

Parental refusal of vaccination and transplantation listing decisions: A nationwide survey

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Abstract: Many professional societies and research studies recommend complete vaccination before pediatric solid organ transplantation. Nevertheless, incompletely vaccinated children often receive transplants. As the number of parents refusing to vaccinate children for nonmedical reasons increases, pediatric transplantation programs face difficult listing decisions. Given the importance of psychosocial criteria in listing decisions, this study explores how parental refusal of vaccination affects those listing decisions. Surveys were emailed to individuals at 195 pediatric solid organ transplantation programs in the United States, with a 71% response rate. Forty-four respondents (39%) reported that their programs have had cases involving parental refusal of vaccination. In response to hypothetical scenarios, 93 respondents (82%) would list a child not vaccinated for medical reasons, whereas only 54 respondents (47%) would list a child whose parents refused vaccination. Only five respondents (4%) reported that their programs had written policies regarding parental refusal of vaccination. These data reveal inconsistencies across pediatric transplantation programs regarding how parental refusal of vaccination affects listing decisions and raise the issue of whether and how the reason for incomplete vaccination should be factored into listing decisions. We recommend further discussion and the development of written guidelines to unify programs' assessments of incompletely vaccinated pediatric transplantation candidates.

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The American Academy of Pediatrics (AAP), the American Society of Transplantation, and numerous research studies recommend that every effort be made to complete appropriate vaccinations before solid organ transplantation in pediatric patients (1–6). Nevertheless, because transplantation should not be delayed for the purpose of completing immunizations (1), it is not uncommon for incompletely vaccinated pediatric patients to receive transplants (2, 3). Reasons given for incomplete vaccination are generally medically based, including too young an age and lack of time during which the child is considered healthy enough to receive immunizations (2, 3).

Yet studies of the general pediatric population indicate that another reason for incomplete immunization has increased in recent years: parental refusal of vaccination for nonmedical reasons (7–9). From a public health perspective, the AAP and the Centers for Disease Control and Prevention strongly endorse pediatric vaccination (10, 11), and the AAP has issued guidelines to help physicians navigate parental refusal of vaccination (10). Given its increasing prevalence, parental refusal of vaccination is very likely to emerge or already be present, as a psychosocial factor in determining listing decisions for pediatric transplantation candidates. However, there are no studies that examine parental refusal of vaccination in the context of solid organ transplantation listing decisions. As parental refusal of vaccination and the use of psychosocial criteria in listing decisions are both under increasing scrutiny, this study explores their intersection

Abbreviations: AAP, American Academy of Pediatrics; MMR, measles, mumps, and rubella; OPTN, Organ Procurement and Transplantation Network; UNOS, United Network for Organ Sharing.

through a survey of pediatric solid organ transplantation programs across the United States.

Material and methods

Subjects

In June 2011, we identified pediatric heart, kidney, and liver transplantation programs in the United States through the Organ Procurement and Transplantation Network (OPTN) database. Using the broad criterion of having performed at least one transplant in a child under the age of ten in the past five yr, we identified 213 pediatric transplantation programs. Contact information for medical directors, surgical directors, or transplant coordinators at each program was obtained through the OPTN database and through program websites. These websites indicated that some individuals were involved in more than one type of organ program at their institutions. Email addresses were not available for nine programs. Each identified individual was emailed and asked to participate in the survey (a maximum of four additional reminders were sent). Nine responded that their hospitals no longer had active pediatric transplantation programs. Surveys were thus distributed to individuals at 195 pediatric solid organ transplantation programs.

Survey instrument

The survey instrument was designed to determine transplantation programs' experiences, views, and policies regarding incomplete vaccination of pediatric patients in the context of listing decisions. Survey questions and hypothetical scenarios were iteratively developed in consultation with pediatric heart, kidney, and liver transplantation physicians and coordinators at our institution. The full survey instrument was then piloted with these individuals for consistency of scenario interpretation and feasibility and was revised before dissemination.

The survey was divided into four sections containing both multiple choice and open-ended questions. The first section covered program characteristics, including type of organ transplanted and average number of transplantations per year, as well as the respondent's role on the transplantation team.

