Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health technology assessment evaluating the treatment and transport options for Priority 1 transfer patients

31 October 2017

Safer Better Care

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent authority established to drive high-quality and safe care for people using our health and social care services in Ireland. HIQA's role is to develop standards, inspect and review health and social care services and support informed decisions on how services are delivered.

HIQA aims to safeguard people and improve the safety and quality of health and social care services across its full range of functions.

HIQA's mandate to date extends across a specified range of public, private and voluntary sector services. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, HIQA has statutory responsibility for:

- **Setting Standards for Health and Social Services** – Developing person-centred standards, based on evidence and best international practice, for health and social care services in Ireland.
- **Regulation** – Registering and inspecting designated centres
- **Monitoring Children's Services** – Monitoring and inspecting children's social services
- **Monitoring Healthcare Safety and Quality** – Monitoring the safety and quality of health services and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health Technology Assessment** – Providing advice that enables the best outcome for people who use our health service and the best use of resources by evaluating the clinical effectiveness and cost-effectiveness of drugs, equipment, diagnostic techniques and health promotion and protection activities.
- **Health Information** – Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care services.

Foreword

Priority 1 transfer patients mostly comprise children who require emergency transfer to specialist centres in the UK to avail of transplantation of a heart or liver. Patients must present at the transplant centre in the UK within four hours of notification of a donor heart becoming available and within six hours of a liver becoming available. There is no dedicated air ambulance service in Ireland for Priority 1 transfers and all services are provided on an "as available" basis; to date transfers have primarily been provided by the Air Corps and Irish Coast Guard. The Department of Health requested a rapid health technology assessment to evaluate the treatment and transport options for Priority 1 transfer patients. The urgency of this request is due to the fact that after 5 November 2017, neither the Irish Air Corps nor the Irish Coast Guard will be available to carry out night-time Priority 1 transfers.

Transplantation is the final treatment option for children with end-stage cardiac or liver failure. Unfortunately, organs from child donors are in very short supply and the ever-increasing demand further exacerbates this problem. In the absence of national paediatric heart and liver transplant services, patients are listed for transplant with the NHS Blood and Transplant in the UK. Paediatric transplant patients are a highly vulnerable group and the transplant journey places a very large emotional, logistical and financial burden on patients and families. The transfer of these patients for transplantation is a rare event. As of 31 October 2017, three Irish children were actively waiting for a transplant in the UK. While short-term survival outcomes are favourable for these patients following transplant, many patients both in Ireland and internationally die while waiting on the transplant list.

Work on the assessment was undertaken by an Evaluation Team from the HTA Directorate in HIQA. A multidisciplinary Expert Advisory Group was convened to advise HIQA during the course of the assessment.

HIQA would like to thank its Evaluation Team, the members of the Expert Advisory Group and all who contributed to the preparation of this report.

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Acknowledgements

HIQA would like to thank all of the individuals and organisations who provided their time, advice and information in support of this health technology assessment.

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Our Lady's Children's Hospital, Crumlin

Children's Hospital Group

Irish Aviation Authority

Woodgate Aviation, Belfast

NHS Blood and Transplant, UK

UK Transplant Register

Organ Donation and Transplant Ireland (ODTI)

Department of Defence

Members of the Evaluation Team:

Members of the HIQA's Evaluation Team were Dr Patricia Harrington (Project Lead), Des Lucey, Dr Kirsty O'Brien, Dr Eamon O'Murchu, Dr Conor Teljeur, and Dr Máirín Ryan.

Conflicts of Interest

None reported.

List of abbreviations used in this report

APOLT	Auxiliary partial orthotopic liver transplantation
BiVAD	Biventricular assist device
CAMTS	Commission on Accreditation of Medical Transport Systems
CCAVB	Congenital complete atrioventricular block
CHD	Congenital heart disease
CTAG	The Cardiothoracic Advisory Group
DBD	Donation after brain death
DCD	Donation after circulatory death
EAS	Emergency Aeromedical Support
EASA	European Aviation Safety Agency
ECMO	Extracorporeal membrane oxygenation
EUnetHTA	European Network for Health Technology Assessment
GOSH	Great Ormond Street Hospital
HCM	Hypertrophic cardiomyopathy
HEMS	Helicopter Emergency Medical Services
HIQA	Health Information and Quality Authority
HSCB	Health and Social Care Board in Northern Ireland
HSE	Health Service Executive
HTA	Health technology assessment
IMSRR	Irish Marine Search and Rescue Region
INR	International normalised ratio
IRCG	Irish Coast Guard
ISHLT	International Society for Heart and Lung Transplantation
LVAD	Left ventricular assist device

MELD	Model for End-stage Liver Disease
NACG	National Aeromedical Coordination Group
NAS	National Ambulance Service
NEOC	National Emergency Operations Centre
NHS	National Health Service
NHSBT	NHS Blood and Transplant
NORS	National Organ Retrieval Service
NWTS	North West and North Wales Paediatric Transfer Service
OLCHC	Our Lady's Children's Hospital, Crumlin
PELD	Paediatric End-Stage Liver Disease (PELD) score.
PICU	Paediatric Intensive Care Unit
RAF	Royal Air Force
RCM	Restrictive cardiomyopathy
SAR	Search and Rescue
SLA	Service Level Agreement
STEMI	ST-Elevation Myocardial Infarction
TAS	Treatment Abroad Scheme
TCAA	The Children's Air Ambulance
VADs	Ventricular Assist Devices
YAA	Yorkshire Air Ambulance

Advice to the Minister for Health and the Health Service Executive

The purpose of the health technology assessment is to provide advice to the Minister of Health and the Health Service Executive (HSE) on the consequences of alternative options for the treatment and transport of Priority 1 transfer patients. Priority 1 transfers are transfers by air from Ireland to another country within eight hours of a patient requiring emergent medical or surgical treatment, without which the patient's life or health is significantly endangered.

- Historically Priority 1 transfers have been primarily provided by the Irish Air Corps and the Irish Coast Guard (IRCG) coordinated by the National Emergency Operations Centre of the National Ambulance Service. Neither are dedicated air ambulance services, but have been provided on an "as available" basis. As these transfers have leveraged off existing state resources, their full economic cost has not accrued to the HSE.
- Due to capacity constraints with the Air Corps and regulatory requirements on the Irish Coast Guard, neither service will be available to provide Priority 1 transfers between the hours of 7pm and 7.30am from 6 November 2017.
- In the absence of national paediatric heart and liver transplant services, Priority 1 transfer patients mostly comprise children who require emergency transfer to specialist centres in the UK to avail of transplantation of a suitable donor heart or liver.
- Patients must present at the transplant centre in the UK within four hours of notification of a donor heart becoming available and within six hours of notification of a liver becoming available. Heart transplant patients are of particular concern due to the very short window of opportunity to avail of a donated heart.
- To date, there have been between one and nine (average five) paediatric transplant Priority 1 transfers each year since 2012. Three quarters of Priority 1 transfers occur between 7pm and 7am.
- The most recently reported five-year survival after first paediatric heart transplant was 84% across both UK transplant centres. The median survival ranges from 13 to 21 years depending on age at transplant.
- The most recently reported five-year survival ranges from 73% to 92% for paediatric liver transplantation. Survival following paediatric liver transplantation is highly variable and depends on the clinical indication for which the transplant

was indicated. The absence of disease recurrence is often noted in paediatric cases.

- International models for Priority 1 transfers include dedicated air ambulance services, which are usually provided by private providers or charity-funded air ambulances. Military and coast guard services are only used for contingency cover when other options have been exhausted.
- An alternative to Priority 1 transfer is the potential to establish Irish paediatric heart and liver transplant services. Key issues for consideration would be a potential reduction in access to donor organs and the ability to maintain competency to ensure a safe and effective service in the context of low volume activity.
- Continuing to avail of UK transplant services will require either alternative options for night-time Priority 1 transfers or the relocation of patients to the UK. Not all patients may be suitable for relocation for either clinical or family reasons. Therefore, relocation does not negate the requirement for a Priority 1 transfer service.
- Current arrangements for transfer of transplant patients to the UK place a substantial emotional, logistical and financial burden on patients and families. The current process for reimbursement of expenses is likely to disadvantage families with limited financial resources.
- A wide range of alternative options, categorised as immediate, short term (within six months) or long term depending on time taken to implementation, were considered.
- The most reliable immediate transfer options are costly. The optimal immediate option is to pay a private provider to deliver a dedicated night-time service. Alternatively the IRCG may be requested to provide a dedicated aircrew at night to operate the Dublin-based helicopter, when it is available.
- Three short-term alternatives were considered worthy of further exploration:
  - A limited renegotiation of the existing contract with CHC Ireland could be explored to allow modification of the IRCG shift periods at one or more bases from 24 hour to 12 hour rosters in order to optimise the availability of the contracted assets to fly patients to the UK at night. The feasibility and cost of this option are uncertain.
  - Philanthropic options, such as a dedicated air ambulance, leased by a registered charity delivering HEMS including Priority 1 transfers at a lower cost than the HSE could negotiate with a private provider.

  - The scope for the IRCG flying patients to the UK within the relevant regulatory framework, and whether it may be possible to carry out this function within a 24 hour shift system having considered any potential safety issues.

- Long-term alternatives provided by the Irish Coast Guard or Air Corps are likely to be the most appropriate. The next contract to provide coast guard services, potentially in 2022, could incorporate provision of an additional aircraft and aircrew with a primary remit to provide air ambulance services. The preferred Air Corps option, albeit at increased cost, may be a GASU-type model, with aircraft provided by the HSE and dedicated crew provided by the Air Corps. Alternatively, the Air Corps could provide an air ambulance service on an "as available" basis.
- The long-term Air Corps options are contingent on availability of sufficient air crew and technical staff. If capacity can be ensured, the long-term Air Corps options are likely attractive in terms of reliability and cost due to the ability to leverage off current state resources.
- Long-term design of an integrated aeromedical service for Ireland could provide resilience by leveraging access to multiple aircraft and aircrews from one or more providers. Such a service, which would encompass pre-hospital and inter-hospital transfers in Ireland, Priority 1 transfers abroad and patient repatriation, would have the potential advantage of providing a more coherent and efficient solution to the national aeromedical requirements.
- While we have not explicitly examined cost-effectiveness, all options identified come with a high budget impact for the State.
- Consideration should be given to resourcing a paediatric transplant liaison officer who would provide comprehensive support to all patients accessing transplant services in the UK and to review the arrangements for the reimbursement of travel and accommodation expenses for these families.
- Selection of options for transport and treatment of Priority 1 transfer patients should be guided by consideration of affordability, the opportunity cost for and impact on other state services and, crucially, the requirement to maximise the delivery of safe, effective patient-centred care.

Arising from the findings above, the HIQA's advice to the Minister for Health and the Health Service Executive is as follows:

If the HSE wishes to continue to provide a night-time Priority 1 transfer service, then the available options can be categorised as immediate, short term (within six months) or long term depending on the time taken to implementation.

The optimal immediate option from 6 November 2017 is to engage a private provider to deliver a dedicated night-time service. Alternatively, the Irish Coast Guard could be requested to recruit a dedicated aircrew to operate the Dublin-based helicopter at night, if available. These options are of a similar high cost to provide, on average, not more than four night-time transfers per annum and are likely not financially sustainable in the longer term.

