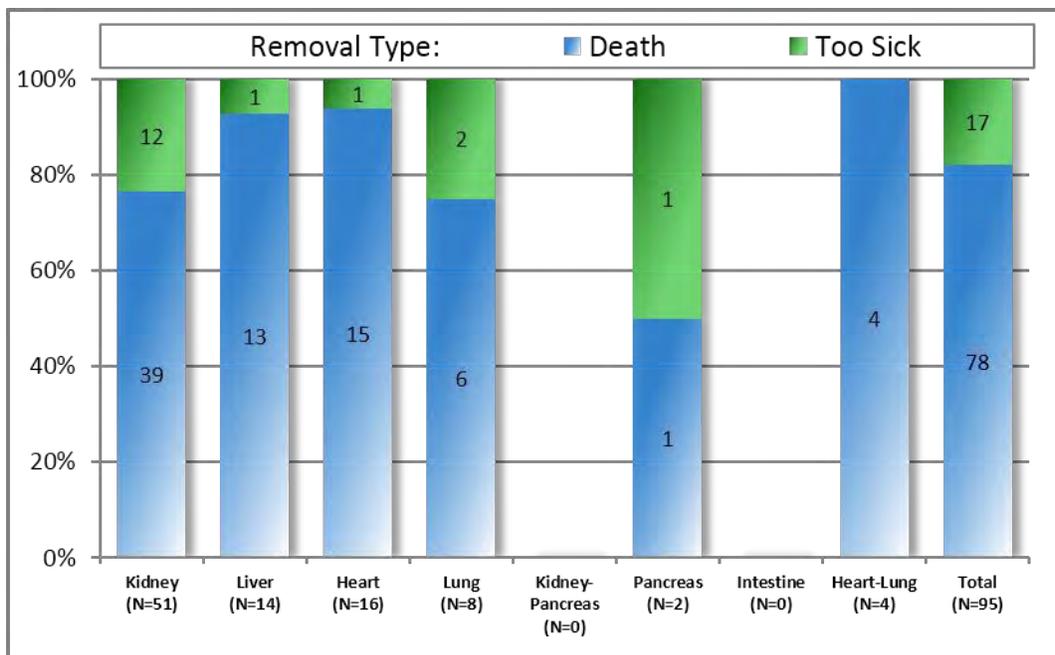


Figure 3. Inactive registrations removed from the WL for death/too sick during 2007-2011 that had been inactive at least 10 years

Upon review of these data, the Committee believes that continual patient notification while remaining inactive for an extended period of time could result in candidates being more involved in their plan of care and could possibly prevent a candidate from dying on the waiting list or from becoming too sick to transplant while waiting.

Data presented to the Committee in July of 2013 illustrate what the impact would have been for transplant programs in 2012 had the original proposed policy been in place. It is important to note that many programs already notify their patients of their waiting list status more often than on an annual basis, but there are a number of transplant hospitals that do not; therefore, the burden of this proposal lies on those outliers who delay notification or never notify their patients.

The charts in figure 4 include data from transplant programs where at least one letter would have been sent as a result of the annual notification in the current proposed policy. The number of letters sent represent the number of patient notification letters that would have been required to be sent in 2012 based on how long registrations had been inactive. In the charts, each bar represents a single program's burden, or the number of letters that each program would have been required to send in 2012. These data likely overestimate the actual impact this policy would have on transplant programs as it assumes the proposed policy exists with no practices or procedures put into place for informing patients. If this proposed policy were to be implemented, it is likely that centers would put practices or procedures into place that would reduce this burden.

Had the proposed policy been in place in 2012, on average, 3 notification letters per heart-lung and intestine program would have been sent, 5 letters per heart program, 6 letters per kidney-pancreas, lung, and pancreas program, 16 letters per liver program, and 110 letters per kidney program would have been sent over the course of the entire year as a result of the annual notification in the current proposed policy.

