

Public Comment Proposal

Guidance on Pediatric Transplant Recipient Transition and Transfer

OPTN/UNOS Pediatric Transplantation Committee

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Contents

Executive Summary	1
Is the sponsoring Committee requesting specific feedback or input about this resource?	2
What problem will this resource address?	2
Why should you support this resource?	2
How was this resource developed?	3
Lost to Follow-up Designation	3
How well does this resource address the problem statement?	8
Which populations are impacted by this resource?	8
How does this resource impact the OPTN Strategic Plan?	8
How will the OPTN implement this resource?	9
How will members implement this resource?	9
This guidance will have no impact on OPOs or histocompatibility laboratories.	9
Will this resource require members to submit additional data?	9
How will members be evaluated for compliance with this resource?	9
How will the sponsoring Committee evaluate whether this resource was successful post implementation?	9
Guidance Document	10

Guidance on Pediatric Transplant Recipient Transition and Transfer

Affected Policies: N/A
Sponsoring Committee: Pediatric Transplantation Committee
Public Comment Period: August 3, 2018 to October 3, 2018

Executive Summary

Suboptimal transition and transfer processes for pediatric transplant recipients have been associated with increased risk of non-adherence with their plan of care and graft loss. Breakdowns in transition and the transfer to adult medical care may contribute to “lost to follow-up” designations for pediatric transplant recipients on OPTN data collection forms. The goal of the guidance is to support improvements in transplant outcomes by reducing instances of graft loss from non-adherence, and by providing guidance to transplant hospitals to improve the transition and transfer process for pediatric recipients. A secondary goal of this guidance is to reduce the incidence of lost to follow-up designations for pediatric transplant recipients. By sharing effective practices for recipient transition and transfer from pediatric to adult medical care, transplant outcome data will be more complete and more representative of clinical practices.

This guidance aligns with the goals of the OPTN Strategic Plan to improve waitlisted patient, living donor, and transplant recipient outcomes. Long term post-transplant survival data are vital to understanding outcomes for all pediatric transplant recipients and developing healthcare policy to improve these outcomes.

Is the sponsoring Committee requesting specific feedback or input about this resource?

The Committee encourages all interested individuals to comment on the proposal in its entirety. The Committee requests feedback on the following items:

- Clinical staff in adult medical care are key stakeholders in the transition and transfer process. Staff members who receive recipients from pediatric transplant programs are encouraged to share feedback on their transfer experiences.
 1. In what ways are recipients (transplanted <18 years old) well prepared or ill prepared for transfer to adult medical care?
 2. Is there specific information about the recipient, or specific transfer practices that have led to an optimal hand-off from a pediatric program to your program?
 3. What practices help you share the recipient's health information back to the pediatric transplant program for OPTN data submission?
- Recipient transfer scenarios may not fit neatly into the three types profiled in the guidance document.
 1. Do you current use, or have you considered, any non-conventional models of transfer to adult medical care, e.g.: transfer routine medical care to a provider not affiliated with a transplant hospital (perhaps nearby to the recipient's place of residence) and arrange for periodic outpatient evaluations with a transplant program outside your institution?

What problem will this resource address?

Suboptimal transition and transfer of pediatric transplant recipients to adult medical care can have detrimental impact on recipient and graft survival. These can lead to recipients' inconsistent or declining engagement with medical providers over time. Even worse, these vulnerable recipients may not receive needed out-patient care to promote long term graft and recipient survival. The end result can be graft dysfunction or loss.

Suboptimal transition and transfer can also create challenges reporting recipients' health information to the Organ Procurement and Transplantation Network (OPTN). This can lead to recipients' designated as "lost to follow-up" OPTN follow-up forms. As a result, OPTN transplant outcomes data does not include the health status of recipients with this designation. OPTN Policy 18.1: *Data Submission Requirements* requires transplant hospitals to submit Transplant Recipient Follow-up (TRF) forms within either: 1) 30 days after the six month and annual anniversary of the transplant date until the recipient's death or graft failure; or 2) 14 days from notification of the recipient's death or graft failure.¹ When there are challenges obtaining the recipient's health information, transplant programs can stay in compliance with Policy 18.1 by submitting a TRF form designating the recipient as lost to follow-up.

Transplant recipients in their late teens, or those pediatric recipients who have aged to early adulthood represent a sizable population of recipients in the U.S. with this designation on OPTN forms. Their transplant survival data are vital to understanding outcomes for all pediatric recipients. These data are then used to inform patients and their families of realistic goals regarding transplantation, and to drive healthcare policy decisions.

Why should you support this resource?

This guidance shares effective practices for pediatric transition and transfer from those transplant programs with average or better than average lost to follow-up designations. The Committee hopes sharing these effective practices will improve the transition and transfer process which will in-turn lead to

¹OPTN Policy 18.1, Data Submission Requirements, https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_18 . Accessed June 29, 2018.

better transplant outcomes by reducing instances of graft loss from non-adherence. Further, rates of lost to follow-up designation will decrease, resulting in more complete data reporting to the OPTN.

How was this resource developed?

In the fall of 2016, the Committee initiated discussions surrounding the concern that lost to follow-up designation be reflective of deficiencies in transition and transfer practices in the transplant community. Central concerns were these deficiencies could impact on recipient and graft survival, and negatively impact the complete understanding of pediatric transplant outcomes. The latter includes critical information for the pediatric transplant community that widely acknowledges the impact of transplantation for pediatric recipients extends beyond measures of recipient and graft survival.^{2, 3, 4, 5, 6} These data reported to the OPTN by transplant programs drive policy decisions, and are used by providers to communicate realistic goals regarding transplantation to patients and their families or guardians. A subcommittee was formed to explore the problem in greater depth and develop solutions. In forming the subcommittee, a representative of the OPTN/UNOS Minority Affairs Committee (MAC) was also recruited.

The Subcommittee met over several conference calls and meetings to develop the guidance. The early sentiment was guidance on “effective practices” would be more meaningful if linked to OPTN data submission and derived with input from the pediatric transplant community.

Lost to Follow-up Designation

To examine if lost to follow up designation is indeed an issue that impacts TRF submission, the Subcommittee examined lost to follow-up rates for heart, kidney, and liver transplant recipients in the U.S. that were transplanted during 2000 to 2010, and were less than 18 years old at the time of transplant.⁷ These data showed:

- Recipients are designated as lost to follow-up in each organ, and the overall 10 year rate of lost to follow-up was similar between pediatric (0-17 years old) and adult (18 years and older) recipients.
- The 10 year lost to follow-up rates were the highest in kidney recipients, followed by liver recipients, then heart recipients.
- Lost to follow-up rates were not uniform across different pediatric age groups.
- The lost to follow-up rate in recipients ages 18-25 years old was similar to recipients ages 12-17 years old:

² Davis, ID, Chang, P, and Nevins, TE, “Successful Renal Transplantation Accelerates Development in Young Uremic Children”, *Pediatrics* 86 no. 4, (1990), 594-600, <http://pediatrics.aappublications.org.proxy.library.vcu.edu/content/86/4/594>. Accessed June 29, 2018.

³ Mendley, SR, et al., “Duration of chronic kidney disease reduces attention and executive function in pediatric patients.” *International Society of Nephrology* (2014), doi: 10.1038/ki.2014.323. Accessed June 29, 2018.