Options to be explored for implementation in the short term include:

- Limited renegotiation of the existing contract with CHC Ireland could be explored to allow modification of the IRCG shift periods at one or more bases from 24 hour to 12 hour rosters in order to optimise the availability of the contracted assets to fly patients to the UK at night. The feasibility and cost of this option are uncertain.
- Philanthropic options, such as a dedicated air ambulance leased by a registered charity delivering HEMS including Priority 1 transfers at a lower cost than the HSE could negotiate with a private provider.
- The scope for the IRCG flying patients to the UK within the relevant regulatory framework, and whether it may be possible to carry out this function within a 24 hour shift system having considered any potential safety issues.

The preferred long-term option is likely to be based around either the Irish Coast Guard or the Air Corps. The Irish Coast Guard could incorporate provision of an additional aircraft and aircrew with a primary remit to provide air ambulance services to be included in the next contract, potentially in 2022 The Air Corps could be engaged either through the provision of an air ambulance service on an "as available" basis or through a GASU-type model with Air Corps providing a dedicated air crew to operate aircraft provided by the HSE. The Air Corps options leverage existing state resources and are contingent on restoration of sufficient staff capacity.

Long-term design of an integrated aeromedical service for Ireland could provide resilience by leveraging access to multiple aircraft and aircrews from one or more providers and would have the advantage of providing a more coherent and efficient solution to the national aeromedical requirements.

Selection of options for transport and treatment of Priority 1 transfer patients should be guided by consideration of affordability, the impact on other state services and, crucially, the requirement to maximise the delivery of safe, effective patient-centred care.

Executive Summary

Introduction

In September 2017, the Health Information and Quality Authority (HIQA) agreed to undertake a rapid health technology assessment (HTA) following receipt of a request from the Office of the Chief Medical Officer at the Department of Health. The purpose of the HTA is to provide advice to the Minister of Health and the Health Service Executive (HSE) on the consequences of alternative options for the treatment and transport of Priority 1 transfer patients to the UK. Priority 1 transfer is defined as:

> The transfer by air from Ireland to another country within 8 hours (from time of notification to NEOC[1] to time of arrival at receiving facility) of a patient requiring emergent medical or surgical treatment, without which the patient's life or health is significantly endangered.

The urgency of this request is due to challenges with the provision of air ambulance for these patients. In the absence of national paediatric heart and liver transplant services, Priority 1 transfer patients mostly comprise children who require emergency transfer to specialist centres in the UK to avail of transplantation of a heart or liver. Patients must present at the transplant centre in the UK within four hours of a donor heart becoming available and within six hours of a liver becoming available.

Priority 1 transfers to date have primarily been provided by the Irish Air Corps and Irish Coast Guard on an "as available" basis. There were nine such transfers in 2016. As these transfers have leveraged off existing state resources, their full economic cost has not accrued to the HSE. Due to staff capacity constraints, the Air Corps stepped down its 24 hour, seven days a week roster to a more limited day time, five days a week roster in June 2016. Following this date, the majority of transfers were undertaken by the Irish Coast Guard. Subsequent to advice provided as part of an audit by the Irish Aviation Authority, the Irish Coast Guard advised that from 5 September 2017, it would no longer be available for transport of Priority 1 transfer patients between the hours of 7.00pm and 7.30am. The Air Corps agreed to provide temporary night time cover for Priority 1 transfers from 5 September 2017 until 6 November 2017 in order to give the Department of Health and the HSE time to identify a solution.

[1] National Emergency Operations Centre (NEOC), which is part of the National Ambulance Service.

Terms of Reference

The purpose of this HTA was to evaluate the options for the treatment and transport of patients who fulfil the criteria for Priority 1 transfer.

This HTA focused on options for the transfer of these patients fulfilling the criteria for Priority 1 transfer, but also explored, at a high level, commissioning paediatric heart and liver national transplantation centres in Ireland as a potential long-term alternative.

The terms of reference for this HTA were to:

- Provide a high-level description of the burden of disease and outcomes associated with paediatric heart and liver transplantation.
- Describe the current approach to the transport of Priority 1 transfer patients from Ireland to the UK.
- Provide a brief overview of services used in the UK for the urgent transfer of patients to specialist transplantation centres.
- Provide a brief overview of the service specifications for paediatric heart and liver transplantation centres.
- Set out the alternative approaches for providing efficient and sustainable treatment or transport of these patients.
- Provide a high-level assessment of the clinical, economic and organisational consequences of the alternative approaches for the treatment or transport of these patients.
- Consider any major ethical or societal implications of adopting alternative approaches for the treatment or transport of these patients.
- Based on this assessment, advise on the potential impact of alternative approaches to the treatment and transport of these patients.

Burden of disease and outcomes

Transplantation is the final treatment option for children in end-stage cardiac or liver failure. Unfortunately, organs from child donors are in very short supply and the ever-increasing demand further exacerbates this problem.

Paediatric heart transplantation is a rare activity. There were 38 paediatric heart transplantations performed at two centres in the UK in 2016. Since 2014, seven Irish children have received a heart transplant in the UK, one of which was transported as a Priority 1 transfer in 2017. The overall number of patients actively waiting for a paediatic heart transplant in the UK more than doubled between 2013 and 2016 (16

to 37). Recent data (to March 2013) indicate that the median waiting time from day of registration on the transplant list was 81 days for those ever classified as urgent, while the median waiting time was 357 days for those never classified as urgent. The most recently reported five-year survival after first paediatric heart transplantation was 84.1% (95% confidence interval: 76.7–89.3). Overall outcomes for survival and major complications are comparable for Irish and UK paediatric heart transplant recipients. Outcomes in the UK are also comparable to that of other experienced international centres. Internationally, the median survival ranges from 13 to 21 years, depending on the age at transplant.

There were 81 paediatric liver transplantations performed at three paediatric centres in the UK during the financial year 2015/2016. Since 2014, fifteen Irish children received a paediatric liver transplant in the UK. The number of patients on the active liver-only paediatric transplant list has ranged between 18 and 42 each year. Data (to March 2013) indicate that the median waiting time to transplant for those listed as elective patients was 72 days and four days for super urgent patients. Super-urgent patients are defined as those who have sudden liver failure and are likely to die within 48 hours unless transplanted. The most recent five-year survival data for elective and super urgent patients were 91.8% and 73.1%, respectively. Similar post-paediatric liver transplantation survival estimates are noted internationally.

Description of the current approach to the transport of Priority 1 transfer patients from Ireland to the UK

The National Emergency Operations Centre (NEOC) was established in 2012 and is responsible for coordinating the transport logistics for Priority 1 transfer patients from Ireland to the UK. Ireland has no dedicated air ambulance service for Priority 1 transfers, and all services are provided on an "as available" basis. To date, there have been three providers for Priority 1 transfers — the Air Corps, the Irish Coast Guard (IRCG) and potentially private air ambulance companies.

Since 2012, there have been 32 Priority 1 transfers for paediatric transplant patients. These missions included 26 liver transplant patients, four heart transplant patients, one kidney transplant patient and one combined liver and kidney transplant patient. Before 2016, the majority of these transfers (94%) were conducted by the Air Corps. However, with services restricted to day time between June 2016 and Sept 2017 due to capacity constraints, the Air Corps only conducted 8% of the transfers. The IRCG conducted 83% of the transfers in this time period. One transfer in 2017 was provided by a commercial airline due to adverse weather conditions.

Since 5 September 2017, the availability of IRCG has been limited to 7.30am to 7.00pm cover. The Air Corps resumed stand-by rosters to provide cover for Priority 1 transfers on a temporary basis until 6 November 2017. Since the resumption of the

stand-by rosters, there have been three night-time Priority 1 transfers conducted by the Air Corps; two transfers took place during the same night. The IRCG has also conducted one daytime transfer from Shannon to London.

Despite the restricted availability of the Air Corps and IRCG during 2016 and 2017, to date, there has never been a requirement to use a private air ambulance provider for Priority 1 transfers.

The absence of night time cover from either the Air Corps or the IRCG after 6 November 2017 is significant given that historically the majority of transfers tend to occur at night — between 2012 and October 2017, 75% of all Priority 1 transfers were conducted between 7.00pm and 7.00am.

Overview of services used in the UK for the urgent transfer of patients to specialist transplantation centres

Transplant services in the UK are centralised in a small number of specialist centres in the UK, with paediatric heart and liver transplant services all located in England. Therefore, those living in Northern Ireland, Scotland and some parts of Wales and England face similar challenges to Ireland in transporting these patients to England within the available time frame. The purpose of this section is to provide an overview of how these countries achieve the safe and timely transfer of paediatric transplant patients and to consider if Ireland can learn from or use any of the current models.

Although air ambulances may not be required, moving organs and organ retrieval teams is logistically difficult as organs and organ retrieval teams need to be able to get to the organ donor and transport the organ to the transplant recipient centre within a short timeframe. Private medical transport companies organise the necessary ground and air transport for organs and organ retrieval teams. They may also organise the transport of transplant recipients when requested by the transplant centre.

In England and Wales, if the patient is well enough and is resident in close proximity to the transplant centre, they make their own transport arrangements. Otherwise, patients travel to the transplant centre via regional specialist transport services. The specialist transport services often have access to air ambulances through charity-funded helicopter air ambulances or private fixed wing air ambulance services.

In Northern Ireland and Scotland, there is access to a dedicated 24/7 service for the transfer of transplant patients. This service is part of a larger specialised transport service. In Northern Ireland, a private company provides a dedicated service for the transfer of patients to Great Britain. The company is the first point of contact for the

recipient transplant coordinator, and it organises the entire transfer including ground transportation. Paediatric liver and heart transplant patients only account for a small proportion (approximately 1%) of the transfers carried out each year by this company. This model is funded by the Health and Social Care Board in Northern Ireland.

In Scotland, ScotSTAR is a specialist transport and retrieval service. It operates as part of the Scottish Ambulance Service and provides a national, coordinated service for the transport of these patients. As in Northern Ireland, paediatric heart and liver transplant patients would account for a small proportion of the patients that ScotSTAR transports every year (< 1%). ScotSTAR has access to two fixed wing air ambulances and three air ambulance helicopters through the Scottish ambulance service. The Scottish Ambulance service is funded by the government.

In the UK, the Royal Air Force and Her Majesty's Coastguard are not routine providers of air ambulance. Their use is limited to contingency cover when other air transport options have been exhausted.

Northern Ireland has adopted a holistic approach to the management of patients required to transfer out of the country for their care. For example, a designated nurse transport coordinator centrally books travel and accommodation for paediatric congenital heart disease patients and their authorised escorts, coordinates subsistence payments and acts a designated point of contact when abroad.

Service specifications for an Irish paediatric heart or liver transplantation service

At present, resources for cardiothoracic surgery at Our Lady's Children's Hospital, Crumlin, are directed towards congenital heart disease. The development of a paediatric heart transplantation service in Ireland would require substantial additional resources and capital investment. Additionally, a paediatric ventricular assist device (VAD) service does not exist in Ireland and would need to be introduced as it is a necessary component of a heart transplantation service. As for paediatric liver transplantation, the national hepatobiliary surgery service at Our Lady's Children's Hospital, Crumlin, has been effectively suspended since 2012. As a result, children who now require many forms of hepatobiliary surgery are referred to UK centres. This service would need to be reinstated prior to the development of a paediatric liver transplantation service.