The second and third sections asked respondents about their programs' actual experiences with cases involving medical reasons for incomplete vaccination as well as cases involving parental refusal of vaccination. These sections also asked respondents to consider two hypothetical scenarios in which their programs were evaluating an incompletely vaccinated child for possible transplantation. The missed vaccines in both scenarios included two live vaccinations (measles, mumps, and rubella [MMR] and varicella) because although inactivated vaccines may be provided after transplantation, live vaccinations are generally contraindicated post-transplantation (4, 5, 12). As was confirmed during the piloting process at our institution, the scenarios were designed such that the only difference interpreted between them was the reason for incomplete vaccination (medical reasons vs. parental refusal); the end result (an incompletely vaccinated child) was the same. In the first scenario, the child was incompletely vaccinated based on healthcare providers' recommendations (Table 1a), and in the second scenario, the incomplete vaccination was due to refusal by the parents (Table 1b). For each scenario, respondents were asked

whether they would list the child for transplantation and whether the reason for incomplete vaccination was an absolute, relative, or non-contraindication to listing. A list of explanations (as shown in Table 4), also devised during the piloting process at our institution, was included for respondents to select why the reason for incomplete vaccination was a contraindication to listing. An open-ended question was included after each scenario for respondents to provide comments.

The fourth section of the survey asked about the existence of written policies regarding incomplete vaccination at respondents' programs. An open-ended question was included for further comments.

Data collection and analysis

The survey was distributed online from July to November 2011 through SurveyMonkey.com (Palo Alto, CA). Each invited participant was provided a numerically coded link to the online survey to ensure that reminder emails were only sent to individuals at programs that had not completed the survey. Responses were de-identified and analyzed in aggregate to ensure confidentiality.

For determination of the number of programs represented, completed surveys in which the respondent indicated involvement with two organ programs were counted as responses from both programs, whereas two surveys returned from respondents at the same organ program (duplicates) were counted as one response from that program. After determining the number of programs represented, the unit of analysis, based on a biostatistical consult at our institution, was the individual survey respondent, with the assumption that the respondent represented the views of his/her program. Therefore, both surveys of the duplicate responses (12 sets of surveys in total) were excluded from data analyses, because despite being at the same program, respondents did not answer the hypothetical scenario questions similarly. Surveys from respondents who indicated involvement in more than one program were only counted once (i.e., as one response) in the data analysis.

Descriptive statistics were used to summarize the findings, and two-tailed p-values were calculated using Fisher's exact test. Comments in response to the open-ended questions were analyzed to identify themes and are used herein to further describe the quantitative findings of this study.

Human subjects oversight

The Institutional Review Board of Stanford University approved the study design and final survey instrument as exempt (Protocol #21462).

Results

Response rate

One hundred and twenty-eight surveys were completed with one program declining to participate, representing 138 of the 195 pediatric solid organ transplantation programs surveyed (response rate of 71%, which is very high for a survey). After the exclusion of duplicate responses from single programs, 114 completed surveys were included in the data analysis.

Table 1. Hypothetical scenarios in survey.

(a) Medical reasons for incomplete vaccination

Your program is evaluating a three-yr-old child for possible transplantation. The child is severely ill and will not survive without a solid organ transplant. The patient has not received several vaccinations, including MMR and varicella, due to medical concerns. As the patient had been too ill and too frequently hospitalized during early childhood, the patient's healthcare providers were reluctant to immunize the child. The parents have been otherwise fully adherent to all other aspects of their child's medical care, and they deferred to the healthcare providers regarding vaccinations.

(b) Parental refusal of vaccination

Your program is evaluating a three-yr-old child for possible transplantation. The child is severely ill and will not survive without a solid organ transplant. The patient has not received several vaccinations, including MMR and varicella, because the parents have refused immunizations. After doing their own reading and research on vaccinations, the parents have concerns about the safety and necessity of vaccines, and they think that there may even be a conspiracy by the pharmaceutical industry to cover up such concerns. All reasonable efforts have already been made to convince the parents to allow vaccination of their child before consideration of transplantation, but the parents still adamantly refuse. The parents have been otherwise fully adherent to all other aspects of their child's medical care.

MMR, measles, mumps, and rubella.

Table 2 summarizes the characteristics of respondents and their programs. Approximately half of respondents (51%) were from kidney transplantation programs, 27% were from heart programs, and 30% were from liver programs; eight respondents reported involvement in two of these organ transplantation programs. The mean number of transplants performed per year at each program varied from two to 50. Programs were located in all regions of the United States, with the largest percentage from the south (37%). Almost all programs were affiliated with a university or located within a teaching hospital (96%).

Of those who completed the survey, 57 (50%) self-identified as medical or surgical directors, whereas 42 (37%) identified themselves as transplant coordinators. Fifteen respondents (13%) declared other roles in their transplantation programs, including physician, nurse practitioner, and physician assistant.