⁴ Icard, P, Hooper, SR, Gipson, DS, and de Ferris, ME. “Cognitive Improvement in Children with CKD after Transplant.” *Pediatric Transplant* 14 (2010): 887-90, <https://doi.org/10.1111/j.1399-3046.2010.01359.x>, Accessed June 29, 2018.

⁵ Herthelius, M, et al. “Renal transplantation in infants and small children.” *Pediatric Nephrology* 27 (2012): 145-150, doi: 0.1007/s00467-011-1962-2. Accessed June 29, 2018.

⁶ Organ Procurement and Transplantation Network, “Ethical principles of pediatric organ allocation” (2014), <https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-of-pediatric-organ-allocation/>. Accessed June 29, 2018

⁷ Lung transplant recipients were not considered due to low numbers of pediatric lung transplants performed.

Table 1: Comparison of Lost to Follow-up Rates up to 10 Years Post-Transplant by Age at Transplant
8, 9

Organ	Recipients 6-11 years old	Recipients 12-17 year old	Recipients 18-25 years old
Kidney	12.1%	20.8%	21.7%
Liver	6.8%	14.4%	11.7%
Heart	4.8%	6.5%	4.9%

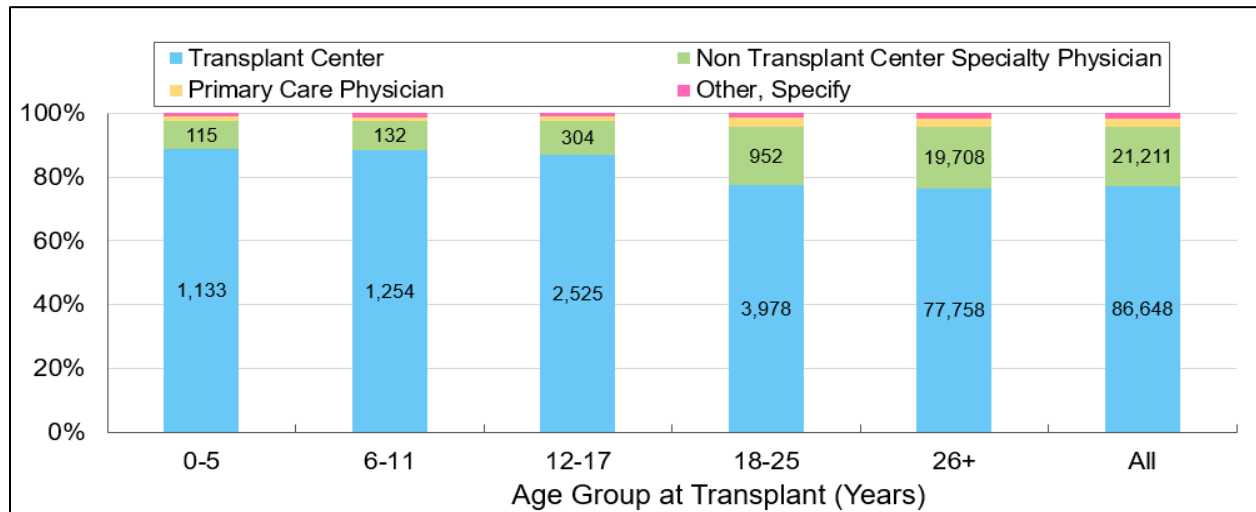
As a result of these data, the Committee focused efforts on identifying effective transition and transfer practices for kidney and liver transplant recipients.

The Subcommittee acknowledged that not all transplant recipients are followed by providers affiliated with a transplant hospital. Literature demonstrates that proximity to a transplant program does impact recipient survival.¹⁰ Subcommittee members agreed there are three common transfer of care scenarios in pediatric transplantation. These include transfer to an adult provider:

1. Within the same transplant hospital
2. At another OPTN transplant hospital, perhaps geographically closer to the recipient
3. Not affiliated with an OPTN transplant hospital, but geographically closer to the recipient

Figure 4 below depicts the types of providers providing follow-up care entered on five year TRF forms for kidney recipients.

Figure 4: Types of Follow-up Provider on Five Year Follow-up Kidney Transplant Recipients 2000-2010



As Figure 4 shows, the majority (~88%) of kidney recipients transplanted from ages 0 to 17 years old were followed by transplant providers five years post-transplant. Approximately 12% of these recipients were followed by non-transplant providers. However, the percentage of kidney recipients ages 18 to 25 years old followed by non-transplant providers increased to approximately 19%.¹¹ Despite this very large percentage of transplant recipients being followed by transplant providers, kidney transplant recipients

⁸ Unpublished reports to OPTN/UNOS Pediatric Transplantation Committee on October 19, 2016 and March 30, 2017. Based on OPTN data as of August 5, 2016 and February 12, 2016 respectively.

⁹ See Appendix, Figures 1-3.

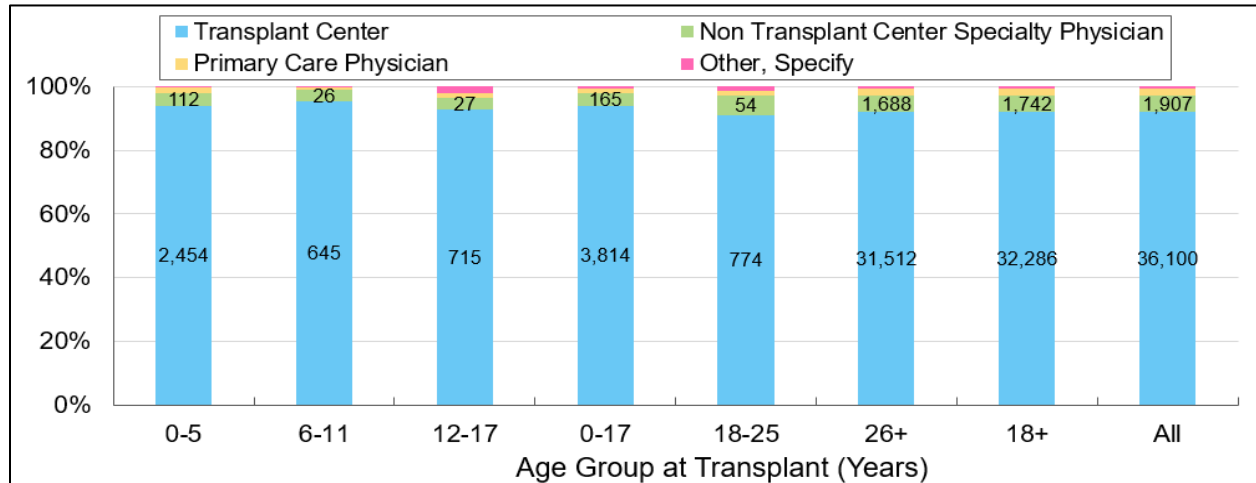
¹⁰ Davis, ID, et al., "Successful Renal Transplantation Accelerates Development in Young Uremic Children", *Pediatrics* 86 no. 4, (1990), page 6.

¹¹ Unpublished reports to OPTN/UNOS Pediatric Transplantation Committee on October 19, 2016.

had 20.8% lost to follow-up designation within 10 years of transplant.

