International Journal of Pediatrics and Adolescent Medicine 9 (2022) 16-21



Contents lists available at ScienceDirect

International Journal of Pediatrics and Adolescent Medicine

journal homepage: http://www.elsevier.com/locate/ijpam



Original article

A systematic approach to transplanting non-resident, non-citizens in an established US pediatric lung transplant program



S. Alhaider ^a, J.M. Maddox ^b, J.S. Heinle ^c, I. Shebaro ^d, G.B. Mallory ^{e, *}

^a Department of Pediatrics, King Faisal Specialist Hospital and Research Centre, Riyadh, Saudi Arabia

^b Transplant Services, Texas Children's Hospital, Houston, TX, USA

^c Michael DeBakey Department of Surgery, Baylor College of Medicine and Texas Children's Hospital, Houston, TX, USA

^d International and Destination Medicine, Texas Children's Hospital, Houston, TX, USA

^e Section of Pulmonology, Department of Pediatrics, Baylor College of Medicine and Texas Children's Hospital, Houston, TX, USA

ARTICLE INFO

Article history: Received 1 December 2020 Received in revised form 12 January 2021 Accepted 14 February 2021 Available online 26 February 2021

Keywords: Lung transplantation Referral International patients Pediatrics

ABSTRACT

Introduction: The Texas Children's Hospital Lung Transplant Program undertook consideration of its first non-resident, non-citizen for lung transplantation in 2011.

Methods: Four referrals from the Royal Embassy of Saudi Arabia were received, and two patients were evaluated from 2011 to 2013.

Results: After a suitable candidate and family was identified, the program adopted a systematic approach to ensure that all the necessary elements of pre-transplant care, informed consent, and post-transplant care could be effectively delivered.

Conclusion: The use of hospital translation services and the development of a strong professional relationship with a well-trained pediatric respirologist in Saudi Arabia combined with an excellent early post-transplant clinical course provide lessons that may be of help to other transplant programs considering international patients as candidates for solid organ transplantation.

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1. Introduction

The World Health Organization has recognized that organ transplantation has become a practice across the world and that ethical and financial considerations have become important issues. On the WHO website [1], there is an acknowledgement that "there are large differences between countries in access to suitable transplantation and in the level of safety, quality, efficacy of donation and transplantation of human cells, tissues and organs." Since the 1990s, the United Network for Organ Sharing (UNOS) in the USA has had policies related to the transplantation of recipients who are not citizens of the USA and who have been given permission by the US government to enter the country for a limited period for medical care. These patients were called "non-resident aliens" and, more recently, "non-resident, non-citizens". Although

* Corresponding author. Section of Pulmonology, Texas Children's Hospital, 6701 Fannin Street, Suite 1040, Houston, TX, 77030, USA.

E-mail address: gbmallor@texaschildrens.org (G.B. Mallory).

Peer review under responsibility of King Faisal Specialist Hospital & Research Centre (General Organization), Saudi Arabia.

there is currently no strictly defined limit to the volume of transplantation of international patients within a given transplant center, UNOS policy has maintained the right to review and audit international transplants [2]. In the past, if and when the number of such transplants exceeded 5% of total organs transplanted in a given center, the Ad Hoc International Relations Committee of UNOS would "perform a formal review". UNOS data from 1988 through 2019 show that non-resident, non-citizens have received just over 1% of total solid organ transplants performed in the United States (8310 compared to a total of 817,931). Although data definitions have shifted over time, it appears that the majority of the non-citizens have been Hispanic in ethnicity. Roughly, 25 to as high as 53 transplant recipients have been designated as Asians since 2001, which includes citizens of Middle Eastern countries but may include East and South Asians as well. Over the same period, pediatric recipients (defined as <18 years of age) have accounted for 8% of all non-resident solid organ transplant recipients.

The USA remains the only nation in the world that accepts noncitizens as suitable candidates for organ transplantation with the same clinical criteria as its own citizens. In the European Union, non-citizens may receive organ transplantation only if no

https://doi.org/10.1016/j.ijpam.2021.02.001

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candidates who are citizens of the European Union accept the offered organ.