Beyond the recruitment of trained medical personnel for a future paediatric heart or liver transplantation service, other resources necessary would include additional operating theatre capacity (including out-of-hours service) and a scale-up of

immunological, microbiological and haematological services with specific expertise in the management of paediatric transplantation patients. Consideration should also be given to whether the expected number of transplants anticipated to take place in Ireland would be sufficient to ensure a safe and effective service.

A significant impact associated with developing an Irish paediatric transplantation service is the potential reduced access to donor organs. Possible risks include a reduction in access to the UK's larger donor pool. The UK operates living donor and split-liver transplantation programmes to improve the availability of donor organs for paediatric patients. Without these services in Ireland, the donor pool available to a national paediatric liver transplant service would be reduced compared with what is currently available to Irish children listed for transplant in the UK. Logistical challenges would likely arise if these services were to be provided to facilitate a national paediatric liver transplant programme as the adult and paediatric liver transplant programmes would not be co-located on the one site. In addition, many transplantations that take place in the UK originate from mainland European donors. Retrieval of organs from European donors would pose similar time critical transport problems to those currently experienced in transporting Priority 1 transfer patients.

Description of the alternative approaches for providing efficient and sustainable treatment or transport

A range of alternative approaches were identified for providing efficient and sustainable treatment or transport of Priority 1 transfer patients. These were divided into immediate, short term (within six months) and long term alternatives, reflecting the requirement to address an immediate need to have a transport solution for Priority 1 transfer patients in place on the 6 November 2017 whilst also exploring sustainable longer term alternatives that could provide improved efficiency.

- The immediate alternatives identified were:
    - fund a dedicated aircraft and aircrew from a commercial provider
    - fund a dedicated Irish Coast Guard aircrew operating an "as-available" IRCG helicopter
    - charter aircraft "as needed"
    - provide financial and logistical assistance to patients and families who choose or are advised based on clinical advice from the National Ambulance Service to relocate to the vicinity of the transplant centre in the UK
    - lease or purchase of a property in the UK for patients and families who choose or are advised based on clinical advice from the National

Ambulance Service to relocate to the vicinity of the transplant centre in the UK
  - continue to work with the limited Air Corps and Irish Coast Guard availability from 6 November 2017 (the "as-is approach").
- The short-term alternatives identified were:
  - the HSE leasing and operating aircraft
  - partnering with a Northern Irish service provider (all-island approach)
  - funding of transport resources through philanthropic partnerships
  - renegotiating the existing contractual arrangements with the Irish Coast Guard to allow 12 hour rosters at one or more bases
  - seeking permission to undertake IRCG Priority 1 missions to the UK under SAR rules
  - procuring public inpatient beds in the UK for selected patients awaiting transplant.
- The long-term alternatives identified were:
  - a 24/7 Air Corps air ambulance to be operated "as available"
  - the HSE and Air Corps replicating the Garda Air Support Unit model
  - requiring an additional Irish Coast Guard aircraft and aircrew for dedicated HEMS activity including Priority 1 transfers plus a switch to a 12 hour roster at all bases at contractual renewal in 2022
  - tendering for a dedicated private air ambulance service
  - setting up paediatric heart and liver transplantation services in Ireland
  - developing a National Integrated Aeromedical Transport Service.
- Other potential alternatives explored were:
  - accessing alternative London airports
  - transferring patients to private hospitals in the UK.

Ethical and societal implications

In the absence of Irish-based paediatric heart and liver transplant programmes, access to the UK programme ensures that eligible children have a possibility of receiving a transplant. Paediatric transplant patients are a highly vulnerable group due to both the severity of their underlying illness and their inability to provide informed consent. Parents must give informed consent and, given the complexity of the transplant journey and the unique nature of each individual, the benefits and harms may be difficult to comprehend.

The transplant journey places a very large emotional, logistical and financial burden on transplant patients and their families which can be partly alleviated through the

provision of appropriate supports such as psychosocial and financial assistance. The current approach to reimbursing travel is likely to disadvantage families with limited financial resources by requiring the parents to have sufficient resources to pay out of pocket before seeking reimbursement and by only covering the cost of flights for a single parent to travel with their child. The funding and reimbursement mechanisms should be revised to minimise this potential source of inequity. It is recommended that strong consideration is given to establishing the role of a transplant liaison officer for paediatric transplant patients to ensure parents have a single point of contact for important information and access to necessary supports.

The complexity of the treatment and post-transplantation care and the need to navigate two healthcare systems suggest the need to provide substantial amounts of information to support families in providing the best care for their children. Adherence is important for achieving the best longer-term outcomes. The complexity of post-transplantation medication regimens means that non-adherence is common. Structures need to be in place to monitor adherence so that non-adherence can be identified early.

The alternative approaches to achieving full 24/7 cover for Priority 1 patient transfers may come at a substantial cost to the HSE with no guarantee that those services would even be used in a given year. The money used to fund transfers could be used elsewhere in the health system, with potentially greater benefit. Value for money should be considered when selecting the approach to adopt for patient transfers.

Assessment of alternative approaches

The alternative approaches were assessed against a number of criteria including clinical, economic, organizational and societal aspects, time horizon to implementation and reliability. To maximise the chance that paediatric patients will access transplant within the required timeframe, actions to be taken can be considered as immediate, short term (up to 6 months) or long term.

Non-transfer options considered are relocating the patient to the UK and developing a paediatric heart and liver transplantation service in Ireland. The relocation of children is neither realistic nor possible in all circumstances. Additionally, relocation to the UK is not feasible for many heart transplant patients without access to hospital beds. Therefore, Priority 1 transfer would still be necessary for those patients who could not relocate to the UK.

The development of an Irish paediatric heart or liver transplantation programme may not be feasible. Key issues for consideration would be potential loss or reduced

access to the donor pool and maintaining competency to ensure a safe and effective service in the context of low volume activity.

The optimal immediate option for transport of Priority 1 transfer patients would consist of sourcing and paying a private provider to deliver a dedicated night time service. An aeroplane and crew based in Dublin airport would be required with this option. An alternative immediate option is for the Irish Coast Guard to recruit a dedicated aircrew to operate the Dublin based helicopter, if available, each evening between 7pm and 7.30am. Both these options are of a similar high cost to provide, on average, not more than four night-time transfers per annum and are likely not financially sustainable in the longer term.

Short-term options can be divided into speculative and available options. Focussing on options with the greatest certainty, the optimal solution may be negotiating changes to the IRCG contract to allow for 12 hour rosters at one or more bases. This option would likely come at a substantial cost, would be provided on an 'as available' basis, and may have some implications for the primary remit of IRCG with regard to SAR. The cost of this option would have to be contrasted with the cost associated with the on-going use of a commercial provider or of a dedicated IRCG crew on standby at the Dublin base. In the short-term it may be possible to identify a commercial provider with more favourable terms than can be achieved as an immediate option.

Two speculative short-term options were identified which should be thoroughly explored, as they may provide less costly but reliable transport solutions. These options are: a philanthropic provider, such as a dedicated air ambulance; the potential for the IRCG to fly patients to the UK under SAR rules. Although these options are likely to be less costly than the alternatives, there is substantial uncertainty regarding their feasibility.

When viewed solely in the context of Priority 1 transfers, three preferred long-term transfer options were identified based on the Irish Coast Guard and the Air Corps. There is an option that the next contract to provide coast guard services (due for renewal in 2022) could incorporate provision of an additional aircraft and aircrew with a primary remit to provide air ambulance services albeit this option will likely come at a higher cost than options utilising the Air Corps. The preferred Air Corps option, albeit at increased cost, may be the GASU-type model with aircraft provided by the HSE and dedicated crew provided by the Air Corps as it provides additional dedicated HEMS capacity including Priority 1 transfers. Alternatively, the Air Corps could provide an air ambulance service on an "as available" basis. However, the Air Corps options are contingent on restoration of staff capacity.

If Priority 1 transfers are considered as part of the wider patient transport services, then the long-term development of an integrated aeromedical service for Ireland could provide a more sustainable and resilient approach and allow for the more cost-effective use of assets and resources than can be achieved by a service only designed for Priority 1 transfers. It would ideally leverage off existing state resources, provide for a level of dedicated HEMS capacity with resilience provided through access to a range of providers potentially including the Air Corps, IRCG, philanthropy and private providers as available.

We have not explicitly examined cost-effectiveness in this assessment. It is noted that all options identified come with a high budget impact for the State and with varying opportunity costs for other state services, and specifically the Air Corps and the Irish Coast Guard neither of which has provision of aeromedical services as a primary remit.

Conclusions

Long term design of a national integrated aeromedical transport service for Ireland could provide resilience by leveraging access to multiple aircraft and aircrews from one or more providers. Such a service, which would encompass pre-hospital and inter-hospital transfers in Ireland, priority 1 transfers abroad and patient repatriation, would have the potential advantage of providing a more coherent and efficient solution to the national aeromedical requirements. While we have not explicitly considered cost-effectiveness, all plausible alternatives identified are associated with a substantial budget impact. Selection of options for treatment and transport of Priority 1 transfer patients should be guided by consideration of the affordability, the impact on other state services and crucially the requirement to maximise the delivery of safe, effective patient-centred care. Consideration should also be given to resourcing a paediatric transplant liaison officer who would provide comprehensive support to all patients accessing transplant services in the UK and to review the arrangements for the reimbursement of travel and accommodation expenses for these families.

1 Introduction

1.1 Background to the request

In September 2017, the Health Information and Quality Authority (HIQA) agreed to undertake a rapid HTA following receipt of a request from the office of the Chief Medical Officer at the Department of Health. The purpose of the HTA is to provide advice to the Minister of Health on the consequences of alternative options for the treatment and transport of Priority 1 transfer patients to the UK.

The urgency of this request is due to challenges with the provision of air ambulance to transfer these patients. In the absence of national paediatric heart and liver transplant services, Priority 1 transfer patients mostly comprise children who require emergency transfer to specialist centres in the UK to avail of transplantation of a suitable donor heart or liver. Patients must present at the transplant centre in the UK within four hours of notification of a donor heart becoming available and within six hours of a liver becoming available. Heart transplant patients are of particular concern due to the very short window of opportunity to avail of a donated heart. As of 31 October 2017, there are three children resident in Ireland listed for heart transplant in the UK with no child listed for liver transplant.

Co-ordination of the transport logistics for paediatric transplant patients from Ireland to the UK rests with the National Emergency Operations Centre (NEOC), which is part of the National Ambulance Service of the Health Service Executive (HSE). The NEOC uses three providers for these transfers – the Irish Air Corps, the Irish Coast Guard (IRCG) and potentially private air ambulance companies. There is no dedicated air ambulance service, and all services are provided on an "as available basis". Priority 1 transfers to date have primarily been provided by the Air Corps and Irish Coast Guard. There were nine Priority 1 transfers in 2016, all paediatric liver transplant patients.