The Committee examined the types of provider entered on five year TRF forms for liver recipients as well. (See **Figure 5**)

Figure 5: Types of Follow-up Provider on Five-Year Follow-up for Liver Transplant Recipients 2000-2010



As Figure 5 shows, the majority (~94%) of liver recipients transplanted from ages 0 to 17 years old were followed by the transplant providers five years post-transplant. Despite this very large percentage of transplant recipients being followed by transplant providers, liver transplant recipients had 14.6% lost to follow-up designation within 10 years of transplant.¹²

Based on these data and the prevalent sentiment in the pediatric transplant community about challenges obtaining recipient health information from unaffiliated providers, the Subcommittee felt gaps in outcome data due to lost to follow-up designation could be minimized by sharing effective practices for transition and transfer.

Input from the Pediatric Transplant Community

To engage the pediatric transplant community in the development of this guidance, the Subcommittee created an online survey to help identify effective transition practices. Any kidney or liver programs active as of January 10, 2018, that performed at least one transplant in a recipient younger than 18 years of age between 2012 and 2016 was invited to complete the survey. The survey was sent to programs' transplant administrators and resulted in a 72% response rate.¹³ Roughly two thirds of responses came from kidney programs, while the remaining third came from liver programs.¹⁴

To support the identification of effective practices, the survey responses were compared to transplant programs with low lost to follow-up rates on TRF forms.¹⁵ The results were stratified over what can be considered small, medium, and large volume transplant programs.¹⁶ The Subcommittee observed the following themes from the survey results:

¹² Unpublished reports to OPTN/UNOS Pediatric Transplantation Committee on October 19, 2016 and March 30, 2017.

¹³ Survey dates January 10, 2018 to February 22, 2018; 206 surveys were sent, 148 responses were received.

¹⁴ Unpublished report to OPTN/UNOS Pediatric Transplantation Committee on April 19, 2018.

¹⁵ Transplant program performance on TRF completion: Below Average = program's 5 year lost to follow-up rate was >10%, Average = program's 5 year lost to follow-up date was between 6-10%, Better than Average = program's 5 year lost to follow-up rate was <5%.

¹⁶ Small Volume = <5 pediatric transplants/year, Medium Volume = 6-9 pediatric transplants/year, Large Volume = at least 10 pediatric transplants/year.

Transition

- There was a lack of clear understanding of “transition” and “transfer”, and these terms were often used interchangeably.
- Not all transplant programs participating in the survey had formalized transition processes.
- There was no relationship between a transplant program having a formalized transition process and average or above average lost to follow-up rates.

Transfer

- While a recipient’s age is a determining factor when to transfer to an adult provider, a recipient’s developmental milestones were a more important consideration than age.
- Transfer from pediatric to adult providers within the same transplant program has benefits (e.g.: plan of care adherence), and was associated with average or better than average of lost to follow-up rates.
- Low volume transplant programs were frequently in close association with an adult transplant program.
- Reluctance to transfer on the part of the parents was reported more frequently by medium and large volume programs, standalone pediatric transplant programs, and kidney programs with below average lost to follow-up rates.

Program case volume and lost to follow-up designation rates:

- Transplant programs with average or below average lost to follow-up rates were more likely to transfer recipients to providers not affiliated with a transplant program as compared to transplant programs with better than average lost to follow-up rates.
- Large volume transplant programs cited extended distances between recipients and the program as a challenge for transferring recipients.

Staff involved:

- Transplant coordinators were most frequently the individuals responsible for contacting other providers for transfer. These individuals were most frequently registered nurses.
- Large volume transplant programs more frequently utilize social workers, transition specialists, or other staff members in transfer discussions.
- Physicians at small volume transplant programs are more frequently involved in the transfer discussion as compared to medium or large volume programs.

Recommendations

The Subcommittee diligently discussed the survey results and linked these results to transplant programs with average or better than average lost to follow-up rates. They also considered published resources available to the pediatric community on transition and transfer practices.^{17, 18, 19} As mentioned earlier, the highest lost to follow-up rates were observed in kidney and liver transplant recipients. However, the Subcommittee felt the practices outlined could be applied to all pediatric transplant programs. The following responsibilities were proposed for each team:

¹⁷ American Academy of Pediatrics (2011), Supporting the Health Care Transition From Adolescence to Adulthood in the Medical Home, *Pediatrics* 128 (1), 182-200, DOI: 10.1542/peds.2011-0969. Accessed June 29, 2018.

¹⁸ Schwartz, LA, et al. (2014), Measures of Readiness to Transition to Adult Health Care for Youth with Chronic Physical Health Conditions: A Systematic Review and Recommendations for Measurement Testing and Development, *Journal of Pediatric Psychology* 39 (6), 588-601, doi.org/10.1093/jpepsy/jsu028. Accessed June 29, 2018.

¹⁹ McManus, M, et al., (2014) Pediatric to Adult Transition: A Quality Improvement Model for Primary Care, *Journal of Adolescent Health*, 56 (1), 73-78, https://doi.org/10.1016/j.jadohealth.2014.08.006. Accessed June 29, 2018.

Pediatric Transplant Team

- Create a written health care transition plan.
- Encourage and provide guidance to recipients' family or guardians about how they can promote independence and self-responsibility during the transition process. Emphasize that recipients must advocate for themselves and ask questions when faced with unfamiliar tests, medications, outpatient clinic practices, or if treatment plans are modified.
- Prepare both the recipient and their family members or guardians for transfer to another provider.
- Assess transition readiness, including critical milestones that should be achieved before transferring to adult care.²⁰ Further, transition plans should be flexible and based on the unique needs of each recipient.
- Stand-alone pediatric transplant programs should carefully assess if the transplant recipient is reluctant to transfer to another provider. This assessment should occur multiple times during the transition process. If the reluctance to transfer continues then the transfer to adult care should be delayed until the cause of reluctance is addressed appropriately.
- Ensure surrogate decision-makers are identified for those recipients with limited decision-making capability. This would include resolution of guardianship or formal legal arrangements, and should be completed before the recipient's 18th birthday. Formal legal arrangements may be necessary to avoid future conflicts, and ensure continuity of a stable support system.
- Consider transfer to an adult provider within the same institution whenever possible.
- Partnerships with adult providers should be established well in advance of transfer.
- Communicate to the OPTN upon each recipient transfer. This will allow accurate assignment of TRF responsibility to the appropriate transplant program. The originating transplant program should communicate to the accepting transplant program when this form reassignment has been performed.
- Provide the transplant recipient with a portable, concise, up-to-date summary of their medical and surgical history, and a detailed list of their medications at the time of transfer.
- If a recipient relocates or a payer requires transfer of a recipient, additional resources may be needed to effectively obtain recipient health information and submit the information to the OPTN.
- Remember that transplant programs that transfer recipients to providers unaffiliated with a transplant program are still responsible for submitting TRF forms for those recipients to the OPTN.²¹
 - To improve health information sharing, the transplant programs should communicate to the accepting provider the need to be kept informed on the recipient's state of health, information required by the OPTN, and the frequency of data submission requirements prior to and at the time of transfer.
 - The originating transplant program should carefully consider the administrative burden of obtaining health information on these recipients when considering staff responsibilities and work volume.

Accepting Adult Providers:

- Provide staff education regarding childhood and adolescence psychosocial development, and the impact of childhood chronic disease on development.
- Be knowledgeable about congenital conditions that lead to organ failure in childhood and that may rarely be seen in adult patients.
- Recognize that transplant recipients who are transferring into their practice may need time to fully adjust to the more rapid pace of an adult outpatient setting.
- Maintain ongoing communication with the pediatric transplant programs to improve recipient transfers and provide needed recipient health information for data reporting.