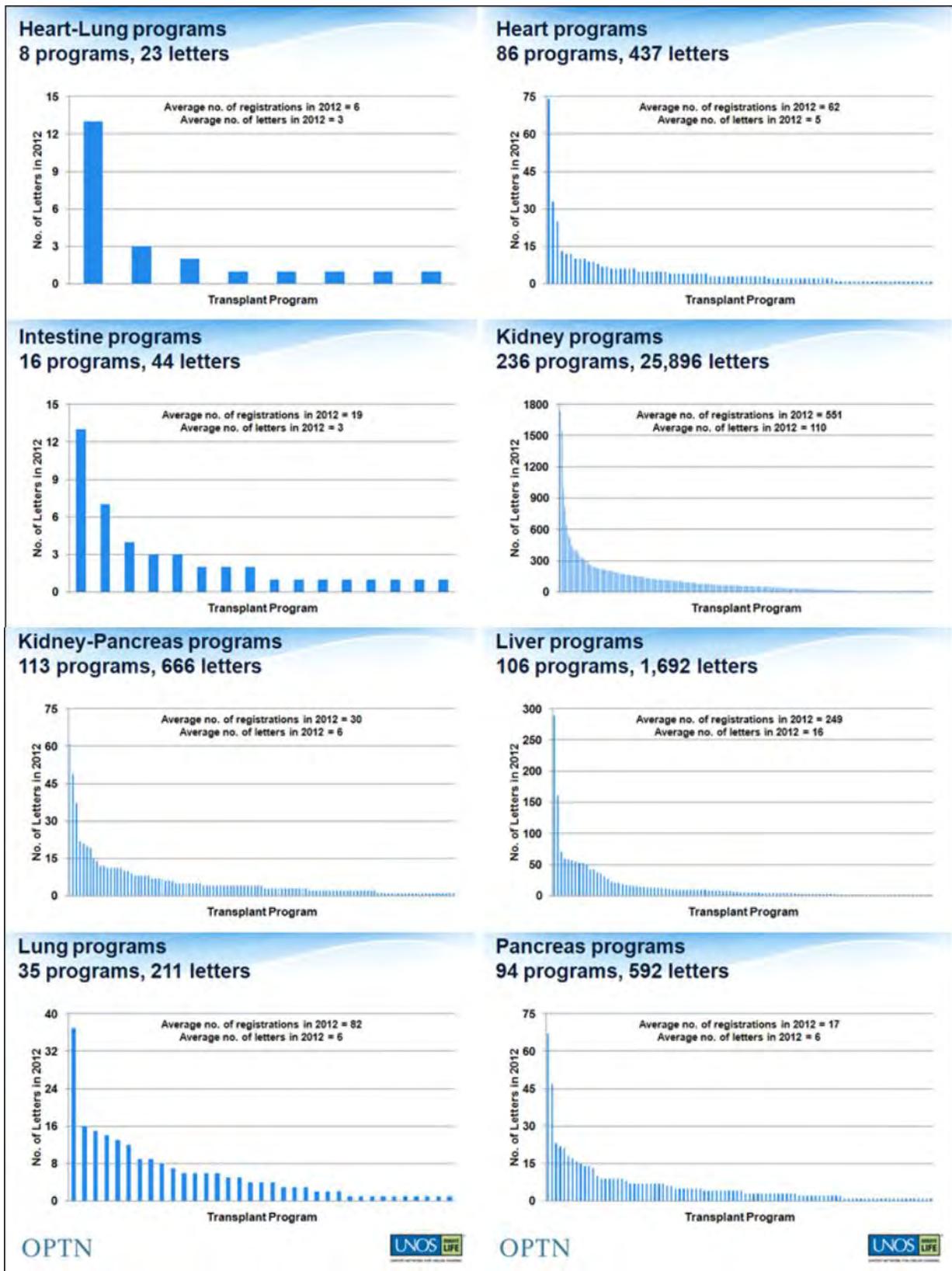


Figure 4. Impact on annual transplant program workload in 2012 from the annual notification requirement of the proposed policy

In response to concerns brought forth by the OPTN's Policy Oversight and Executive Committees, the Transplant Coordinators Committee requested additional data to help them determine what shorter waiting period to propose before being required to notify a patient of their inactive waiting list status. Data presented back to the TCC in December of 2013 led the Committee to modify the original proposed policy to also include an earlier patient notification, at the 90th consecutive day of inactivity.