Since its inception in 2002, the Lung Transplant Program at Texas Children's Hospital has performed over 220 lung transplants in recipients from two months of age to 21 years of age. In early 2011, the program received four referrals through the Royal Embassy of Saudi Arabia for consideration of lung transplantation. Although occasional referrals of individual patients from other countries had been received in previous years in our program, it appeared to us that, for the first time, there might be viable candidates with adequate financial resources for lung transplantation to be possible. Many nations in the world do not have private or public insurance coverage for citizens who seek organ transplant care in the USA. Mexico and other central American countries are examples. The Arab nations of the Middle East are a notable exception. Organ transplantation itself and the care after transplantation involve such high expenses that most US hospitals have chosen to limit or avoid charity care for non-resident, non-citizens without the financial means to pay for care. With rare exceptions, US insurers, private and public, do not accept applications from non-citizen, non-residents. In this paper, we report the process by which we assessed these referrals and undertook to evaluate in a fair and thorough manner if and when a given individual patient from another nation was an appropriate and suitable candidate. The process resulted in a successful transplant and the development of a substantive clinical relationship with a pediatric respirologist who is both able and willing to provide follow-up care in partnership with our transplant team. We now have accumulated further information about long-term outcomes and the evolution of the consultative relationship.

2. Methods

UNOS approved the Texas Children's Hospital Program in July 2002, and the first lung transplant recipient was transplanted in October 2002. The Department of International and Destination Medicine at Texas Children's Hospital receives patient referrals from international patients and forwards the contents of those referrals to relevant clinicians. In 2011, our program received referral information on four patients from Saudi Arabia with the request for lung transplant evaluation. The information accompanying initial referral of these patients was exceedingly concise and generally excluded any and all psychosocial information. Despite specific requests for more information, clinicians often must decide on accepting referrals without complete information. One patient was referred in February and April, respectively, and two were referred in June of 2011. Three of the patients had a diagnosis of idiopathic pulmonary arterial hypertension (PAH) and ranged in age from four to 17 years. Two died before evaluation could be scheduled while still in Saudi Arabia. An infant with suspected surfactant dysfunction syndrome and associated interstitial lung disease was referred at eight months of age. The referral information unfortunately did not clarify her level of respiratory insufficiency, nor was any information about her parents' education or expectations provided. The time between her referral and evaluation was 5.5 months and was delayed as we sought more data as to her clinical status and clinical course. Her case will be discussed in detail below.

A boy of eight years of age with severe idiopathic PAH was referred in June 2011 and he was evaluated in August of 2011. Although an email contact between the referring cardiologist and one of the transplant pulmonologists was made, key data remained missing through the time of the patient's arrival in the USA. Despite the missing data, the patient and his father arrived in the USA by commercial air flight. The patient was seen in the clinic the day after arrival. His father spoke no English and a distant cousin from Florida assisted the hospital's Arabic interpreter in initial communication. The patient's exercise capacity was severely compromised by dyspnea at rest and symptoms of chronic heart failure. He was taking oral sildenafil and bosentan in appropriate doses but no inhaled or parenteral prostacyclin. As the patient's PAH was severe and life-threatening based on echocardiography, we recommended admission to the intensive care unit (ICU) to initiate epoprostenol as a continuous intravenous infusion to optimize medical therapy prior to a decision regarding listing. The father seemed to understand and accept our recommendations. The boy was admitted to the ICU but with an uptitration of epoprostenol over three days, and he developed severe fluid overload with bilateral pleural effusions and repeated emesis supervened. The patient's father insisted that the epoprostenol be discontinued and despite a careful attempt at communicating the fact that this action would disgualify him for transplant, the father did not relent. Unfortunately, the patient did not recover and died in the ICU less than two weeks later. We learned during the hospitalization that the father had unilaterally discontinued inhaled iloprost in Saudi Arabia several months earlier

Our second referral had been hospitalized due to respiratory failure from early infancy until her transfer to our institution. She was 15 months of age on arrival by medical transport, accompanied by her married parents. She had received no immunizations and was grossly under-nourished. The diagnosis of a familial surfactant dysfunction disorder with interstitial lung disease had been made in Saudi Arabia and was confirmed by genetic testing. She had been receiving continuous nasogastric feedings. Her parents accepted our plan for testing and all therapies as a means of establishing her suitability for lung transplantation, which they communicated via the hospital's Arabic interpreter. Within one month, the mother returned to Saudi Arabia to attend to the couple's other children.