²⁰ See Appendix, Table 1.

²¹ OPTN Policy 18.1, Data Submission Requirements, page 4.

The Subcommittee recognized the value that existing resources have for this discussion. Online resources from other organizations were included in this the guidance to further support to enhancements to institutional policies or procedures on transition and transfer.

The Committee carefully reviewed the guidance. Members verbalized their support for the document and the guidance would meet a need in the transplant community. Members were cognizant that adult transplant programs are critical partners in the transition and transfer process. The Committee asked that adult transplant programs share their feedback to “improve the catch” when accepting a recipient from a pediatric transplant program. Some members shared a concept of a hybrid approach to transferring a recipient to a provider not affiliated with a transplant hospital, perhaps in circumstances when a recipient’s residence was geographically distant from the pediatric transplant hospital. This would entail an agreement for outpatient following between a local provider and another adult transplant program in closer proximity to the recipient. The Committee recommended the guidance document be distributed for the fall 2018 public comment period (18-Yes, 0-No, 0-Abstain)

How well does this resource address the problem statement?

There are numerous manuscripts in peer-reviewed literature that describe the challenges of adolescent development and risk-taking often associated with this population, the impact of clinical non-adherence in patients with chronic illnesses, and the implications of gaps in transition and transfer for transplant recipients.²² To-date, there is no guidance on effective transition or transfer practices from the OPTN. Though not binding to OPTN members, guidance documents developed by the OPTN are valuable resources to the transplant community. Transplant professionals participating in the survey affirmed substantial interest for more information on these topics.

The Committee believes the document carefully conveys the importance of diligently reporting transplant recipient medical information to the OPTN, distinguished between transition and transfer, articulated why these processes occur at challenging for pediatric transplant recipients, clarified OPTN data submission responsibilities, and shared well thought-out recommendations developed in partnership with the pediatric transplant community.

Which populations are impacted by this resource?

As mentioned previously, the highest rates of lost to follow-up designation appeared in kidney and liver transplant recipients. In 2017, 646 kidney recipients and 475 liver recipients turned 18 years old.²³ Though the data supported the need for guidance targeted to kidney and liver transplant programs, the recommendations in the guidance can be used by all pediatric transplant programs to enhance transition and transfer of recipient to adult care.

How does this resource impact the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no impact to this goal
2. *Improve equity in access to transplants:* There is no impact to this goal
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* Suboptimal transition and transfer of pediatric transplant recipients to adult medical care can have detrimental impact on recipient and graft survival. These can lead to recipients’ inconsistent or declining engagement with medical providers over time. Even worse, these vulnerable recipients may not receive

²² Axelrod, DA, et al., “The Interplay of Socioeconomic Status, Distance to Center, and Interdonor Service Area Travel on Kidney Transplant Access and Outcomes” (2010), page 4.

²³ Based on OPTN Data as of December 31, 2017.

needed out-patient care to promote long term graft and recipient survival. The end result can be graft dysfunction or loss.

This guidance shares effective practices for pediatric transition and transfer from those transplant programs with average or better than average lost to follow-up designations. The Committee hopes sharing these effective practices will improve the transition and transfer process which will in-turn lead to better transplant outcomes by reducing instances of graft loss from non-adherence.

4. *Promote living donor and transplant recipient safety:* There is no impact to this goal
5. *Promote the efficient management of the OPTN:* There is no impact to this goal

How will the OPTN implement this resource?

This guidance document will be posted to the OPTN website, and will not require programming in UNetSM. Throughout public comment and all follow-up discussions about this proposal, UNOS staff will consider if additional instructional support is necessary to supplement this guidance document.

How will members implement this resource?

This guidance will have no impact on OPOs or histocompatibility laboratories.

If a transplant program implements the practices contained in this guidance, they may need to:

- Enhance or refine their transition practices to be recipient-driven.
- Develop and maintain relationships with providers that accept pediatric recipients for on-going medical care.
- Develop internal policies or procedures to ensure accepting providers receive the information needed for transfer and help these providers “perfect the catch” on the receiving end.
- Allocate additional resources to obtain recipient health information from outside providers. This may take the shape of additional staff time to contact outside providers and report the information to the OPTN.

Will this resource require members to submit additional data?

No, this resource does not require members to submit additional data submission.

How will members be evaluated for compliance with this resource?

Guidance from the OPTN does not carry the weight of policies or bylaws. Therefore, members will not be evaluated for compliance with this document.

How will the sponsoring Committee evaluate whether this resource was successful post implementation?

It will be challenging to establish causation of a decrease in lost to follow-up designation based on this guidance document and corresponding education/outreach. In order to assess if the guidance and related education/outreach may have contributed to a decrease lost to follow-up designation, the Committee will monitor the lost to follow-up rates for liver and kidney transplants, with a focus on those recipients transplanted at less than 18 years old. The OPTN will report this information to the Committee at regular intervals following approval by the Board.

Guidance Document

All the language in the white paper below is proposed new language; underlines have been omitted for easier reading.

Tracking Pediatric Transplant Outcomes Following Transition and Transfer to Adult Care

Summary and Goals

The goal of this guidance is to reduce the incidence of lost to follow-up designations for pediatric transplant recipients. Long term recipient and graft survival data are critical to understanding organ transplant outcomes. These data are used to help the transplant community develop healthcare policy (e.g.: in organ allocation) and guides their clinical decision making (e.g.: in determining acceptable travel distance and cold ischemic times for organ recovery). Additionally, transplant professionals use these data when counseling patients' families and guardians regarding expected outcomes and to set realistic goals regarding transplantation.

Many lost to follow-up designations are the result of breakdowns in the transition and transfer to adult medical care. By sharing effective practices for recipient transition and transfer from pediatric to adult medical care, transplant outcome data will be more complete and more representative of clinical practices. Suboptimal transition and transfer processes have been shown to be associated with increased risk of non-adherence and graft loss. A secondary goal of the guidance is to improve the transition and transfer process which will in-turn lead to better transplant outcomes by reducing instances of graft loss from non-adherence.

Contents

20	Summary and Goals	10
21	Contents	10
22	Background	11
23	Recommendations	13
24	Additional Resources	15
25	Conclusion	15
26	Appendix	16

27 How to Effectively Track Pediatric Transplant Outcomes 28 Following Transition and Transfer to Adult Care

Background

29 The OPTN/UNOS Pediatric Transplantation Committee (Committee) is charged with examining long-term
30 outcomes in pediatric organ transplantation. The accuracy of data used to perform this analysis is critical
31 to understanding recipient and graft survival. These data are used to develop healthcare policy and guide
32 clinical decision making. Additionally, transplant professionals use these data when counseling patients'
33 families or guardians regarding expected outcomes and to set realistic goals regarding transplantation.