Prior to 2016, the majority of Priority 1 transfers were undertaken by the Air Corps. Due to staff capacity constraints, the Air Corps stepped down its 24 hour, seven days a week roster to a more limited day time, five days a week roster in June 2016. This was to provide the necessary space to the Air Corps to rebuild a safe capability. Following this date, the majority of transfers were undertaken by the IRCG. Subsequent to advice provided as part of a review by the Irish Aviation Authority, the IRCG advised that from 5 September 2017, it would no longer be available for transfer of Priority 1 transfer patients between the hours of 7.00pm and 7.30am. This was to ensure that the IRCG remains compliant with requirements specified in the 2012 European aviation safety regulations. Despite on-going Air Corps capacity

constraints, an interim arrangement was made with the Department of Defence for the Air Corps to provide temporary contingency measures and provide night time cover for Priority 1 transfers from 5 September 2017 until 6 November 2017. This step up in service was provided by the Air Corps to allow time for alternative arrangements to be made and cannot be continued beyond the 6 November 2017 for safety and operational reasons.

A rapid HTA evaluating the treatment and transport options for Priority 1 transfer patients was requested by the Department of Health with the Approval of the Minister for Health on 29 August 2017, with HIQA to report by the end of October 2017.

1.2 Defining aeromedical transport services in the context of this report

The National Aeromedical Co-ordination Group defines **Priority 1 transfer** as:

> The transfer by air from Ireland to another country within 8 hours (from time of notification to NEOC to time of arrival at receiving facility) of a patient requiring emergent medical or surgical treatment, without which the patient's life or health is significantly endangered.

To date, the majority of those fulfilling these criteria have been paediatric patients transferring to the UK to undergo heart or liver transplant surgery. By definition, these transfers are unscheduled with no advance notice. Historically these transfers have often taken place at night. Patients who are transferred to the UK by air, but who do not fall within the definition of Priority 1 are referred to as scheduled transfers.

There are currently two national services that are involved in the aeromedical transport of patients to the UK, the Irish Coast Guard (IRCG) and the Air Corps. For the purpose of this report, the following definitions will be used when describing the types of mission undertaken by these services:

Search and Rescue (SAR) missions are the prime function of the IRCG, they are limited to the Irish Marine Search and Rescue Region (IMSRR), which corresponds with the Irish Flight Information Region (FIR) - approximately 200 miles off the West Coast of Ireland, 30 miles off the South Coast and dividing the Irish Sea. SAR can be defined as:

> Search and Rescue (SAR) comprises the search for and provision of aid to persons who are, or are believed to be, in imminent danger of loss of life. The

> two operations – search and rescue – may take many forms, depending on whether they are both required or not, on the size and complexity of the operation and on the available staff and facilities.(1)

SAR services can be defined as:

> SAR services are defined as the performance of distress monitoring, communication, coordination and search and rescue functions, including provision of medical advice, initial medical assistance and medical evacuation, through the use of public and private resources, including cooperating aircraft, vessels and other craft and installation.(1)

Helicopter Emergency Medical Services (HEMS) is a globally recognised term to describe the use of helicopters for the transport of patients to hospital. The European Aviation Safety Agency's (EASA) regulations for Air Operations define a HEMS flight as:

> A flight by a helicopter operating under a HEMS approval, the purpose of which is to facilitate emergency medical assistance, where immediate and rapid transportation is essential, by carrying: (a) medical personnel; (b) medical supplies (equipment, blood, organs, drugs); or (c) ill or injured persons and other persons directly involved.(2)

Under these definitions, a Priority 1 transfer is considered a HEMS flight and must follow civil aviation rules.

The Emergency Aeromedical Support (EAS) is categorised as HEMS and is limited primarily to pre-hospital patient transfers. It provides rapid access to appropriate treatment for high acuity patients, specifically where land ambulance transit times would not be clinically appropriate. It operates seven days a week in daylight hours from Custume Barracks, Athlone. The aircraft and crew are provided by the Air Corps; the NAS provides an advanced paramedic. This service operates within the Republic of Ireland, and is generally not available to undertake transfers to the UK.

Other HEMS provision within Ireland is provided by the Air Corps and the IRCG on an "as available" basis. These air ambulance services include inter-hospital transfer of patients with serious illness/injury within Ireland and mostly take place on a scheduled basis while Priority 1 transfer is the unscheduled element of this service.

An important consideration in the difference between these definitions is the crew configuration involved particularly the number and type of medical personnel that is needed in each situation.

For the purpose of this report, it must be noted that while all Priority 1 transfers are of equal urgency there is a distinction in terms of the level of support required during the transfer. Aeromedical services range from air taxi to air ambulance services. Air ambulance is where a plane or helicopter has been adapted to allow a patient to be safely transported and where some level of medical support is provided. Air taxi refers to the use of an aircraft to expedite the urgent transfer of a patient, but where no reconfiguration or medical support is required. Priority 1 transfers are all undertaken as airport to airport air transfers, therefore from a regulatory perspective they are considered to be a normal transport task where the risk is no higher than for routine air travel.

1.3 Terms of Reference

The purpose of this HTA is to evaluate the options for the transport of patients who fulfil the criteria for Priority 1 transfer.

As noted, to date, the majority of those fulfilling these criteria have been children requiring urgent transfer to the UK to undergo heart or liver transplant surgery following notification of a suitable donor organ becoming available. This HTA will focus on options for the transfer of these patients, but will also explore at a high level commissioning paediatric heart and liver national transplantation centres in Ireland as a potential long-term alternative.

The terms of reference for this HTA were to:

- Provide a high-level description of the burden of disease and outcomes associated with paediatric heart and liver transplantation.
- Describe the current approach to the transport of Priority 1 transfer patients from Ireland to the UK.
- Provide a brief overview of services used in the UK for the urgent transfer of patients to specialist transplantation centres.
- Provide a brief overview of the service specifications for paediatric heart and liver transplantation centres.
- Set out the alternative approaches for providing efficient and sustainable treatment or transport of these patients.
- Provide a high-level assessment of the clinical, economic and organisational consequences of the alternative approaches for the treatment or transport of these patients.
- Consider any major ethical or societal implications of adopting alternative approaches for the treatment or transport of these patients.

- Based on this assessment, advise on the potential impact of alternative approaches to the treatment and transport of these patients.

1.4. Overall Approach

Following initial discussions and scoping exercise the Terms of Reference of this assessment were agreed between HIQA and the Department of Health.

HIQA convened an Expert Advisory Group comprising representation from relevant stakeholders including the Department of Defence; Air Corps; Irish Coast Guard; National Ambulance Service; Department of Health; Health Service Executive; nursing administration at Our Lady's Children's Hospital, Crumlin; Organ Donation and Transplant Ireland; clinical experts from transport medicine and paediatric cardiology and hepatology/gastroenterology services; and representation from relevant patient groups. The role of the Expert Advisory Group was to inform and guide the process, provide expert advice and information, and to provide access to data where appropriate. A full list of the membership of the Expert Advisory Group is available in the acknowledgements section of this report.

Members of an Expert Advisory Group are expected to:

- Contribute to the provision of high quality and considered advice by the Authority to the Minister for Health.
- Contribute fully to the work, debate and decision making processes of the group by providing expert guidance, as appropriate.
- Be prepared to provide expert advice on relevant issues outside of group meetings, as requested.
- Provide advice to the Authority regarding the scope of the analysis.
- Support the Evaluation Team led by the Authority during the assessment process by providing expert opinion and access to pertinent data, as appropriate.
- Review the draft report from the Evaluation Team and recommend amendments, as appropriate.
- Contribute to the Authority's development of its approach to HTA by participating in an evaluation of the process on the conclusion of the assessment.

HIQA appointed an evaluation team comprising staff from the HTA directorate to carry out the assessment. The EAG formally met on one occasion. Meetings were arranged with all stakeholders prior to the EAG meeting to gain a better understanding of the issues involved so to inform development of the draft version of the report. Draft versions of the report were reviewed and endorsed by the EAG.

The final report was submitted to the HIQA Executive Management Team and Board and then to the Minister for Health and HSE as advice and published on the HIQA website.

2 Burden of disease and outcomes

2.1 Introduction

The purpose of this chapter is to describe the burden of disease and outcomes associated with paediatric heart and liver transplantation. The National Ambulance Service has identified this group as the patients that typically fulfil the criteria for Priority 1 transfer from Ireland to the UK (explored in more detail in Chapter 3).

Paediatric heart and paediatric liver transplantation are not available in Ireland and patients are therefore listed for transplant in the UK. The Liver Advisory Group and the Cardiothoracic Advisory Group in the UK outline the referral and registration process for non-UK nationals.[3, 4] Eligible Irish patients can be placed on the UK national transplant list following registration with National Health Service Blood and Transplant (NHSBT). Nationals of a non-UK country may only be registered on a transplant list after they have been accepted by an NHS consultant as suitable for treatment. It is the responsibility of the consultant registering such a patient on the transplant list to confirm that they have been accepted under Ireland's Treatment Abroad Scheme or similar arrangements. Patients may be listed on only one transplant list at a time. Patients are required to consent to the transfer of their data onto the UK Transplant Registry, which is maintained by NHSBT on behalf of transplant services in the UK. The registry holds detailed information about each patient awaiting any organ transplant. The specific mechanisms surrounding donor allocation are discussed in the relevant sections of this chapter. Typically, patients awaiting heart transplantation are in hospital, often maintained on inotropic support, whereas patients awaiting liver transplantation are not always hospitalised and may travel from home to the UK if a donor liver becomes available.

The time between removal of an organ from a donor and implantation into the recipient is critical to the success of the transplant. UK transplant centres request a four-hour transfer window for heart transplantation and six-hour window for liver transplantation; this refers to the time between the recipient's family receiving a call advising that a suitable organ is available and the time the child arrives through the doors of the hospital.

In organ donation, cold ischemic time refers to the amount of time that an organ is chilled or cold and not receiving a blood supply. In general, the sooner an organ can be transplanted, the better. For hearts, the generally accepted cold ischemic time is four hours, while for the liver the generally accepted cold ischemic time is six to ten hours. Warm ischemic time refers to the amount of time that an organ remains at body temperature after its blood supply has been stopped or reduced. In the event

of "deceased brain dead" organ recovery, the warm ischemic time is very minimal because the time that the heart stops is virtually the same time that the organs are cooled. For a "deceased circulatory dead" organ recovery, warm ischemic time is longer as it includes the amount of time that the organ is not being properly perfused prior to death.

To provide context in relation to the volume of transplant surgery undertaken by the NHSBT, there were 38 paediatric heart transplantations performed at two centres in the UK in 2016. These were all "donation after brain death" transplantations. There were 98 paediatric liver-only transplantations performed at three paediatric centres in the UK in 2016, this included 17 living-donor transplantations. Since 2014, seven children from Ireland received a heart transplant and 15 received a liver transplant in the UK.