Upper gastrointestinal barium radiography demonstrated significant gastroesophageal reflux. She underwent an elective Nissen fundoplication and gastrostomy placement 3.5 weeks after arrival without operative complication. However, she could not be weaned from mechanical ventilatory support after surgery and she underwent elective tracheostomy two weeks later. Aggressive nutritional therapy resulted in a steady improvement in growth. Immunizations were administered.

The Texas Children's Hospital Lung Transplant team determined that this young girl appeared to be a medically suitable candidate for lung transplantation. We had lengthy discussions about candidacy for this procedure in our hospital in this international patient. After considerable deliberation, we felt that the major indications and contraindications for an international patient would need to be consistent with our usual expectations and requirements for US citizens, which we reviewed and applied to her case in a systematic fashion:

- 1) **Primary indication is end-stage lung disease which will not improve and has not responded to maximal medical therapy.** Our patient showed no signs of being able to be weaned from mechanical ventilatory support two months after tracheostomy and nearly three months after fundoplication. Other children with similar genetic disorders had undergone lung transplantation for the same indication in our institution.
- 2) No medical or surgical contraindications. The degree of pulmonary hypertension was mild and was easily managed with oxygen supplementation, mechanical ventilation, enteral sildenafil, and low dose diuretic therapy. There was no other organ dysfunction or evidence of chronic infection or immunodeficiency. She had no previous chest surgery.

Table 1		
Features	of bronchiolitis	obliterans.

Feature	Bronchiolitis obliterans
Onset	After first year
Clinical feature	Insidious cough, wheeze, and shortness of breath
Chest X-ray	Hyperinflation
Pulmonary function test	Fixed airflow limitation and reduced diffusion capacity
Cat scan	Air trapping, mosaic pattern, reticular infiltrate, bronchiectasis with bronchial wall thickening
Lavage	Neutrophil predominant
Biopsy	Inflammation and scarring sparing the alveoli and alveolar duct

The treatment ranges from supportive therapies with oxygen supplementation, airway hydration, antibiotics, and pulse IV therapy with steroids, especially in the younger age group with a short duration of initial presentation and the presence of lung infiltrate (49).

- 3) Adequate familial resources. We expect informed and engaged parents who are likely to have the mental and emotional ability to provide follow-up care and with whom a trust relationship can be developed. This requirement was of some concern because our patient's parents were never inclined to spend more than a few hours in the hospital at her bedside. Members of our team attempted with the hospital's Arabic interpreters to assess their likelihood of being able to take over entirely after transplantation and recovery. We were also concerned about language and cultural barriers to understanding. The parents, especially the father who stayed with the patient in the USA, were unfailing in their clear indication of trust and their gratitude for the care provided to their daughter. Both parents were teachers in their home community.
- 4) Communication. Communication between and among parents, the referring physician, involved specialist physicians at home, and the transplant center nurses and physicians is an essential ingredient in successful post-lung-transplant care for all patients. Complications occur frequently after pediatric lung transplantation with unanticipated timing and frequency. Information related to changes in SaO2 (pulse oximetry), symptoms of all kinds, body temperature, and oral intake must be communicated to the transplant team in a timely manner. This communication requirement was a major concern for the transplant team. There was both language and cultural barriers between our team and the family. Furthermore, the sparseness of the medical record before and on arrival of the patient was of great concern if this was likely to be the norm after transplantation.
- 5) Adequate resources to pay for the transplant hospitalization and follow-up costs. The Kingdom of Saudi Arabia has established an excellent track record of fiscal responsibility over many years with other complex patients referred to our institution. The Royal Embassy of Saudi Arabia provided a Letter of Guarantee for payment of the patient's care and an agreement to cover follow-up care recommended by the transplant center.

To address the problems of communication and after-care, and before a decision was made on listing this second referral for transplant in our program, the senior transplant pulmonologist (GBM) engaged a pediatric respirologist in the patient's home country (SA). He was identified via contributions on the international list-serve known as Ped-Lung [3]. Ped-Lung has become an active forum for case discussion, problem solving, and policy issues and has a broad audience and participation from interested clinicians around the world. GBM emailed SA and asked of his potential interest in being involved in the post-transplant care of our transplant candidate and about the laboratory and clinical capabilities of his institution—the King Faisil Specialist Hospital and Research Centre. SA indicated that therapeutic drug levels of tacrolimus and other drugs, full laboratory facilities including viral PCR testing, flexible bronchoscopy services, and lung function testing were available in his home institution. Furthermore, SA provided his curriculum vitae. His fellowship director confirmed his high regard for SA as a clinician and ethical professional. Lastly, SA proposed a mini-fellowship at Texas Children's Hospital in pediatric lung transplantation. The purpose of this training was not to provide complete training in transplant care but to familiarize SA with common problems, our approach to pre- and post-transplant care, and to establish a personal line of communication.