34
35 The Committee recognized there are gaps in data reported to the OPTN that may influence their
36 analyses. One of these gaps is created by the number of recipients being reported as “lost to follow-up.”
37 This designation is available for a transplant program to enter on Transplant Recipient Follow-up (TRF)
38 forms if the program is unable to obtain the recipient’s health information. This may be due to losing
39 contact with the recipient, the recipient relocating, or being referred to another healthcare provider for
40 post-transplant medical care. One of the primary circumstances in which a transplant recipient is
41 designated as “lost to follow up” is the transition from pediatric to adult care, which encompasses the
42 transfer of the pediatric recipient to a provider who is equipped to deliver care to an adult transplant
43 recipient. In some circumstances, this provider may not be associated with an OPTN member transplant
44 hospital.

45
46 By identifying and promoting effective transfer and transition practices, the Committee hopes to decrease
47 the number of pediatric recipients lost to follow-up after they transition to adult care, which will in turn
48 increase the accuracy and transparency of the recipient data available to the OPTN, the transplant
49 community, and the public. Suboptimal transition and transfer processes are associated with increased
50 risk of non-adherence and graft loss. A secondary goal of the guidance is to improve the transition and
51 transfer process which will in-turn lead to better transplant outcomes by reducing instances of graft loss
52 from non-adherence to a recipient’s treatment plan.

53
54 Transition ideally begins in late childhood and early adolescence and involves many stakeholders. This
55 occurs during a challenging stage of development, the complexities of which are well documented in
56 medical literature.^{1, 2, 3, 4, 5, 6, 7} This is even more challenging in children with complex medical conditions,
57 which would include transplant recipients.⁸ Further complicating this progression to autonomous care is

¹Park, MJ, et al., “The health status of young adults in the United States, *Journal of Adolescent Health* 39 (2006),
<https://doi.org/10.1016/j.jadohealth.2006.04.017>. Accessed June 27, 2018.

² Keith, D, Cantarovich, M, Paraskevas, S, Tchervenkov, J, “Recipient age and risk of chronic allograft nephropathy in primary deceased kidney transplant”, *Transplant International* 19 (2006), <https://doi.org/10.1111/j.1432-2277.2006.00333.x>. Accessed June 27, 2018.

³ U.S. Government Accountability Office, *End-stage renal disease: Characteristics of kidney transplant recipients, frequency of transplant failures, and cost to Medicare* (2007), <https://www.gao.gov/assets/270/267345.pdf>. Accessed June 27, 2018.

⁴ Dobbels, F, Van Damme-Lombaert, R, Vanhaecke, J, De Geest, S, “Growing pains: non-adherence with immunosuppressive regimen in adolescent transplant recipients”, *Pediatric Transplantation* 9 (2005), doi10.1111/j.1399-3046.2005.00356.x. Accessed June 27, 2018.

⁵ Hazen, E, Schlozman, S., Beresin, E, “Adolescent psychological development: A review”, *Pediatrics in Review* 29 (2008), DOI: 10.1542/pir.29-5-161. Accessed June 27, 2018.

⁶ Giedd, J, “The teen brain: insights from neuroimaging”, *Journal of Adolescent Health* 42, (2008), <https://doi.org/10.1016/j.jadohealth.2008.01.007>. Accessed June 27, 2018.

⁷ Steinberg, L, “A social neuroscience perspective on adolescent risk-taking”, *Developmental Review* 28 (2008), <https://doi.org/10.1016/j.dr.2007.08.002>. Accessed June 27, 2018.

⁸ Andreoni, KA, Forbes, R., and Andreoni, RM, “Age-Related Kidney Transplant Outcomes Health Disparities Amplified in Adolescence”, *JAMA Internal Medicine* 16 (2013), doi:10.1001/jamainternmed.2013.8495. Accessed June 29, 2018.

58 the transfer to an adult medical provider when the recipient reaches early adulthood. Clear plans for
59 transition have been identified as an effective practice across many disciplines in pediatric health care.^{9, 10}
60

61 As pediatric transplant recipients reach this vulnerable age, health professionals often find it challenging
62 to effectively transition the recipients from pediatric to adult care. There are broadly acknowledged facts
63 that may negatively impact transition:

- 64 • Lack of optimization in the transition process
- 65 • Many youth are ill-equipped to receive care in the adult system
- 66 • Adult providers may lack knowledge and skills to care for young adults with childhood-onset
67 chronic conditions
- 68 • Inadequate health insurance and transition services funding^{11, 12, 13, 14, 15}

69 Acknowledging the linkages between less than effective transition, the challenges associated with
70 recipient transfer during a challenging developmental time, and the impact of these on recipient data
71 submission, the Pediatric Committee examined lost to follow-up rates for heart, kidney, and liver
72 transplant recipients in the U.S. who were transplanted during the period 2000 to 2010, and were less
73 than 18 years old at the time of transplant. The data showed diverse lost to follow-up rates across all
74 organs, with the highest for kidney recipients, than liver recipients.¹⁶

75 There are three common models of transfer of care to an adult provider:

- 76 • Transfer to an adult transplant physician within the same transplant program
- 77 • Transfer to an adult transplant physician at another transplant program, usually geographically
78 closer to the recipient
- 79 • Transfer to an adult provider who is not associated with a transplant program, but geographically
80 closer to the recipient

81 Responsibility for completion of the TRF forms will differ, depending on the model of transfer used. For
82 those recipients transferred to adult providers at another transplant program, the responsibility for
83 completion of the TRF forms will follow them to the new transplant center following an official handoff of
84 this duty. For those recipients transferred to an adult provider not associated with a transplant program,
85 the responsibility for completion of the TRF forms will continue to reside with the transplanting program.¹⁷

⁹ American Academy of Pediatrics, Supporting the Health Care Transition From Adolescence to Adulthood in the Medical Home, *Pediatrics* 128 (2011), 182-200, DOI: 10.1542/peds.2011-0969. Accessed June 29, 2018.

¹⁰ Schwartz, L.A., et al., Measures of Readiness to Transition to Adult Health Care for Youth with Chronic Physical Health Conditions: A Systematic Review and Recommendations for Measurement Testing and Development, *Journal of Pediatric Psychology* 39 (2014), 588-601, doi.org/10.1093/jpepsy/jsu028. Accessed June 29, 2018.

¹¹ Unpublished reports to OPTN/UNOS Pediatric Transplantation Committee on October 19, 2016.

¹² McDonagh, JE, "Growing up and moving on. Transition from Pediatric to Adult Care", *Pediatric Transplantation* 9 (2005), <https://doi.org/10.1111/j.1399-3046.2004.00287.x>. Accessed June 29, 2018.

¹³ Rosen, DS, et al., "Transition to adult health care for adolescents and young adults with chronic conditions: Position paper for the society for adolescent medicine", *Journal of Adolescent Health* 33 (2003), https://www.adolescenthealth.org/SAHM_Main/media/Advocacy/Positions/2003-Transition_from_Child-Centered_to_Adult_Health-Care_Systems_for_Adolescents_with_Chronic_Conditions.pdf. Accessed June 29, 2018.

¹⁴ Watson, AR, "Noncompliance and transfer from paediatric to adult transplant unit", *Pediatric Nephrology* 14 (2000), <https://doi.org/10.1007/s004670050794>. Accessed June 29, 2018.

¹⁵ Knauth, A, Verstappen, A, Reiss, J, and Webb GD, "Transition and transfer from pediatric to adult care of the young adult with complex congenital heart disease", *Cardiology Clinics* 24 (2006), <https://doi.org/10.1016/j.ccl.2006.08.010>. Accessed June 29, 2018.