Experiences with incomplete vaccination

Seventy-three respondents, or 64%, reported that their programs have had experience with cases involving medical reasons for incomplete vaccination (Table 3). Twenty-nine of those respondents reported that their programs have encountered more than 10 such cases since program inception.

Forty-four respondents, or 39%, reported that their programs have encountered listing decisions involving a child whose parents or caregivers refused vaccination. Four respondents reported that their programs have experienced more than four cases involving parental refusal of vaccination since program inception.

Views of different reasons for incomplete vaccination

Respondent views of incomplete vaccination due to medical reasons as compared to parental refusal were assessed through hypothetical scenarios (Table 4). In response to the scenario of a child

Table 2. Program and respondent characteristics

<i>Subjects*</i>	
Programs surveyed	195
Programs responding (% response rate)	138 (71%)
Total completed surveys analyzed	114
<i>Program characteristics</i>	
<i>Organ type transplanted**</i>	
Heart (n, %)	31 (27)
Kidney (n, %)	58 (51)
Liver (n, %)	34 (30)
Other (n, %)	11 (10)
Intestine	9
Lung	2
Pancreas	1
Mean number of transplantations per year (standard deviation)	12 (8)
Range	2–50
<i>Program location***</i>	
Northeast (CT, MA, ME, NH, NJ, NY, PA, RI, VT) (n, %)	23 (20)
Midwest (IA, IL, IN, KS, MI, MN, MO, ND, NE, OH, SD, WI) (n, %)	30 (26)
West (AK, AZ, CA, CO, HI, ID, MT, NM, NV, OR, UT, WA, WY) (n, %)	19 (17)
South (AL, AR, DC, DE, FL, GA, KY, LA, MD, MS, NC, OK, SC, TN, TX, VA, WV) (n, %)	42 (37)
<i>Affiliation with a university or located in teaching hospital</i>	
Yes (n, %)	109 (96)
No (n, %)	5 (4)
<i>Individual respondent characteristics</i>	
<i>Role in transplantation team</i>	
Medical director (n, %)	50 (44)
Surgical director (n, %)	7 (6)
Transplant coordinator (n, %)	42 (37)
Other (n, %)	15 (13)
Physician	9
Nurse practitioner	5
Physician assistant	1

*See text for explanation.

**Eight respondents reported involvement with more than one type of organ transplantation program.

***Regions divided by US Census Bureau definitions.

who was not fully vaccinated due to medical reasons, 93 respondents (82%) would list the child for transplantation. Only eight (7%) would not list, and 12 respondents were unsure (11%).

The distribution of responses to the scenario involving parental refusal of vaccination was statistically significantly different ($p < 0.001$). Only 54 respondents (47%) would list the child who was incompletely vaccinated due to parental refusal. Twenty-five respondents (22%) would not list the child for transplantation, and a larger number (34 or 30%) were unsure of their listing decision.

Respondents were then asked to clarify whether the reason for incomplete vaccination was an absolute, relative, or non-contraindication to listing. The majority of respondents (88, or 77%) did not view medical reasons for incomplete vaccination as a contraindication to listing. Nineteen respondents (17%) viewed medical reasons as a relative contraindication to listing, and only two (2%) expressed that medical reasons were an absolute contraindication to listing. For those who responded that medical reasons were a contraindication or who were unsure, the largest contributing factor selected from a list provided (shown in Table 4) was the inability to give live vaccinations after transplantation (91%).

The distribution of responses to the scenario involving parental refusal of vaccination was also statistically significantly different ($p < 0.001$). Only 38 respondents (33%) did not view parental refusal of vaccination as a contraindication to listing the child for transplantation. Fifty-one respondents (45%) viewed this reason as a relative contraindication to listing, and eleven respondents (10%) answered that parental refusal of vaccination was an absolute contraindication to listing. For those who answered that parental refusal of vaccination was a contraindication or who were unsure, the inability to give live vaccinations after transplantation was viewed as less important than concerns about adherence to post-transplantation care (53% vs. 70%, respectively, $p < 0.001$). Fifty percent expressed concern that the parents would be difficult to work with or that disagreements could not be resolved. These concerns were reported despite the explicit statement in the hypothetical scenario

that the parents were adherent to all aspects of their child’s medical care except vaccinations.

Written comments further suggest that many respondents viewed refusal of vaccination as a proxy for the parents’ overall actions and beliefs. The theme of non-adherence was again raised; as one respondent noted, “Non-adherence to this recommendation would be viewed as concerning for wider non-adherence in general.” This same respondent also commented that lack of immunizations itself was not a significant barrier to transplantation, suggesting that he/she would strongly consider parental refusal of vaccination in determining listing decisions: “While incomplete or delayed vaccinations may increase risk of a poor outcome after transplant, the delta risk is relatively small and can be managed by appropriate monitoring and/or prophylaxis.”