Before listing, the patient's primary transplant pulmonologist obtained agreement from the family and the Royal Embassy of Saudi Arabia that the patient would stay in the USA for the first year after transplant, which is the period during which she is at greatest risk of acute allograft rejection and serious primary viral infections. She was listed 3.5 months after arrival in the USA while her mother was still in Saudi Arabia. Donor organs became available, and she underwent bilateral lung transplant 51 days after listing. She was discharged from the hospital on room air with the tracheostomy tube decannulated 15 days after surgery. Her mother and brother arrived from Saudi Arabia, and she was discharged to a local apartment with her family. She was in excellent health at her threemonth post-transplant hospitalization at which time, two additional older siblings had travelled from Saudi Arabia to reunite the entire nuclear family. It was at this point that SA arrived in Houston and was able to meet the patient and her family and familiarize himself with her post-transplant care. Infant lung function testing and chest radiography showed excellent allograft function. The patient recently returned for her seven-year post-transplant evaluation, and her general health and allograft function appear to be excellent. The patient is now 10 years of age and has continued in the care of SA. She was last evaluated in the USA in July of 2019, at which time she was healthy with normal lung function and her chest CT scan showed no evidence of bronchiolitis obliterans, which is a manifestation of chronic lung allograft rejection. She remains on daily tacrolimus, mycophenolate, and low dose prednisolone. Her parents have maintained her gastrostomy tube as a preferred route for medication administration. She attends regular school, and her body mass index is within the lower limits of normal. Communication between the transplant center and SA has continued over these years.

3. Discussion

The senior author (GBM) had a significant experience with international patients in the 1990s while at the St. Louis Children's Hospital as a transplant pulmonologist in the most active pediatric lung transplant program in the world during that era. Pediatric patients from Canada, Israel, Saudi Arabia, Australia, Japan, and Mexico were transplanted in St. Louis over a nine-year period. Some families (from Israel, Japan, and Mexico) were required to raise all or a substantial portion of potential hospital, physician, and

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medical costs of pre- and post-transplant care due to the lack of any or complete insurance coverage from the home countries before their initial transplant evaluation. The magnitude of costs involved in pre-transplant, transplant hospitalization, and post-transplant care can easily exceed \$1 million in complicated patients and, in the absence of a bottomless source of charity care, would disgualify the vast majority of medically suitable lung transplant candidates from countries without adequate insurance or governmental coverage in most US hospitals. In the 1990s, among our patients, only Canada, Australia, and Saudi Arabia covered the preponderance of costs of those patients. Efficient and regular communication and professional partnership was established with respect to home physicians caring for the transplant recipients, particularly those from Japan and Israel, which benefited the transition of those patients to home care. Notably, the communication with respect to post-transplant care was extremely limited in the child from Saudi Arabia. Only in the latter case did the physicians providing followup care at home have limited facility in the English language. We used this first-hand experience of one member of our transplant

team to contribute to the programmatic criteria noted above. In an iteration of policies from 2010, UNOS policy 6.0 addressed transplantation for non-resident aliens and had several requirements with respect to such candidates, which appears to be intact in 2020 (Table 1). The policy prescribed non-discrimination; that is, non-resident, non-citizens should be evaluated and considered by the same criteria as US citizens. We embraced this concept in our program. In addition, UNOS recommended that only centers with a "historical pattern of international referral" should

take on such patients, perhaps related to the ability to overcome language and cultural barriers. Texas Children's Hospital has a dedicated International and Destination Medicine team with longstanding experience in facilitating international referrals and providing international patient coordination for patients throughout the world. Furthermore, UNOS policy added that the transplant center should have a reputation for management of primary and end-stage organ disease and transplantation, which is a requirement that our center meets as a leading pediatric academic institution in the USA. Lastly, UNOS recommended that involved transplant centers should engage in transplant training for under-served nations. The mini-fellowship in lung transplantation given to SA certainly fulfilled part of this recommendation. In addition, the Baylor College of Medicine through the Pediatric Pulmonology Section of the Department of Pediatrics has trained two pediatric pulmonologists from the Arabian Peninsula in the last two decades.