Figure 5 shows the percentage of inactive periods that are at least 1, 2, 3, 4, 5, and 6 months long that end up being a year or longer for registrations ever waiting on the waiting list during 2007-2011, excluding any multi-organ or intestine registration. The data show that 38-44% of inactive periods that are at least one month long and 44-50% of inactive periods that are at least two months long end up being a year or longer. The Committee chose 90 days as the shorter time period because approximately half (48-57%) of all inactive periods that are at least three months long end up being a year or longer.

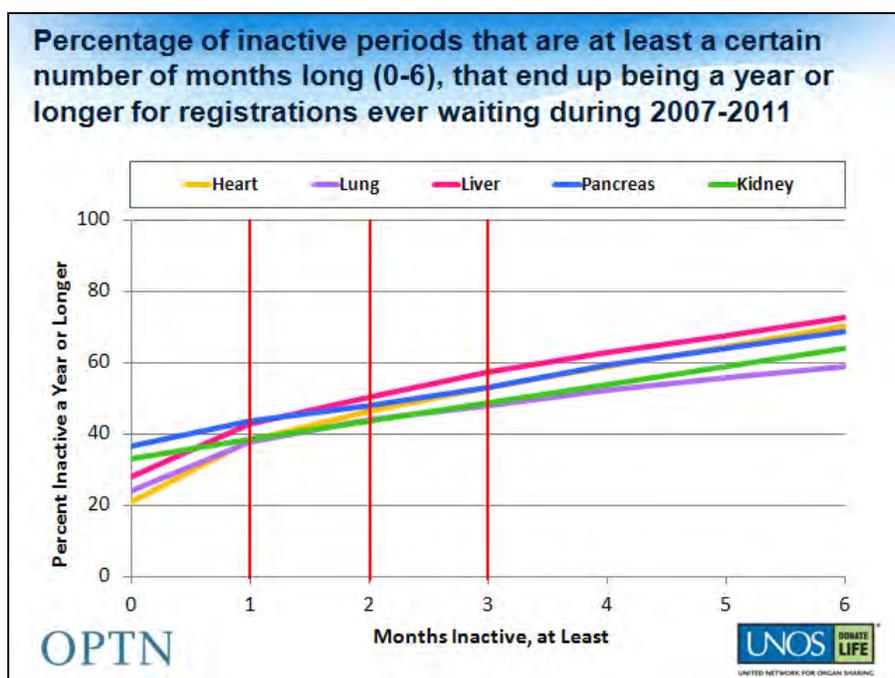


Figure 5. Percentage of inactive periods at least 0, 1, 2, 3, 4, 5, and 6 months long that end up being a year or longer for registrations ever waiting during 2007-2011

Table 1 shows additional data from transplant programs where at least one letter would have been sent as a result of the 90 consecutive day notification in the current proposed policy was examined. The number of letters sent represented the number of patient notification letters that would have been required to be sent in 2012 as a result of the 90 consecutive day notification component of the proposed policy. The intent of this additional, earlier notification is to prevent candidates from being inactive for unnecessary extended period of times. As the data in Figure 5 show, approximately half of the candidates that are inactive for 90 consecutive days end up being inactive for over a year; therefore, notifying candidates at 90 consecutive days may prevent the annual notification for candidates who should not be inactive for an extended period of time.

Had the proposed policy been in place in 2012, on average, 2 notification letters per heart-lung program would have been sent, 4 letters per intestine program, 8 letters per lung program, 9 letters per pancreas program, 10 letters per heart program, 11 letters per kidney-pancreas

program, 31 letters per liver program, and 205 letters per kidney program would have been sent over the course of the entire year as a result of the 90 consecutive day notification in the current proposed policy.

Program	No. of Programs	No. of Letters	Average No. of Registrations in 2012	Average No. of Letters Sent in 2012
Heart-Lung	12	29	5	2
Intestine	23	81	18	4
Lung	54	455	70	8
Pancreas	116	1,038	14	9
Heart	115	1,129	57	10
Kidney-Pancreas	131	1,493	27	11
Liver	128	3,904	221	31
Kidney	246	50,476	529	205

Table 1. Impact on annual transplant program workload in 2012 from the 90 day notification requirement of the proposed policy

Expected Impact on Living Donors or Living Donation

Not applicable

Expected Impact on Specific Patient Populations

There is no known impact on specific patient populations.