2.2 Paediatric heart transplantation

2.2.1 Introduction

Heart transplantation is the final treatment option for children in end-stage cardiac failure. While an adult cardiothoracic transplant service is provided by the Mater Misericordiae Hospital in Dublin, a paediatric cardiothoracic transplantation service does not exist in Ireland. Patients are referred to the UK from Our Lady's Children's Hospital, Crumlin, (OLCHC) through a shared care programme to one of two transplant centres (Great Ormond Street Hospital in London or Freeman Hospital in Newcastle). More than 30 paediatric heart transplants are performed annually in the UK between the two specialist centres.[5] Worldwide, approximately 100 centers perform a total of over 500 paediatric heart transplants each year.[6]

Over the previous two decades, significant improvements in surgical expertise, immunosuppression regimens and intensive care techniques have vastly improved the outlook for these children, and it is predicted that the majority of grafts implanted today will last for at least 15 years.[7] This inevitably means that patients transplanted as young children will require re-transplant during adolescence or early adulthood. With organ donation currently at severely low levels, the prospect of receiving a second transplant is poor. The goal of transplant programmes is often to postpone transplantation as long as possible and to ensure careful management of the post-transplant phase in order to improve the longevity of donated organs.[7]

2.2.2 Service configuration in the UK

A comprehensive transplantation service for infants and children referred with cardiac failure and who have not responded to maximum conventional treatment

exists in the UK.[5] There are seven licensed heart transplant centres in the UK: Birmingham, Great Ormond Street Hospital in London, Glasgow, Harefield, Manchester, Newcastle and Papworth. The centre in Newcastle transplants adult and paediatric patients, while Great Ormond Street Hospital transplants paediatric patients only. The remaining centres transplant adult patients only.

The service in the UK integrates with NHS services for heart failure, cystic fibrosis/respiratory medicine and pulmonary hypertension. The service also closely integrates with the Ventricular Assist Devices (VADs) for Children as a Bridge to Heart Transplant service. Due to the small number of paediatric thoracic transplants performed each year, the transplant service is limited to two centres to ensure expertise is maintained. Clinical outcomes are monitored by NHS England in collaboration with NHS Blood and Transplant (NHSBT).

Patients are listed for heart transplant if there are no contraindications and when their quality of life and or survival are likely to be improved by a transplant. Patients are categorised as urgent or non-urgent. The development of VADs has enabled some patients with end-stage heart failure to be supported until such time as a suitable donor heart is identified. VADs may also be used to treat reversible complications of heart failure that are potential contraindications to heart transplantation (for example, kidney dysfunction or high pulmonary vascular resistance). The overall demand for heart transplantation is likely to increase with the use of this technology.[5]

Globally, 29.6% of paediatric heart transplants are bridged with mechanical circulatory support.[8] The most common mechanical support is the left ventricular assist device (LVAD), which is used in 17.5% of transplants, followed by the biventricular assist device (BiVAD), which is used in 5.9% of transplants, and extracorporeal membrane oxygenation (ECMO), which is used in 4.1% of transplants.[8] A paediatric VADs service is not available in Ireland. Patients who deteriorate on the waiting list and are suitable for VADs are transferred electively to Great Ormond Street Hospital and maintained there, awaiting transplantation.

In organ donation, "cold ischemic time" refers to the amount of time that an organ is chilled or cold and not receiving a blood supply. The acceptable cold ischemic time for donated hearts is short compared to most other donated organs. This currently makes long-distance transport of hearts undesirable, although organ retrieval from Europe is occasionally necessary because of limited paediatric organ supply.[5] Some centers internationally have demonstrated acceptable outcomes with longer ischemia times[9]; however, many reports demonstrate that longer ischemia times are associated with higher risk of mortality.[10, 11] In the US, a study utilising the UNOS database of over 11,700 patients undergoing heart transplantation demonstrated

that the ischemia time was shown to be an independent risk factor for survival with an odds ratio of 1.7 (95% confidence interval (CI): 1.0–2.8) in patients with an ischemic time of more than six hours and an odds ratio of 1.4 (1.3–1.6) in patients with an ischemic time of between four and six hours ($p<0.05$ for both).[11]

2.2.3 Indications for transplant in the paediatric patient

Diagnoses leading to paediatric heart transplantation are age-specific and have changed during the past decades. The range of left heart anomalies, summarised as hypoplastic left heart syndrome, was one of the reasons for the introduction of infant paediatric heart transplantation. In the last two decades, organ shortage, especially for neonates, has meant that primary transplant is an impractical therapy for the large number of infants with hypoplastic left heart syndrome.[12] Attempts towards reconstructive, palliative surgery in this patient population led to staged surgery (Norwood stage 1 to 3 or Fontan procedure)[13] and has become the primary treatment option.

For this reason, the percentage of recipients listed for paediatric heart transplantation with the diagnosis of congenital heart disease (CHD) has decreased worldwide since the 1990s.[6] Still, CHD (which includes hypoplastic left heart syndrome) remains the most common indication for paediatric heart transplantation in the infant age group.[6] The second most common indication, cardiomyopathy, may be characterised as dilated (75%), restrictive (12%), mycoarditic (8%) or hypertrophic (5%).[14] Table 2.1 lists the proportions of patients undergoing paediatric heart transplantation internationally by indication and by age group (from the International Society of Heart and Lung Transplantation, 2016).[15]

Table 2.1 Indications for heart transplantation in children, 2009 to 2015[15]

Age (year)	CHD (%)	Myopathy (%)	Re-Transplant (%)	Others (%)
<1	55	38	0.3	7
1-5	41	44	4	11
6-10	35	44	6	15
11-17	23	54	8	15

CHD, congenital heart disease; Re-Tx, cardiac re-transplantation

Simmonds et al. identified all Irish children (n=22) who underwent paediatric heart transplantations in the UK between 1990 and 2013.[16] Table 2.2 lists their indications for transplant. The most common indication for transplant was dilated cardiomyopathy (n=15), accounting for over two thirds of all transplants, followed by congenital heart disease (n=6).

Table 2.2 Diagnoses of Irish children undergoing heart transplantation, 1990 to 2013[16]

Diagnoses	N=
1. Dilated cardiomyopathy	**15**
Mitochondrial	2
Left ventricular non-compaction	2
Myocarditis	1
MYBPC3 gene	1
Idiopathic	9
2. Congenital*	**6**
Fontan	2
Glenn	2
Right ventricular hypoplasia	1
Rastelli–paced	1
3. HCM/RCM + CCAVB	**1**

CCAVB, congenital complete atrioventricular block; HCM, hypertrophic cardiomyopathy; MYBPC3, myosin binding protein C; RCM restrictive cardiomyopathy.
*Three of the six patients with congenital heart disease had hypoplastic left heart syndrome and had undergone a Glenn shunt with failing systemic right ventricle.

2.2.4 Selection criteria

The Cardiothoracic Advisory Group (CTAG), on behalf of NHS Blood and Transplant (NHSBT) issued its heart transplantation organ allocation policy document on 23 June 2017.[3] In the selection process of a suitable recipient, priority is given to the sickest candidate, while ensuring the risk associated with transplantation is within acceptable limits (chance of survival more than 50% at one year). Paediatric patients are defined as those aged less than 16 years.

There are three tiers of allocation: the non-urgent heart allocation scheme, the urgent heart allocation scheme and the super-urgent heart allocation scheme (although this tier is restricted to adults only). Paediatric patients who have advanced heart failure and a very poor short-term prognosis are prioritised by placing them on the urgent heart allocation scheme as opposed to the non-urgent heart allocation scheme.

Hearts are allocated to individual named patients on a UK and Ireland basis for those on the super-urgent and urgent lists. For patients on the non-urgent list, hearts are allocated on a centre basis for local allocation. The same allocation process applies to Irish and UK transplant recipients.

Paediatric donor hearts are offered to all patients in the urgent heart allocation scheme (paediatric and "small adult" patient categories) before being offered to

patients in the super-urgent heart allocation scheme adult patient category and then the urgent heart allocation scheme adult patient category. Urgent heart allocation scheme patients in the paediatric and "small adult" patient category are ordered by time spent waiting on the urgent heart allocation scheme. There is no blood group priority, and patients in the "small adult" patient category rank alongside those in the paediatric group. Urgent heart patients in the adult patient category are subsequently offered paediatric donor hearts and are ranked by 1) blood group, 2) local zonal/non-zonal centre and 3) length of time spent waiting on the urgent heart allocation scheme since registration.[3]

2.2.5 Surgical technique

Paediatric heart transplantation for complex congenital heart disease (CHD) remains a technically challenging procedure and requires a well-trained team of surgeons, anaesthestists, nurses, cardiologists and critical care specialists.[17] Most often, recipients have had one or sometimes numerous previous open heart surgeries (such as the Norwood procedure alluded in Section 2.2.3) prior to transplantation.

In general, the transplantation procedure is similar to adult heart transplantation in children with cardiomyopathy who have structurally normal extra cardiac circulatory systems.[18] However, in children with structural congenital heart disease, the arterial and venous malformations can pose a challenge to the success of the transplant procedure itself. Additional donor structures, such as the aortic arch and branch pulmonary arteries, may be needed to enable transplantation in a child with hypoplasia of the aortic arch or branch pulmonary arteries. Venous anomalies, such as a left-sided superior or inferior vena cava, may necessitate routing of venous blood to the appropriate location in the chest to complete the required anastomoses.[19, 20]

Successful outcomes start with organ selection and organ retrieval. Appropriate selection of the donor organ is important, including ensuring blood group compatibility.[19] Outcomes are adversely affected where the donor is more than two and half times or less than half the weight of the recipient.[21] Likewise donor age may have significance for paediatric recipients,[22] whereas gender seems to have no significant impact on outcomes. Varying from routine donor heart retrieval, additional donor tissue, including the full length of the venae cavae superior and the innominate vein as well as the entire aortic transverse arch and the branch pulmonary arteries, may be explanted.[17]

Reconstructive surgery, known as Norwood stage 1 to 3 or Fontan procedure, is a palliative surgical procedure in patients with single-ventricle physiology.[17] Nowadays, heart transplantation is reserved for those few newborns who do not

seem suitable for this procedure.[12] Late haemodynamic complications such as heart failure, cyanosis and protein-losing enteropathy following the Fontan procedure frequently result in an evaluation for a paediatric heart transplantation. Often more than one factor may lead to transplantation.[23] Marginal liver function, coagulopathy and distorted anatomy from several previous heart operations often serve as significant challenges for the surgical team.[24]

2.2.6 Outcomes

2.2.6.1 Outcomes in the UK

Transplant activity

There were 38 paediatric heart transplantations performed at two centres in the UK in 2016. These were all "donation after brain death" transplantations. Previously, in the financial year 2014/2015, 37 paediatric heart transplants were performed.[5] Since 2014, seven Irish children received a paediatric heart transplantation in the UK.

Most centres in other countries perform far fewer transplants per year. Internationally, 136 centres perform between one and four paediatric heart transplants annually, 28 centres perform between five and nine paediatric heart transplants annually and 22 perform 10 or more paediatric heart transplants annually.[8]

Waiting list

The overall number of patients actively waiting for a heart transplant in the UK increased substantially from 16 in 2013 to 37 in 2016.[25] The number of patients on the urgent transplant list has increased from zero in 2007 to 12 in 2016, with an average of 6.1 patients on the list on the 31 March each year.[25] Of the 37 paediatric patients on the active heart transplant list on 31 March 2016, Great Ormond Street Hospital (GOSH) had the largest proportion (65%) of the transplant list. Seven patients at Newcastle and five at GOSH were on the urgent list at this time. Of the 37 listed patients, 76% of the recipients were male and the median age was six years.

Post-registration outcomes

In NHSBT's 2015/2016 annual report on cardiothoracic transplantation, post-registration outcomes between 1 April 2012 and 31 March 2013 are reported.[25]

Of the **non-urgent** heart patients, within six months of listing, 0% of patients were

transplanted while 8% died waiting. One year after listing, there were no patients actively waiting on the routine list; 75% had been moved to the urgent list, 8% had been removed; and 17% had died waiting. This indicates that none of the non-urgent patients had received a transplant.