Table 3. Actual experiences and written policies

	n (%)
Respondents reporting that their programs have had cases involving:	n = 114
Medical reasons for incomplete vaccination	73 (64)
Parental or caregiver refusal of vaccination	44 (39)
Respondents reporting that their programs have written policies regarding:	n = 114
Incomplete vaccination	14 (12)
Parental refusal of vaccination	5 (4)

Table 4. Responses to hypothetical scenarios

	Scenario 1: Medical Reasons for Incomplete Vaccination (n,%)	Scenario 2: Parental Refusal of Vaccination (n,%)
<i>Would you list this child for transplantation?*</i>	n = 114	n = 114
Yes	93 (82)	54 (47)
No	8 (7)	25 (22)
Unsure	12 (11)	34 (30)
Prefer not to answer	1 (1)	1 (1)
<i>Is the given reason for incomplete vaccination a contraindication to listing?*</i>	n = 114	n = 114
Yes; an absolute contraindication	2 (2)	11 (10)
Yes; a relative contraindication	19 (17)	51 (45)
No; not a contraindication	88 (77)	38 (33)
Unsure	5 (4)	14 (12)
Prefer not to answer	0 (0)	0 (0)
<i>If the reason is a contraindication or you are unsure, why?</i>	n = 22	n = 74
Increased risk of graft failure and death	6 (27)	16 (22)
Inability to give live vaccinations after transplantation	20 (91)	39 (53)
Risk of non-adherence to post-transplantation care and medications	3 (14)	52 (70)
Potential risk to other immunosuppressed patients whom this child will encounter	8 (36)	19 (26)
Worry that parents will be difficult to work with or that other disagreements between the medical team and the family will not be able to be resolved	–	37 (50)

*The difference in responses to this question between the two scenarios was statistically significant ($p < 0.001$).

Additional written comments raised questions of informed consent and the parents' understanding of medical harms. One respondent wrote that the medical team "would need to converse with the family about their understanding of risk, given a mortality associated with transplantation vs. much lower risk of problems with vaccination." Another respondent cited potential difficulties with the doctor-patient relationship: "I think refusal to immunize despite the reassurance of the transplant team would indicate a lack of trust between the family and care providers." A third respondent was more forthright about how parental refusal of vaccination is viewed at his/her program: "Parents have a right to refuse immunizations, and we have a right to refuse to transplant."

Written policies regarding incomplete vaccination

Ninety respondents (79%) answered affirmatively that their programs had "any method for ensuring complete vaccination before transplantation." While the survey did not ask specifically what these methods were, several respondents wrote that these methods involved discussions with families: "There must be a shared decision-making analysis done with the family in this setting so they understand the benefits and drawbacks." One respondent noted that infectious disease consults were utilized, whereas other respondents cited their programs' requirements for vaccination records: "We require documentation of immunizations and serologic evidence of response to those vaccines."

Fourteen respondents (12%) reported that their programs had written policies regarding incomplete vaccination in the context of listing decisions of pediatric patients (Table 3). One additional respondent wrote that his/her program was in the process of developing such a policy. In contrast and despite at least 55% of respondents considering parental refusal of vaccination as a contraindication to listing in the hypothetical scenario, only five respondents (4%) reported that their programs had written policies specifically regarding parental refusal of vaccination in the context of listing decisions.

Discussion

Our study reveals that a significant proportion of pediatric solid organ transplantation programs in the United States have had experience not only with medical reasons for incomplete vaccination but also with parental refusal of vaccination. The fact that respondents indicate that their programs have already encountered parental refusal

of vaccination is not surprising given the growing prevalence of this issue in recent years (7-9). One nationwide survey of parents found that almost twelve percent had refused one or more recommended immunizations (including MMR and varicella) for their children (13). Additionally, despite the strong public health rationale for pediatric vaccination, the current legislative landscape in the United States facilitates parental refusal of vaccination. Twenty states allow parents to refuse immunizations based on philosophical grounds (14), the meaning of which varies widely by state and is defined as broadly as "free exercise of religious rights and/or moral (philosophic) rights" on school forms in Vermont (15) to simply "contrary to my belief" in California (16).