¹⁶ Unpublished reports to OPTN/UNOS Pediatric Transplantation Committee on October 19, 2016 and March 30, 2017. Based on OPTN data as of August 5, 2016 and February 12, 2016 respectively.

¹⁷ OPTN Policies 18.1 *Data Submission Requirements*, and 18.2 *Timely Collection of Data*,

86 The Committee then created and administered an on-line survey of transition practices. They compared
87 survey responses to transplant programs with low, average, or better than average lost to follow-up rates
88 on TRF forms identified in OPTN data.¹⁸ The results were stratified over what can be considered small,
89 medium and large volume transplant programs.¹⁹ This comparison highlighted those effective practices
90 that may promote average or better than average lost to follow-up rates.

91 The Committee observed the following themes from the survey results:

- 92 • A defined transfer age varied among transplant programs. Such a practice may not be in the best
93 interest of long-term follow up. In general, the younger the recipient at transfer, the worse the lost
94 to follow-up rate. Instead, a recipient's developmental milestones and maturity should be strongly
95 considered to determine when to begin the transition process and when to transfer a recipient to
96 an adult provider.
- 97 • The absence of a formalized transition process was noted at small volume transplant programs,
98 but was not associated with below average lost to follow-up rates. The lower case volume at
99 these programs may inherently allow staff to focus more on recipient-centric indicators for
100 transition and transfer readiness, and focus less on transition processes.
- 101 • Low volume centers were frequently in close association with an adult center. The transfer of care
102 to an adult transplant physician within the same program likely contributes to the low lost to follow
103 up rates observed at low volume centers.
- 104 • Transfer to adult providers within the same transplant program has its benefits and is associated
105 with lower rates of lost to follow-up designation.
- 106 • Transplant programs should commit resources to diligent follow-up of those recipients who reside
107 extended distances from the transplant program and to report these data to the OPTN.
- 108 • Transplant programs with average or below average lost to follow-up rates were more likely to
109 transfer recipients to unaffiliated providers compared to transplant programs with better than
110 average lost to follow-up rates.
- 111 • Physicians at small volume transplant programs are more frequently involved in the transfer
112 discussion as compared to medium or large volume programs.
- 113 • Large volume transplant programs more frequently utilize social workers, transition specialists, or
114 other staff members in transfer discussions.
- 115 • Reluctance to transfer care on the part of the parents was reported more frequently by medium
116 and large volume programs, standalone pediatric transplant programs, and kidney programs with
117 below average lost to follow-up rates.
- 118 • Large volume transplant programs cited geographic location as a challenge for transferring
119 recipients. This may reflect pre-transplant referrals from a wide geographic area, or programs that
120 operate outreach care clinics.
- 121 • Transplant coordinators were most frequently the individuals responsible for contacting other
122 providers for transfer. These individuals were most frequently registered nurses.

123 Recommendations

124 Successful transition and transfer practices must balance the needs of the recipients and
125 families/guardians, regulatory requirements, payer factors, hospital policies, transplant program
126 resources, and OPTN member obligations. Though the highest lost to follow-up rates were observed in
127 kidney and liver transplant recipients, the practices outlined can be applied to all types of transplant
128 programs.

129
130 The following are the responsibilities proposed for each team:

https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_18. Accessed June 29, 2018.

¹⁸ Transplant program performance on TRF completion: Below Average = program's 5 year lost to follow-up rate was >10%, Average = program's 5 year lost to follow-up date was between 6-10%, Better than Average = program's 5 year lost to follow-up rate was <5%.

¹⁹ Small Volume = <5 pediatric transplants/year, Medium Volume = 6-9 pediatric transplants/year, Large Volume = at least 10 pediatric transplants/year.

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Pediatric Transplant Team:

- Create a written health care transition plan.
- Encourage and provide guidance to recipients' family/guardians about how they can promote independence and self-responsibility during the transition process. Emphasize that recipients must advocate for themselves and ask questions when faced with unfamiliar tests, medications, outpatient clinic practices, or if treatment plans are modified.
- Prepare both the recipient and their family members/guardians for transfer to another provider.
- Assess transition readiness, including critical milestones that should be achieved before transferring to adult care.²⁰ Further, transition plans should be flexible and based on the unique needs associated with each recipient.
- Stand-alone pediatric transplant programs should carefully assess if the transplant recipient is reluctant to transfer to another provider. This assessment should occur multiple times during the transition process. If the reluctance to transfer continues then the transfer to adult care should be delayed until the cause of reluctance is addressed appropriately.
- Ensure surrogate decision-makers are identified for those recipients with limited decision-making capability. This would include resolution of guardianship or formal legal arrangements, and should be completed before the recipient's 18th birthday. Formal legal arrangements may be necessary to avoid future conflicts, and ensure continuity of a stable support system.
- Consider transfer to an adult provider within the same institution whenever possible.
- Partnerships with adult providers should be established well in advance of transfer.
- Communicate each recipient transfer to the OPTN. This will allow accurate assignment of TRF responsibility to the appropriate transplant program. Guidance and frequently asked questions can be found on the TransplantPro website.²¹
- Provide the transplant recipient with a portable, concise, up-to-date summary of their medical and surgical history, and detailed list of their medications.
- If a recipient relocates or a payer requires transfer of a recipient, additional resources may be needed to effectively obtain recipient health information and submit the information to the OPTN.
- Remember that transplant programs that transfer recipients to providers unaffiliated with a transplant program are still responsible for submitting TRF forms for those recipients to the OPTN.²²
 - To improve health information sharing, the transplant programs should communicate to the accepting provider the need to be kept informed on the recipient's state of health, information required by the OPTN, and the frequency of data submission requirements prior to and at the time of transfer.
 - The originating transplant program should carefully consider the administrative burden of obtaining health information on these recipients when considering staff responsibilities and work volume.

Accepting Adult Providers:

- Provide staff education regarding childhood and adolescence psychosocial development and the impact of childhood chronic disease on development.
- Be knowledgeable about congenital conditions that lead to organ failure in childhood and that may rarely be seen in adult patients.
- Recognize that transplant recipients who are transferring into their practice may need time to fully adjust to the more rapid pace of an adult clinic.
- Maintain ongoing communication with the pediatric transplant programs to improve recipient transfers and provide needed recipient health information for data reporting.

²⁰ See Appendix, Table 2.

²¹ <https://transplantpro.org/news/tied-enhancements-allow-for-self-service-on-recipient-follow-up-forms/>. Accessed June 29, 2018.

²² OPTN Policies 18.1: *Data Submission Requirements*, and 18.2: *Timely Collection of Data*.

179 Additional Resources

180 Additional resources for the recipient's transplant team are available below:

- 181 • American Academy of Pediatrics – *Guidance on adolescents transitioning to adult care*²³
- 182 • New England Journal of Medicine – *Operational Standard for Transitioning Pediatric Patients to*
183 *Adult Medicine*²⁴
- 184 • Organ Procurement and Transplantation Network –
 - 185 ○ UNOSConnect: *Special Considerations and Challenges in Management of Children and*
186 *Adolescents Presenting to Adult Transplant Centers, and Smoothing the Path to Adulthood: A*
187 *Transition Clinic for Kidney Transplant Recipients*²⁵
 - 188 ○ *What Every Parent Needs to Know*²⁶

189
190 In addition to this guidance for transplant hospitals from the OPTN, transition guidance specifically for
191 transplant recipients can be found on the AST Pediatric Transition Portal.²⁷

192 Conclusion

193 Long term recipient and graft survival data are critical to understanding organ transplant outcomes. This
194 guidance will hopefully reduce the incidence of lost to follow-up designation by sharing effective practices
195 for recipient transition and transfer from pediatric to adult medical care. Consequently, transplant outcome
196 data will be more complete and representative of clinical practices.