Of the **new urgent** heart only registrations, within six months of listing, 62% of patients were transplanted while 18% died waiting. At one and three years post-registration, fewer patients were still waiting as they were removed from the transplant list.

Median waiting time to transplant

Between 1 April 2010 and 31 March 2013, the median waiting time to donor transplant for paediatric patients registered on the heart transplant list was 96 days (95% CI: 61–131). The median waiting time for patients that were "never urgent" was 357 days (95% CI: 0–839) and "ever urgent" was 81 days (95% CI: 56–106).[25]

In the same time period, the median total ischaemia time (this encompasses warm and cold ischemia times, or from "cross-clamp to reperfusion") for paediatric "donation after brain death" heart transplants was 3.7 hours (interquartile range, 3.2–4.3 hours).

Survival

The NHS Blood and Transplant's annual report for 2015/2016 includes 30-day, one-year and five-year survival data.[25] Thirty-day and one-year survival rates are based on transplants performed during the period 1 April 2011 to 31 March 2015, while five-year survival rates are based on transplants performed in the period 1 April 2007 to 31 March 2011.

For the 124 paediatric heart transplants that were performed in the period 1 April 2011 to 31 March 2015, 30-day outcome information was known for all 124 patients. Thirty-day unadjusted patient survival for these heart transplants is shown in Table 2.3. There was no evidence of a statistically significant difference in survival between Great Ormond Street and Newcastle.

Table 2.3 NHSBT 30-day patient survival after first paediatric heart transplant, by centre, 1 April 2011 to 31 March 2015[25]

Centre	Number of transplants	Number of deaths	% 30-day survival (95% CI) (unadjusted)
Freeman Hospital, Newcastle	61	3	95.1 (85.5–98.4)
Great Ormond Street Hospital	63	2	96.8 (87.9–99.2)
UK	124	5	96.0 (90.6–98.3)

For the 124 paediatric heart transplants that were performed in the period 1 April 2011 to 31 March 2015, one-year outcome information was known for 113 patients. One-year unadjusted patient survival for these heart transplants is shown in Table 2.4. There was no evidence of a statistically significant difference in survival between Great Ormond Street and Newcastle.

Table 2.4 NHSBT one-year patient survival after first paediatric heart transplant, by centre, 1 April 2011 to 31 March 2015[25]

Centre	Number of transplants	Number of deaths	% 1 year survival (95% CI) (unadjusted)
Freeman Hospital, Newcastle	61	7	88.5 (77.4–94.4)
Great Ormond Street Hospital	63	6	90.5 (80.0–95.6)
UK	124	13	89.5 (82.6–93.8)

For the 133 paediatric heart transplants that were performed in the period 1 April 2007 and 31 March 2011, five-year outcome information was known for 116 patients. Five-year unadjusted patient survival for these heart transplants is shown in Table 2.5. There was no evidence of a statistically significant difference in survival between Great Ormond Street and Newcastle.

Table 2.5 NHSBT five-year patient survival after first paediatric heart transplant, by centre, 1 April 2007 to 31 March 2011[25]

Centre	Number of transplants	Number of deaths	% 5 year survival (95% CI) (unadjusted)
Freeman Hospital, Newcastle	61	10	83.6 (71.7–90.8)
Great Ormond Street Hospital	72	11	84.4 (73.6–91.1)
UK	133	21	84.1 (76.7–89.3)

2.2.6.2 Outcomes in Ireland (shared care programme)

Simmonds et al. report on outcomes of the shared care programme between the Republic of Ireland and the UK (outcome of shared care for paediatric cardiac transplantation between two nations with different healthcare systems).[16] The medical records of all children who were referred to Great Ormond Street Hospital or to the Freeman Hospital from Ireland and underwent cardiac transplantation between January 1990 and September 2013 were retrospectively studied.

During the 23-year period between January 1990 and September 2013, 22 patients (16 girls, 6 boys) underwent 23 transplants. The procedures were performed at Great Ormond Street Hospital, London, (n = 18) and at the Freeman Hospital, Newcastle upon Tyne (n = 5). One patient underwent retransplantation for extensive coronary graft vasculopathy. The most common diagnosis was dilated cardiomyopathy, followed by congenital heart disease. Patient characteristics of this group are detailed in Table 2.6.

Table 2.6 Patient demographics of shared care programme[16]

Patient demographics	
Median age at transplant	3.2 years (range 0.3–13.3 years)
Median age at listing	30 months (range 0.1–13.3 years)
Median waiting list time	2.8 months (range 0.3–14 months)
Median time to return to the referral center from the time of transplant	3 weeks (range 2–8 weeks)

Simmonds et al. report on outcomes comparing the referral centre (Irish patients transferred from OLCHC) and the transplant centre (Great Ormond Street Hospital or to the Freeman Hospital excluding patients referred from OLCHC). Overall outcomes for survival were comparable between the referral and transplant centres, as were the major complications of rejection and coronary vasculopathy (complications that significantly affect postoperative mortality).

Rates of rejection were similar between the referral and transplant centers, with five-year freedom from rejection of 84.4% at the referral center and 79.8% at the transplant center ($p = 0.691$ by log-rank Mantel-Cox).[16]

Coronary vasculopathy was investigated by collecting data from the most recent coronary intravascular ultrasound examination. Data were available for four patients from the referral center and for 74 from the transplant center. There was no significant difference in median values for maximum or mean intimal thickness or stenosis between the groups and the proportions of Stanford grade were also similar.[16]

Graft survival was similar between the referral and transplant centers, with five-year survival of 87.5% at the referral center and 84.4% at the transplant center (p = 0.471 by log-rank Mantel-Cox).[16]

2.2.6.3 International comparison

Outcomes in the UK are comparable to that of other experienced centres internationally. In the current era, the expected one-year survival rate is 80-90%, the two-year survival rate is 80-85% and the five-year survival rate is approximately 70-80% in experienced centers.[20, 26, 27] Universal experience is that that beyond 10 years, a slow attrition rate continues, and a number of children require an additional transplant procedure, usually due to graft vasculopathy.

The International Society for Heart and Lung Transplantation collects exhaustive data globally related to paediatric heart transplantation. Between January 1982 and June 2014, the median survival of patients less than one year of age was 20.7 years following transplant; for patients aged 1–5 years, the median survival was 18.2 years; for patients aged 6–10 years, the median survival was 14.0 years; and for those aged 11–17 years, the median survival was 12.7 years.[8]

2.3 Paediatric liver transplantation

2.3.1 Introduction

The liver carries out multiple life-sustaining functions and despite intensive research efforts, no practical artificial device is yet available to replace a failing liver. A multitude of indications exist for liver transplantation in paediatric patients. These can broadly be classified as the following:

- cholestatic disorders
- metabolic liver diseases with or without cirrhosis
- acute liver failure
- acute and chronic hepatitis
- tumours of the liver.[28]

By far the most common indication is biliary atresia, a childhood disease of the liver in which one or more bile ducts are abnormally narrow, blocked or absent. In fact, the first ever orthotopic liver transplant (liver transplanted to the normal anatomic location) was performed in 1953 to treat biliary atresia in a three-year old.[29]

In the early years, survival after paediatric liver transplantation was low (11%-39%).[30, 31] Since then, long-term survival has improved to up to 90% with long-

term graft survival rates of more than 80%.[28, 32] Additionally, the average age of paediatric transplant recipients has steadily declined, with a continuous increase of patients transplanted within the first year of life due to continuing improvements of surgical and interventional techniques as well as perioperative neonatal and paediatric intensive care medicine.[28]

2.3.2 Service configuration in the UK

In the absence of a national paediatric liver transplant service, children from Ireland requiring liver transplantation are transferred to one of three hospitals in the UK, most commonly King's College Hospital in London. The indications for paediatric liver transplantation contrast strongly with those for adults. In the adult population, the commonest reasons among transplanted patients are alcoholic liver disease, hepatitis from viral infections (hepatitis B and C) and fatty liver disease. The predominant conditions in children are biliary atresia (a neonatal biliary disease resulting in 40-70% of primary transplants), congenital metabolic conditions including alpha-1-antitrypsin deficiency, tumours and acute liver failure. Also of note is that paracetamol toxicity, the commonest cause of acute liver failure necessitating transplant in adult patients, is an uncommon indication for transplant in children.

The NHS Annual Report on Liver Transplantation presents information on the UK transplant list, transplant activity and transplant outcomes between 1 April 2006 and 31 March 2016, for all seven centres performing liver transplantation in the UK.[33] Of these seven centres, four perform adult liver transplantation and three perform paediatric liver transplantation. While paediatric liver transplants are undertaken in King's College Hospital, London; Birmingham Children's Hospital and Leeds General Infirmary, Irish paediatric liver transplant recipients are typically assessed for and subsequently transferred to King's College Hospital only.

The Liver Advisory Group in the UK recently updated its policy for the selection of patients for liver transplantation in April 2017.[4] The following conditions are considered for transplantation in paediatric patients:

1. Acute liver failure. This constitutes a multi-system disorder in which severe acute impairment of liver function with encephalopathy occurs within eight weeks of the onset of symptoms and no recognised underlying chronic liver disease

2. Chronic liver disease

    a. Biliary atresia

    b. Alpha-1-antitrypsin deficiency

    c. Autoimmune hepatitis

d. Sclerosing cholangitis
e. Caroli's syndrome
f. Wilson's disease
g. Cystic fibrosis
h. Progressive familial intrahepatic cholestasis (all types)
i. Alagille's syndrome
j. Glycogen storage disease types 3 and 4
k. Tyrosinaemia type 1
l. Graft versus host disease
m. Budd-Chiari syndrome
n. Any aetiology leading to hepatopulmonary syndrome or portopulmonary hypertension

3. Liver tumours
    a. Unresectable hepatoblastoma (without active extra hepatic disease)
    b. Unresectable benign liver tumours with disabling symptoms
4. Metabolic liver disease with life-threatening extra-hepatic complications
    a. Crigler-Najjar syndrome
    b. Urea cycle defects
    c. Hypercholesterolaemia
    d. Organic acidaemias
    e. Primary hyperoxaluria
    f. Glycogen storage disease type 1
    g. Inherited disorders of complement causing atypical haemolytic uraemic syndrome

The Liver Advisory Group, on behalf of NHS Blood and Transplant (NHSBT), outlines referral pathways to the UK national transplant list.[4]

The criteria agreed by consensus at the Liver Advisory Group are intended to match overall patient numbers to the availability of donated organs. Unlike the adult population, however, the situation for children is less clear. Organs from child donors are in very short supply. Children can benefit from part of an adult donor organ, either reduced or split between two recipients.