The results of this study further demonstrate that the reason for incomplete vaccination matters in listing decisions, with a vast difference in the percentage of respondents willing to list a hypothetical child who was not vaccinated for medical reasons than a child whose parents refused vaccination. National surveys have shown that, despite robust evidence that vaccinations are safe and effective (17-19), parents refuse vaccinations for numerous reasons including the belief that the risk of adverse events is too high (13) and distrust of medical professionals (20). These concerns are, in fact, the same as those raised by respondents to our survey in explaining their rationales for their listing decisions in the parental refusal scenario.

Moreover, our data reveal inconsistencies across pediatric transplantation programs in how much of a contraindication to listing (absolute, relative, or not) different reasons for incomplete vaccination (including parental refusal) are considered. The nonidentical sets of surveys returned from multiple respondents within a single program further suggest that there is intraprogram variability as well; even respondents at the same program disagreed on the hypothetical listing decisions and whether parental refusal of vaccination was a contraindication to listing. These results match other studies that have shown inconsistent use of psychosocial criteria in listing decisions. One investigation found no consensus on the weighing of psychosocial criteria, including medical noncompliance, in transplantation program listing decisions (21). Another study found little uniformity across pediatric transplantation centers in their use of neurodevelopmental delay as a psychosocial criterion (22).

Should the reason for incomplete vaccination, and specifically parental refusal of vaccination, be factored into listing decisions? One analysis of

the medical and legal literature concluded that psychosocial criteria should only be taken into account if they reliably differentiate between candidates' potential benefits from transplantation (23). In other words, the reason for vaccination should *only* be considered if it can predict, or affect, how likely a child is to benefit from transplantation. Assuming incomplete vaccination itself confers the same risks irrespective of the reason why full immunization did not occur, two incompletely vaccinated children ought to be given similar listing decisions according to the principle of justice.

However, as many survey respondents expressed, there may be legitimate grounds to consider the reason for incomplete vaccination in listing decisions: a concern that parental refusal of vaccination might indicate wider non-adherence issues and thus a lower chance of graft survival post-transplantation. Although non-adherence is an important factor in listing decisions, if a child is to be denied an opportunity to receive a transplant, the case for non-adherence must be strong. Parental refusal of vaccination must be viewed in the context of other aspects of a thorough psychosocial assessment (e.g., have the parents kept appointments, adhered with other medications, and gathered a support system). Each patient would need to be evaluated individually – making it potentially unethical to use parental refusal of vaccination as an absolute contraindication to listing in the absence of other supporting information.

In addition, more research should be conducted to determine adherence to post-transplantation regimens by parents who refuse vaccination so that transplantation teams can make data-driven decisions. As suggested by recent studies of listing decisions (24, 25), written policies or tools would encourage systematic appraisal and the reduction in subjective bias in making psychosocial assessments.

Nevertheless, a case-by-case assessment that considers the entirety of the patient's likelihood of successfully benefiting is critical. As one respondent noted, "It seems odd that parents accept all the toxic medications and extraordinary medical and surgical care associated with transplant but not the immunizations, but they do and this is a total disconnect. I have not seen poor compliance in any of these families."

Limitations to our study design include that respondents' views may represent their individual perspectives rather than the views of others at their programs (as seen in some duplicate responses), or as in the eight cases where individuals indicated involvement in two organ programs,

may not accurately reflect the views of both programs. We also acknowledge that responses to hypothetical scenarios may not exactly correlate to decision-making in the clinic. However, 39% of respondents have experienced cases of parental refusal at their programs, and they may have had those cases in mind while completing the survey. Our study also showed a wide variability in how programs consider parental refusal, a discrepancy that could also be expected to be present during decision-making in actual cases. Future research could build on this study's results by surveying a broader range of individuals at transplantation programs and by collecting information on how actual cases involving parental refusal of vaccination were decided.

The results of this study reveal that many pediatric solid organ transplantation programs have experienced parental refusal of vaccination and that there is inconsistency among and within programs on how to consider this psychosocial factor in listing decisions. We recommend further discussion, data gathering, and the development of written guidelines to help unify program responses to cases of incomplete vaccination of pediatric transplantation candidates. As one respondent astutely offered: "Perhaps the United Network for Organ Sharing (UNOS) should develop a policy regarding mandatory immunizations for pediatric transplants."

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Authors' contributions

JML drafted the initial survey instrument and subsequent revisions, performed the data collection and initial data analysis, drafted the initial manuscript and subsequent revisions, and approved the final manuscript as submitted. KK reviewed and revised the survey instrument, critically reviewed the quantitative and qualitative data analyses, critically reviewed the manuscript, and approved the final manuscript as submitted. DM conceptualized the initial study idea and design, reviewed and revised the survey instrument, critically reviewed the data analysis and manuscript, and approved the final manuscript as submitted.

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