²³ <https://www.aap.org/en-us/about-the-aap/aap-press-room/pages/Helping-Adolescents-Transition-to-Adult-Health-Care.aspx>. Accessed June 29, 2018.

²⁴ <https://catalyst.nejm.org/operational-standard-pediatric-transition-adult/>. Accessed June 29, 2018.

²⁵ <https://unosconnect.unos.org/UI/LandingPage.aspx>. Accessed June 29, 2018.

²⁶ https://optn.transplant.hrsa.gov/media/2464/weparentntk_optn.pdf. Accessed June 29, 2018.

²⁷ <https://www.myast.org/education/specialty-resources/peds-transition>. Accessed June 29, 2018.

197 **Appendix**

198 **Figure 1: Lost to Follow-up Rates at 1 through 10 Years after Transplant for Kidney Transplants**
 199 **Performed during 2000 - 2010 by Age at Transplant²⁸**

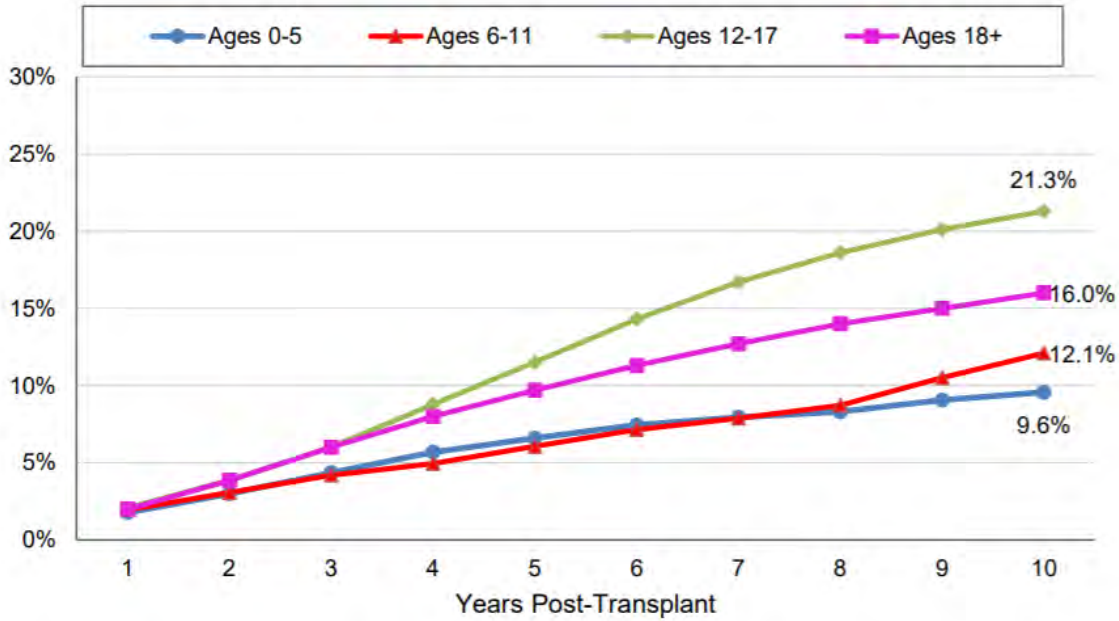
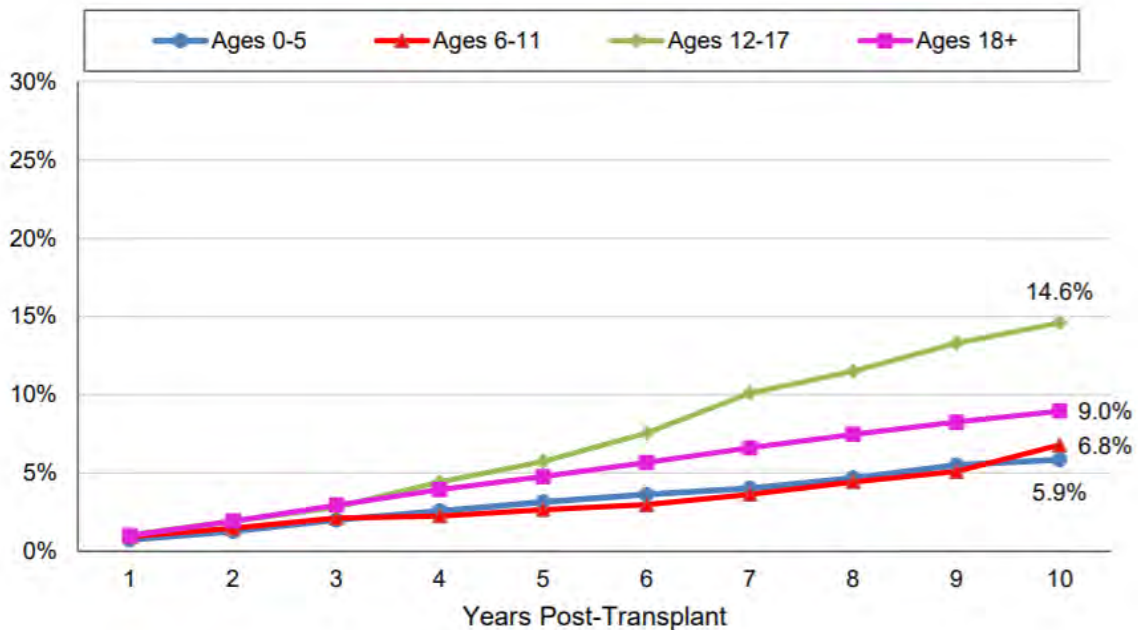


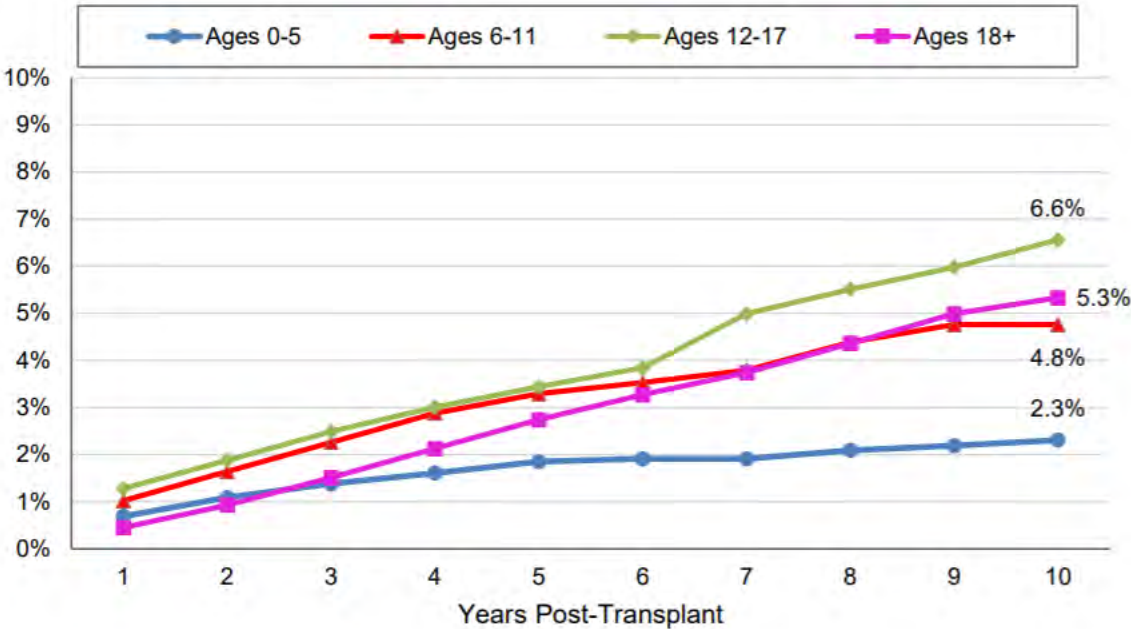
Figure 2: Lost to Follow-up at 1 through 10 Years after Transplant for Liver Transplants Performed during 2000 - 2010 by Age at Transplant²⁹