2.3.3 Elective and super-urgent selection criteria

There are two categories of patient: "super urgent" and "elective". "Super urgent" patients have sudden liver failure and are likely to die within 48 hours unless transplanted.[33] The criteria for selection of "super urgent" and "elective" liver transplantation in children are included in Appendix 1.[4]

2.3.4 Types of liver transplantation

Many different methods of liver transplantation exist. Firstly, the donor may be deceased (also known as cadaveric donor) or living (less commonly performed). Within cadaveric transplantation, the donor may be "deceased brain dead" (whereby death has been confirmed neurologically, but the circulatory system is functioning) or "deceased circulatory dead" (whereby the circulatory system has failed). In terms of placement in the recipient's abdomen, "orthotopic" liver transplantation refers to placement of the donor organ in the normal anatomic location of the liver (most commonly performed) and "heterotopic" refers to placement in a different location (this occurs when the native liver is not removed during the procedure). Finally, a full-size (or "whole") liver may be transplanted, or the liver may be split in more than one segment (also known as "partial liver transplantation").

2.3.4.1 Cadaveric versus living-donor liver transplantation

Cadaveric donation is the most common form of transplantation. Cadaveric donation may be "donation after brain death" or "donation after circulatory death" (see below).

Living-donor liver transplantation is now also possible, due to the successful development of split-liver transplant in partial liver transplantation (explained below).[28] The advantages of living-donor liver transplantation are the use of an optimal healthy donor, minimal ischemic time, elective surgery and timing of transplantation according to the recipients' need.[28]

2.3.4.2 Donation after brain death versus donation after circulatory death

Donation after brain death (DBD) is the most common form of transplantation. The organ is removed from donors whose death has been confirmed using neurological criteria (also known as brain-stem death or brain death).[34] Neurological criteria for the diagnosis and confirmation of death apply in circumstances where brain injury is suspected to have caused irreversible loss of the capacity for consciousness and irreversible loss of the capacity for respiration and the patient requires mechanical ventilation to sustain life.

Donation after circulatory death (DCD), previously referred to as donation after cardiac death or non-heartbeating organ donation, refers to the retrieval of organs for the purpose of transplantation from patients whose death is diagnosed and confirmed using circulatory criteria.[35] Organ donation after circulatory death (DCD) has been shown to increase the organ donor pool. DCD can be performed either as "controlled donation" (planned withdrawal of medical support) or as "uncontrolled donation" (typically out-of-hospital circulatory arrest).[28] By comparison to DBD, increased rates of ischemic cholangiopathy and mildly reduced graft survival due to prolonged warm ischemia time occurs in DCD liver transplantation.[36, 37] While not widely available internationally, DCD is endorsed in Ireland.[38]

2.3.5 Surgical technique

As noted in Section 2.2.2, organs from child donors are in very short supply. However, children can benefit from part of an adult donor organ, either reduced or split between two recipients.

2.3.5.1 Full-size versus split liver transplantation

The technique of full size liver transplantation in children is equivalent to adult liver transplantation. Partial liver grafts can be obtained by living-donor liver donation or by splitting a cadaveric donor organ. The determination of the eight anatomical liver segments, first described by Couinaud in 1957, is essential.[39, 40] Two standard splitting procedures exist: the anatomical splitting (dividing the liver at Cantlie's line) and splitting along the falciform ligament.[41] Splitting of the left lateral segment is technically easier to perform than the true right/left lobe split procedure. The left lateral segment is also the smallest part of the liver compared to the extended right, the anatomical left or the right liver lobe and is preferentially used in partial liver tranplantation.[28]

In small infants, even the left lateral segment of the liver is often too large and techniques to cut down left lateral lobes may be used to prevent graft-size mismatching and the so-called "large-for-size" syndrome.[42] Due to size mismatch (large graft in small recipient), primary closure of the abdominal wall after partial liver transplantation is often not possible and should not be enforced in order to prevent compromising graft perfusion by external pressure. In these cases, abdominal wall closure is performed in stages during the first week post-transplant after continuous recovery of the graft from reperfusion injury and oedema or accomplished by using mesh grafts.[43]

2.3.5.2 Auxiliary transplantation (APOLT)

A special surgical technique is auxiliary liver transplantation with implantation of a partial graft without fully removing the native liver.[44] This technique is also known as auxiliary partial orthotopic liver transplantation (APOLT). APOLT can be successfully performed in children with acute fulminant liver failure or in children with metabolic liver diseases without primary hepatocellular dysfunction or cirrhosis.[45] The rationale to perform APOLT in patients with metabolic diseases is to provide sufficient liver mass containing the missing enzyme to correct metabolic function. In case of graft failure, the patient's native liver is still present to secure general liver function. Furthermore these patients preserve the option for later genetic therapy if this can be provided to correct metabolic function in the future.[45] If APOLT is performed in acute fulminant liver failure, for example, due to severe hepatic necrosis (viral/toxic), the immunosuppressive therapy can be ceased if the native liver recovers, resulting in an atrophy of the transplanted liver.[46]

2.3.6 Outcomes

2.3.6.1 Overview

Improvements in overall survival over the past three decades have made liver transplantation the treatment of choice for children with advanced acute and chronic liver disease.[47] One of the unique advantages seen in paediatric recipients is the absence of disease recurrence during long-term follow-up. Common indications for transplantation in paediatrics include biliary atresia and inborn metabolic diseases; these do not recur during long-term follow-up.[47] This contrasts sharply to the adult experience of transplanting patients with hepatitis B and C and hepatocellular carcinoma.

Paediatric liver transplant candidates are a distinct population from adult transplant recipients. Risk of disease recurrence, type of graft, potential for life years gained, and potential length of exposure to immunosuppressive medications are major factors affecting outcomes.[48, 49]

Most of the complications of liver transplantation, early and long-term, relate to the need for immunosuppression. Clinical outcomes reflect the following complications:[47]

1. Excess immunosuppression (cancer and opportunistic infections)
2. Inadequate immunosuppression (acute allograft rejection, chronic rejection and late graft dysfunction)
3. Nonimmune complications (cancer, cardiovascular risk factors, and renal disease).

Although the risk is substantial for both children and adults, the potential impact of renal

dysfunction and cardiovascular disease on a child may be even more significant, in part because children may live long enough to develop significant end-organ damage.[47]

The Model for End-stage Liver Disease (MELD) is a widely adopted and validated tool that predicts survival among different populations of patients with advanced liver disease.[50] The Paediatric End-Stage Liver Disease (PELD) score was subsequently developed for paediatric patients.[51] The parameters selected as a basis for this score included total bilirubin, international normalised ratio (INR), serum albumin, age less than one year and evidence of failure to thrive.[47]

2.3.6.2 Outcomes in the UK

NHS Blood and Transplant hold a large database of all transplants in the UK. A six-monthly analysis is carried out jointly by the Royal College of Surgeons' clinical effectiveness unit and NHS Blood and Transplant.[52] In the adult population, 90-day survival after elective liver transplant is over 95%, and patients who survive the first 90 days live on average more than 20 years after transplant. Paediatric transplantation has comparable results, with 80–85% 10-year survival excluding newborns. UK Transplant data shows that patients transplanted between the ages of two and nine years have the best long-term patient and graft survival.

The NHS Annual Report on Liver Transplantation presents information on the UK transplant list, transplant activity and transplant outcomes between 1 April 2006 and 31 March 2016, for all seven centres performing liver transplantation in the UK.[33] Data for the annual report were obtained from the UK Transplant Registry, at NHS Blood and Transplant, that holds information relating to donors, recipients and outcomes for all liver transplants performed in the UK.

There were 81 paediatric liver transplantations performed at three paediatric centres in the UK during the financial year 2015/2016. Of these, 64 were deceased donor paediatric liver transplantations; 55 were for recipients on the elective list; and nine were for recipients on the super-urgent list. Furthermore, 17 were living-donor transplantations, one for a recipient on the super urgent list and 16 for recipients on the elective list. Preliminary data show that between 1 January 2016 and 31 December 2016, a total of 98 liver transplantations were performed in the UK. Since 2014, 15 Irish children received a paediatric liver transplantation in the UK.

To maximise organ viability and successful transplantation, the total ischaemic time should be minimised. The national median cold ischaemia time for transplants from deceased brain dead (DBD) donors has remained relatively stable over the 10-year period, at nine hours. The median cold ischaemia time in the last financial year ranged between seven and nine hours for all transplant centres. The corresponding median for deceased circulatory dead (DCD) donor transplants has decreased from 11 hours

in financial year 2006/2007 to six hours in financial year 2015/2016. However, this is based on very few paediatric recipients transplanted from a DCD donor.

Transplant activity – super urgent transplantation

In financial year 2015/2016, there were 10 super-urgent paediatric liver transplants. Nine of these were from deceased brain dead donors. One was a living donor. The national median waiting time to transplant for super-urgent patients is four days. The median waiting time to transplant is shortest at Leeds and longest at King's College, but there is no statistically significant difference across the three centres.

Survival following super urgent transplantation

One year unadjusted patient survival for 42 transplants between 1 April 2011 and 31 March 2015 is shown in Table 2.7.[33] There were no patient deaths in Leeds.

Table 2.7 NHSBT one-year unadjusted patient survival for paediatric deceased donor super urgent first liver transplants, 1 April 2011 – 31 March 2015[33]

Centre	Number of transplants	1-year survival %‡	(95% CI)
Leeds	5	-	-
King's College	27	79.5	(57.2–91.0)
Birmingham	10	80.0	(40.9–94.6)
Total	42	82.2	(66.1–91.2)

‡ Survival rates for transplant types with less than 10 transplants are not presented due to small numbers

Table 2.8 shows the unadjusted five year paediatric patient survival for 56 transplants between 1 April 2007 and 31 March 2011, nationally and by centre.[33]

Table 2.8 NHSBT five-year unadjusted patient survival for paediatric deceased donor super urgent first liver transplants, 1 April 2007 – 31 March 2011[33]

Centre	Number of transplants	5-year survival %‡	(95% CI)
Leeds	6	-	-
King's College	29	75.7	(55.7–87.6)
Birmingham	19	78.9	(53.2–91.5)
Total	56*	73.1	(59.4–82.8)

* Includes 2 patients transplanted at a non-paediatric centre

‡ Survival rates for transplant types with less than 10 transplants are not presented due to small numbers

Auxiliary transplants are excluded from the results in the above tables. The survival

rates presented in the two tables have wide confidence intervals due to the small number of transplants performed and should, therefore, be interpreted with caution.

Transplant activity – elective transplantation

The number of patients on the active liver only transplant list has ranged between 18 and 42 each year.[33] Between 2015 and 2016 the number increased from 36 to 42. As an indication of post-registration outcomes for paediatric patients listed for a liver transplant, the proportion of patients transplanted six months, one and two years after joining the list was 74%, 85% and 89% between April 2013 and March 2014, respectively. The median waiting time to transplant for elective patients (registered between 1 April 2010 and 31 March 2013) was 72 days.