In September 2012, UNOS issued a new policy governing non-US citizen candidates for transplant. This new policy eliminated most of the previous elements. Non-discrimination and guidelines for referral forbidding inter-institutional contracts remain. As of 2020, the Ad Hoc International Relations Committee is given the responsibility to monitor the non-resident, non-citizen transplant activity in the USA and provide an annual report related to listings and transplantations of these individuals by transplant center. There are no strict rules as to an acceptable volume in absolute or relative number that is considered acceptable or ethical.

The published medical literature on international



Fig. 1. Flow diagram of communication involved in referral of patient from Saudi Arabia.

Thin arrows indicate the initial flow of communication by which the patient was introduced to the transplant clinician in the USA. The thicker black arrows indicate the lines of communication that subsequently developed among three key clinicians to assure the possibility of efficient post-transplant care.

transplantation is surprisingly sparse. Four articles, published in Transplantation Proceedings from 2010 through 2012, have focused on issues encountered by Taiwanese patients with chronic liver disease seeking overseas liver transplantation, mostly in Mainland China [4–7]. Problems related to organ transplantation in Singapore have also been addressed [8]. Controversies over what has come to be called transplant tourism have engendered a great deal of commentary but, not surprisingly, little in the way of objective reporting, other than reporting common complications and selected outcomes [9-11]. The Declaration of Istanbul on Organ Trafficking and Transplant Tourism in 2008 established a clear set of guidelines which may or may not have influenced the incidence of transplant tourism but did not address the legitimate practice of "travel for transplantation" [12]. More recently, the US experience with transplantation of non-resident, non-citizens has been analyzed noting no major change in volume or practice [13].

Recent publications indicate that although heart and lung transplantation is now performed in modest numbers in Saudi Arabia, the overwhelming preponderance of recipients are of adult age [14,15]. It is conceivable that referral of selected infants and children from the Arabian Peninsula to the United States will continue for the near future.

We believe that our experience may help other referring and transplant centers confront and solve the sometimes difficult issue of offering care to individuals from other countries. We learned from our experience with our first referral who proved not to be a suitable candidate for transplantation for both medical and psychosocial reasons. We learned that the priorities and styles differ substantially between clinicians in Saudi Arabia and the US. It is less than ideal to consider the candidacy of patients with limited referral information. We believe that a patient and understanding approach and use of our veteran Arab interpreters affiliated with the Department of International and Destination Medicine in our institution has been essential. We have distilled the principles and lessons from this experience below.

- Transplant indications and contraindications need to be applied uniformly to all potential transplant candidates. For this reason, detailed information from the past medical history is mandatory (Appendix A).
- Transplant evaluation and pre-transplant care should be the same for non-resident aliens as for US citizens. Approved candidates should be listed and wait in the same way that any other listed candidates would.
- Psychosocial information should ideally be obtained in detail from the families of international patients because of the inevitability of barriers that may interfere with communication, building of trust, and care of a sick child. We recommend detailed inquiries while avoiding intrusiveness and showing cultural sensitivity as much as possible (Appendix B).
- Experience with international referrals and with patients and families from the nation of origin of any proposed international patient can be extremely helpful. In the absence of facility in the English language on the part of the patient's family, interpreter availability 24 h per day is mandatory. We believe that an extended duration of stay in the USA can provide an opportunity for non-English speaking children and families to enroll in English language courses, which are currently widely available in any urban area in the US.
- Cultural differences between patients and families and the extant culture in the USA may complicate the kind of trust relationship that we believe is an essential aspect to post-transplant care. We presented in some detail the unfortunate case history of one referral who came to our institution to

illustrate the kind of problems that such cultural differences can sometimes raise.

• Communication and developing a relationship before transplantation with an English-speaking, appropriately trained subspecialist in the home country is, we believe, also mandatory. Fortunately, a new generation of English-speaking, welltrained pediatric subspecialists has established itself in most of the nations in the Arab Gulf. Our establishment of a personal and professional relationship with SA will be a major factor in enhancing the chances of our patients having a favorable medium- and long-term outcome although the same process should not be expected of all referring physicians. We include a diagram outlining the complexity of communication that arose in these and subsequent patients (Fig. 1).