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²⁸ Unpublished reports to OPTN/UNOS Pediatric Transplantation Committee on October 19, 2016 and March 30, 2017.

Figure 3: Lost to Follow-up at 1 through 10 Years after Transplant for Heart Transplants Performed during 2000 - 2010 by Age at Transplant²⁹



201 **Table 1: Developmental Stages/Milestones of Adolescence and Young Adulthood, and Suggested Clinic Visit**
 202 **Developmental Subjects**²⁹

	Early adolescence ages ~10-13 years*	Mid adolescence ages ~ 14-16 years*	Late adolescence ages ~ 17-21 years and beyond*
<i>Cognitive, affective & moral</i>	<ul style="list-style-type: none"> • Concrete thinking • Beginning development of abstract thought in some • Inability to grasp long-term outcome of current decisions • Heightened emotional arousability • Sensation seeking • Early exploratory behaviors (e.g. smoking, violence) • Reward oriented • Development of early moral concepts 	<ul style="list-style-type: none"> • Increased intellectual functioning and abstract thinking • May revert to concrete thinking in confusing or stressful situations • May begin to perceive future consequences of actions but not utilize in decision making • Sense of omnipotence and invincibility • Heightened vulnerability to risk taking • May have difficulty regulating affect and behavior • Questioning of moral conventions • Development of personal code of ethics • Emergent fervent ideology 	<ul style="list-style-type: none"> • Complex abstract thinking (some may never fully achieve) • More future oriented: can act on long-term plans, delay gratification, set limits • Greater emotional stability • Idealism but sometimes absolutism, with intolerance of opposing views • May be swayed by religious and political ideology that promise answers to complex questions
<i>Self- concept/identity formation</i>	<ul style="list-style-type: none"> • Fantasy and present-oriented • Self-conscious about appearance, body image and attractiveness 	<ul style="list-style-type: none"> • Increased introspection • May question meaning of life and have intense feelings of inner turmoil and misery • Concern with attractiveness 	<ul style="list-style-type: none"> • Progression of personal identity • More stable body image; attractiveness may remain important
<i>Family and peers</i>	<ul style="list-style-type: none"> • Beginning of emotional separation from parents and early effort toward independence • Need for privacy • Beginning of strong same gender peer identification and affiliation 	<ul style="list-style-type: none"> • Further emotional separation from parents and family • Struggles and conflicts over autonomy • Strong peer identification and involvement 	<ul style="list-style-type: none"> • Separation from family emotionally and physically • Peer group / peer values begin to diminish in importance • Formation of stable relationships with increasing involvement of love and commitment

²⁹ Bell, L.E., et al., (2008) Adolescent Transition to Adult Care in Solid Organ Transplantation: A Consensus Conference Report, *American Journal of Transplantation* (8) 11, 2230-2242, <https://doi.org/10.1111/j.1600-6143.2008.02415.x>. Accessed June 29, 2018.

	Early adolescence ages ~10-13 years*	Mid adolescence ages ~ 14-16 years*	Late adolescence ages ~ 17-21 years and beyond*
<i>Sexual</i>	<ul style="list-style-type: none"> • Examination of own sexual feelings • Progression of sexual identity development & orientation 	<ul style="list-style-type: none"> • Questions of sexual orientation • Initiation of sexual relationships (often superficial) • Sexual experimentation • Aware of risks of pregnancy and sexually transmitted diseases, but may not consistently act upon the knowledge 	<ul style="list-style-type: none"> • Consolidation of sexual identity
<i>Relationship to society</i>	<ul style="list-style-type: none"> • Adaptation to middle/early secondary school years 	<ul style="list-style-type: none"> • Assessment of skills and opportunities • Early educational and/or vocational plans • Realistic role models critically important 	<ul style="list-style-type: none"> • Career decisions central • University/college/vocational experience with increased self-responsibility • Progression of workforce capability and financial independence
<i>Suggested subjects to explore and discuss at clinic visits discuss</i>	<ul style="list-style-type: none"> • Introduce concept of private confidential visits to parents and patient • Simple directed interactive questions to patient • Straightforward interactive counselling • Discuss healthy lifestyle choices 	<ul style="list-style-type: none"> • Enquire about friends, free time activities, home life, school • Ask in non-threatening, non-judgmental manner about experimentation with drugs, alcohol or sexual activity, and about any trouble with the law • Discuss healthy living 	<ul style="list-style-type: none"> • Discuss healthy living habits and personal interventions for improving overall wellness • Identify unhealthy living habits and their consequences • Build upon questions from earlier age ranges (left of table)

204 **Table 2: Critical Milestones for Patients to Achieve Prior to Transfer to Adult Care**³⁰

- Understanding of and ability to describe the original cause of their organ failure, need for transplantation
 - Initial education may have been primarily provided to their parents; repetition is necessary to ensure they understand their condition
- Awareness of the long and short term implications of the transplant condition on their overall health and other aspects of their life (e.g. infection prevention, cancer surveillance, academic and vocational aspirations)
- Comprehension of the impact of their illness on their sexuality and reproductive health, including
 - the impact of pregnancy on their own wellbeing
 - the effect of their medications on fertility
 - Any potential teratogenicity of their medications
 - The role of genetic counselling, and genetic risk of their disease recurrence in future offspring, if pertinent to their condition
 - their own increased susceptibility for sexually transmitted disease
- Demonstration of a sense of responsibility for their own healthcare
 - Knowledge of the names, (and shapes/colors), indications and dosages of their transplant and ancillary medications (or carry that information in wallet/purse)
 - Call for their own prescription refills and renewals
 - Prepare their own medication dose boxes, if not done by their pharmacist
 - Independently communicate their health care needs to their providers
 - Know when and how to seek urgent medical attention, including health emergency telephone number(s)
 - Ability to make, keep a calendar of, and follow through with their own health care appointments
 - Understanding of their medical insurance coverage and eligibility requirements
- Capacity to provide most self-care independently
- An expressed readiness to move into adulthood
- Ownership of their medical information in a concise portable accessible summary

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³⁰ Bell, L.E., et al., (2008) Adolescent Transition to Adult Care in Solid Organ Transplantation: A Consensus Conference Report, page 9.