Expected Impact on OPTN Strategic Plan, and Adherence to OPTN Final Rule

This new policy addresses the OPTN Strategic Plan's Goal of increasing access to transplants by informing candidates on the waiting list with an inactive status that they are not eligible to receive an organ offer. This also meets the OPTN Strategic Plan's Vision by promoting effective and safe care for persons with organ failure.

Plan for Evaluating the Proposal

Over time, this proposal should cause transplant hospitals to reevaluate their listing practices. Annually, for the first few years, the Committee will review data on the number of active and inactive candidates on the waiting list by organ type as well as the length of time candidates wait in an inactive status. The Committee will also monitor organ refusal rates and candidate delistings by transplant program as well as the number of letters that were sent.

The need for an annual data review will be assessed after the policy has been in place for a few years. In addition, the Committee will monitor candidate inactive waiting times for transplant programs to look for programs that may be briefly activating candidates and then inactivating them again to avoid the cumulation of time at an inactive status that would result in sending a patient notification.

Additional Data Collection

This proposal does not require additional data collection.

Expected Implementation Plan

If public comment is favorable, this proposal will be presented to the Board I November 2014, and if approved, will become effective on February 1, 2015.

This proposal will not require programming in UNetSM. Transplant Programs will need to have a process in place to determine when their candidates have been inactively waiting on the waiting list for 90 consecutive days and also for one consecutive year and then notify those candidates. UNOS staff have developed a Microsoft Excel macro that, in conjunction with the “create a custom report” tool in the UNetSM Waitlist application, will help transplant programs with this. The Microsoft Excel macro will allow the user to filter the results provided when creating a custom report in UNetSM and modify them as they see fit. OPTN data requests may initially increase to provide programs with this information until they are able to put processes in place.

Communication & Education Plan

Types of Communication or Education	Audience(s)	Delivery Method(s)	Timeframe
Communication: Policy notice following board approval	Transplant Coordinators Data Coordinators Transplant Administrators Transplant Physicians/Surgeons PR/Public Education Staff Transplant Program Directors Transplant Social Workers Organ Candidates	Blast e-mail, OPTN and UNOS websites	1 month after board approval
Communication: Include policy on Waitlist Notification Quick Reference Guide http://optn.transplant.hrsa.gov/resources/professionalsources.asp?index=14	Same as above	Print	1 month after board approval
Education: Explanation of inactive status and how to create and use the “Create a Custom Report” tool in the UNet SM Waitlist application along with the Microsoft Excel macro. Communication of effective practices.	Same as above	Professional & patient resources	Within 3 months after board approval

Compliance Monitoring

UNOS site survey staff will review a sample of medical records for transplant candidates who have been waiting in an inactive status for 90 consecutive days and those waiting one consecutive year or longer without interruption, for documentation that the transplant hospital provided written notification to the candidate including all of the following:

- The most recent date the candidate became inactive,
- That the candidate cannot receive organ offers while inactive, and
- A telephone number at the candidate's transplant hospital to contact for more information

Site survey staff will also verify that the written notification was sent to the candidate within 14 days of any of the following qualifying events:

- 90 consecutive days
- 365 consecutive days
- Annually, thereafter, for as long as the candidate remains inactive

Policy Proposal

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

This proposed policy below is new and will follow Policy 3.5 Patient Notification

3.5.A Patient Notification of an Extended Inactive Status

Transplant hospitals must provide written notification to candidates with an inactive waiting list status when the candidate has been inactive for:

- 90 consecutive days
- 365 consecutive days
- Annually, thereafter, for as long as the candidate remains inactive

The 90 day written notification must be sent to the candidate within 14 days of the 90th consecutive day of inactivity.

The annual written notification must be sent to the candidate within 14 days of their inactive status anniversary date.

The notification must include *all* of the following:

1. The most recent date the candidate became inactive,
2. That the candidate cannot receive organ offers while inactive, and
3. A telephone number at the candidate's transplant hospital to contact for more information

Transplant hospitals must maintain a copy of this notification and document in the candidate medical record the date the notification was sent.