In conclusion, we have reported our experience with the first international referrals of pediatric candidates for lung transplantation to our active pediatric lung transplant program and how we developed criteria and implemented them with regard to a progressively ill young child from Saudi Arabia. At Texas Children's Hospital, we have subsequently accepted additional referrals of non-resident, non-citizens, some of whom have moved forward to successful lung transplantation. We have found this process valuable as we sought to extend appropriate and ethical care to a nonresident transplant candidate within the usual boundaries and practice of lung transplantation in our center while, at the same time, respecting the defined guidelines established by UNOS.

Author statement

The roles of individual authors has not changed. The revision hereby submitted was performed by the senior author alone with the tacit approval of the other authors.

Dr. Alhaider was involved in conceptualization of the project and in editing the original and final drafts of the paper.

Mrs. Maddox was involved in reviewing the original manuscript and in validating clinical information.

Dr. Heinle was involved in the conceptualization of the project and in editing drafts of the paper.

Mrs. Shebaro was involved in conceptualization of the project, administrative oversight, and in editing later versions of the manuscript.

Dr. Mallory was involved in the conceptualization of the process, coordinating co-authors, wrote the original draft of the manuscript and in editing and reviewing other authors' edits into the final version of the manuscript.

All co-authors approved of the final version of the manuscript and its submission to the International Journal of Pediatric and Adolescent Medicine.

Ethical statement

There are no unresolved ethical issues within the manuscript.

Financial

The authors have no financial disclosures or conflicts of interest relevant to the content of this manuscript. There is no institutional agreement between King Faisil Specialist Hospital and Research Centre and Texas Children's Hospital with reference to directed transplant candidate referrals.

Appendix A

Essential Medical Information before Transplant Evaluation

Referring Physician's information: specialty, training, language skills, email address, professional affiliation.

Designated specialist physicians in home community and country in the event of successful lung transplantation for ongoing care – likely a pediatric pulmonologist/respirologist and possibly a transplant physician to help in management of immunosuppression and antimicrobial interventions.

Capabilities at the tertiary care center of choice in home nation:

- Lung function testing
- Bronchoscopic services
- Histopathology
- Therapeutic drug monitoring: tacrolimus+/-mycophenolate, voriconazole
- Microbiology with PCR capabilities
- Radiography including high quality CT scanning

Diagnosis and natural history of primary disease leading to referral.

- Age and means of diagnosis
- Serial testing: echocardiography, cardiac catheterization, BNP for pulmonary hypertension; blood gases, oxygenation trajectory over time, episodes of respiratory failure, ventilatory settings if on mechanical ventilation, size and model of tracheostomy (if relevant) respiratory microbiology
- Nutritional status with growth curve to include both height and weight
- Complications such as renal insufficiency, gastroesophageal reflux, developmental deficits, epilepsy
- List, duration and reasons for any hospitalizations in the year preceding referral
- List of all medications used in the previous year with reasons for initiation and discontinuation of all relevant medications
- Genetic testing results, if relevant
- Copies of consultations performed in any other referral center, even if performed solely by review of records and testing

Appendix **B**

Psychosocial Information on International Solid Organ Transplant Referrals

Family Structure:

- Parents age, health status, literacy, marital status, language skills, and openness to learning English before, during, or after referral
- Siblings age, health status, likelihood of travel with patient and parent, and language skills
- Location of home, size of city, medical facilities, primary care physician (name, email address, specialty), and distance to tertiary care medical center and/or nearest appropriate pediatric specialist
- Home surroundings unhealthy environment (tobacco smoke, indoor cooking, hygiene), animals in the home, indoor plumbing, and bathroom facilities

Any history of mental health problems in patient or among family members and relevant therapy via pharmacotherapy and/or counseling.

Family faith.

- Does the family belong to a particular religion?
- How strongly does religious practice play a role in the family?
- Would the family want to make personal contact with a member of their religion in Houston?

Willingness and ability for parent and patient to spend extended time (6–18 months) in Houston depending on status of evaluation, duration of waiting for organs, and minimum stay of 3–6 months after transplant.

Willingness and ability to return to Houston for periodic reevaluations for months and years after transplantation.

Visual abstract

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijpam.2021.02.001.

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