Survival following elective transplantation

Table 2.9 shows the unadjusted one-year paediatric patient survival for all 210 transplants (excluding auxiliary transplants) from 1 April 2011 to 31 March 2015, nationally and by centre.[33]

Table 2.9 NHSBT one-year unadjusted patient survival for paediatric elective deceased donor first liver transplants, 1 April 2011 – 1 March 2015[33]

Centre	Number of transplants	1-year survival %	(95% CI)
Leeds	29	96.4	(77.2–99.5)
King's College	109	95.4	(89.3–98.1)
Birmingham	72	95.8	(87.6–98.6)
Total	210	95.7	(91.9–97.7)

Table 2.10 shows the unadjusted five-year paediatric patient survival for all 202 transplants (excluding auxiliary transplants) from 1 April 2007 to 31 March 2011, nationally and by centre.[33]

Table 2.10 NHSNT five-year unadjusted patient survival for paediatric elective deceased donor first liver transplants, 1 April 2007 – 1 March 2011[33]

Centre	Number of transplants	5-year survival %	(95% CI)
Leeds	44	86.3	(72.0–93.6)
King's College	91	93.2	(85.4–96.9)
Birmingham	67	94.0	(84.8–97.7)
Total	202	91.8	(87.0–94.9)

2.3.5.3 International comparison

Similar post-paediatric liver transplantation survival estimates are noted internationally. The Australian and New Zealand Liver Transplant Registry Report, 2011, reports a survival post-paediatric liver transplantation of approximately 96% at one year, 92% at five years and 84% at 10 years.[53] Lower estimates are reported in most US cohorts, with survival estimated at approximately 93% at one year, 87% at five years and 81% at 10 years.[54]

2.4 Discussion

Transplantation is the final treatment option for children in end-stage cardiac or liver failure. Unfortunately, organs from child donors are in very short supply and the ever-increasing demand further exacerbates this problem. Paediatric heart or liver transplantation is not available in Ireland and patients are, therefore, listed for transplant in the UK.

The time between removal of an organ from a donor and implantation into the recipient is critical to the success of the transplant. UK transplant centres request a four-hour transfer window for heart transplantation and six-hour window for liver transplantation; this refers to the time between the recipient's family receiving a call advising that a suitable organ is available and the time the child arrives through the doors of the hospital.

Paediatric heart transplant is a rare activity. There were 38 paediatric heart transplantations performed at two centres in the UK in 2016. These were all "donation after brain death" transplantations. Since 2014, seven Irish children received a heart transplant in the UK, one of which was transported as a Priority 1 transfer in 2017. Demand exceeds donor organ availability. The overall number of patients actively waiting for a paediatric heart transplantation in the UK more than doubled between 2013 and 2016 (16 to 37). Increased demand is also reflected in the number of patients on the urgent transplant list, with the numbers increasing from zero in 2007 to twelve in 2016, with an average of six patients on the list each year.

The five year survival after first paediatric heart transplant between 1 April 2007 and 31 March 2011 was 84.1% (95% CI: 76.7–89.3) across both UK centres. Overall outcomes were noted to be comparable for Irish and UK paediatric heart transplant recipients between 1990 and 2013, including complications such as coronary vasculopathy and graft rejection. Outcomes in the UK are comparable to that of other experienced centres internationally.

Many forms of liver transplantation exist. Separate from full-size liver transplantation, children can also benefit from part of an adult donor organ, either reduced or split between two recipients. Both cadaveric (deceased) and living-donor liver transplantation are possible. Within cadaveric donation, "deceased brain dead" indicates death was confirmed neurologically (but the circulatory system is functioning), while "deceased circulatory dead" indicates that the circulatory system has failed. Deceased brain dead is preferable as the warm ischemic time is minimised. Living-donor liver transplantation is now possible due to split-liver surgical techniques.

There were 81 paediatric liver transplantations performed at three paediatric centres in the UK during the financial year 2015/2016. Of these, almost 80% were deceased donor liver transplantations. Over two thirds of recipients were on the elective list and just over 10% of recipients were on the super-urgent list. Preliminary data show that between 1 January 2016 and 31 December 2016, a total of 98 paediatric liver transplantations were performed in the UK. Fifteen Irish children have received a liver transplantation since 2014.

The number of patients on the active liver only paediatric transplant list has ranged between 18 and 42 each year in the UK. There are two categories of patient — "elective" patients and "super urgent" patients, who have sudden liver failure and are likely to die within 48 hours unless transplanted. The median waiting time to transplant is four days for super-urgent patients and 72 days for elective patients. The five-year survival rate was 73.1% for super-urgent patients and 91.8% for elective patients based on most recent available data (1 April 2007 – 31 March 2011). Similar post-paediatric liver transplantation survival estimates are noted internationally.

2.5 Key points

- A paediatric heart or liver transplantation service does not exist in Ireland. Therefore, children are assessed for and listed on the NHSBT transplant list in the UK.
- The time between removal of an organ from a donor and implantation into the recipient is critical to the success of the transplant. UK transplant centres request a four-hour transfer window for heart transplantation and six-hour window for liver transplantation; this refers to the time between the recipient's family receiving a call advising that a suitable organ is available and the time the child arrives through the doors of the hospital.
- There were 38 paediatric heart transplantations performed at two centres in the

UK in 2016. These were all "donation after brain death transplantations. Since 2014, seven Irish children have received a heart transplant in the UK, of which one was transported as a Priority 1 transfer in 2017.

- The overall number of patients actively waiting for a paediatric heart transplantation in the UK increased substantially from 16 in 2013 to 37 in 2016. The number of patients on the urgent transplant list has increased from zero in 2007 to 12 in 2016, with an average of 6.1 patients on the list on the 31 March each year.
- Between 1 April 2010 and 31 March 2013, the median waiting time to deceased donor transplant for paediatric patients registered on the heart transplant list was 96 days. The median waiting time for patients that were "never urgent" was 357 days and "ever urgent" was 81 days.
- As an indication of post-registration outcomes, of the non-urgent heart patients, 0% of patients were transplanted within six months of listing, while 8% died waiting. One year after listing, there were no patients actively waiting on the non-urgent list; 75% had been moved to the urgent list, 8% had been removed and 17% had died waiting, indicating that none had received a transplant.
- The five-year survival after first paediatric heart transplant, between 1 April 2007 and 31 March 2011, was 84.1% across both UK centres. Between 1990 and 2013, there were no significant differences in survival between Irish and UK children receiving heart transplantation
- There were 81 paediatric liver transplantations performed at three paediatric centres in the UK during the financial year 2015/2016. Of these, 64 were deceased donor paediatric liver transplantations; 55 were for recipients on the elective list; and nine were for recipients on the super-urgent list. Furthermore, 17 were living-donor transplantations, one for a recipient on the super urgent list and 16 for recipients on the elective list. Fifteen Irish children have received a liver transplant in the UK since 2014.
- The number of patients on the active liver only transplant list has ranged between 18 and 42 each year. From 2015 to 2016, the number increased from 36 to 42.
- As an indication of post-registration outcomes for paediatric patients listed for a liver transplant, the proportion of patients transplanted six months, one and two years after joining the list was 74%, 85% and 89% between April 2013 and March 2014, respectively.
- There are two categories of patient — "elective" patients and "super urgent"

patients, who have sudden liver failure and are likely to die within 48 hours unless transplanted.

- The median waiting time to transplant for super-urgent patients (registered between 1 April 2010 and 31 March 2013) was four days, and the five-year survival was 73.1% (between 1 April 2007 and 31 March 2011).
- The median waiting time to transplant for elective patients (registered between 1 April 2010 and 31 March 2013) was 72 days, and the five-year survival was 91.8% (between 1 April 2007 and 31 March 2011).

3 Description of the current approach to the transport of Priority 1 transfer patients from Ireland to the UK

The purpose of this chapter is to describe the current approach to the transport of Priority 1 transfer patients from Ireland to the UK. A high level description of the services capable of providing transport for Priority 1 transfer patients is provided as well as a description of how transport logistics are coordinated. The use of Priority 1 transfers is outlined as well as the factors that have impacted the provision of this service.

As noted in Chapter 2, in the absence of paediatric heart and liver transplant services in Ireland, Priority 1 transfer patients mostly comprise children who require emergency transfer to hospitals in the UK to avail of transplantation following notification of the availability of a suitable donor organ. The majority of heart transplants for these patients are undertaken in Great Ormond Street Hospital in London with the majority of liver transplants occurring in King's College Hospital in London. To maximise the likelihood of a successful transplantation, patients must be through the doors of the hospital in the UK within four hours of being notified of a heart becoming available and within six hours of being notified of a liver becoming available. As of 31 October 2017, there are three children resident in Ireland on UK transplant lists awaiting a heart transplant and none awaiting a liver transplant. This is a dynamic list, with the possibility that patients can be added to or removed from the list at any time.

3.1 Background

The recommendations of the HIQA report of the *Inquiry into the circumstances that led to the failed transportation of Meadhbh McGivern for transplant surgery, and the existing inter-agency arrangements in place for people requiring emergency transportation for transplant surgery*, which was published in 2011, forms the basis of the air ambulance service arrangements currently in operation in Ireland.[55]

On the 2 July 2011, delays were experienced in coordinating air transportation, which resulted in a child failing to reach the UK in time for a liver transplant at King's College Hospital, London. At the request of the then Minister for Health, an inquiry was undertaken by HIQA to ascertain the events that culminated in the failure to provide integrated care for this patient and to review inter-agency arrangements for the provision of emergency transport.

The HIQA inquiry recommended that a range of measures should be introduced to ensure properly coordinated, safe and timely transport of transplant recipients. Recommendations included:

- establishment of a single coordinating agency, the National Aeromedical Co-ordination Centre (NACC), in the National Ambulance Service as the single point of contact for all parties involved
- a transport logistics plan for each patient on a transplant waiting list
- appropriate clinical engagement between the National Aeromedical Co-ordination Centre and the hospital or hospitals involved.

A National Aeromedical Coordination Centre was subsequently established and is operated by the National Ambulance Service. Governance of the processes is provided through a National Aeromedical Coordination Group comprising representation from the relevant State agencies and service providers. This group monitors performance against key performance indicators concerning the provision of services to patients.

3.2 Transport providers

The National Emergency Operations Centre (NEOC)**,** which is part of the National Ambulance Service, uses three providers for Priority 1 transfers — the Irish Air Corps, the Irish Coast Guard (IRCG) and potentially private air ambulance companies. There is no dedicated air ambulance service, and all three services are provided on an "as available" basis.

3.2.1 Irish Air Corps (IAC)

The Irish Air Corps is the air component of the Permanent Defence Forces, based at Casement Airbase, Baldonnel, County Dublin. The role of the Air Corps, under the Defence Acts, is to contribute to the security of the State by providing for the military air defence of its airspace. The Air Corps provides a broad range of services in accordance with its primary security role. It also undertakes a diverse range of non-security-related tasks. Inter-hospital transfer is one such non-security task.

Through a Service Level Agreement (SLA)(56) between the Department of Health and the Department of Defence, the Air Corps provides air ambulance patient transport. Air ambulance services are provided using the most appropriate aircraft on an "as available" basis; that is, there are no dedicated aircraft. Air ambulance services include:

- inter-hospital transfer of patients with serious illness/injury

- inter-hospital retrieval
- air transport of patients requiring specialised emergency treatment in the UK and further afield
- air transport of organ retrieval teams within Ireland.

The Air Corps has been assisting the Department of Health since the 1960s. The first formal Service Level Agreement (SLA) between the Department of Defence and the Department of Health for the provision of air ambulance services by the Air Corps was put in place in 2005 and revised in 2007. The SLA was developed in consultation with the HSE, which coordinates these services. The SLA was further revised in 2011.

The SLA defines the totality of the relationship between each agency in respect of the provision of air ambulance services and defines the terms and conditions, within which air ambulance services operate. The scope of the agreement, which includes air transport of patients requiring specialised emergency treatment in the UK, makes it clear that the availability of services is dependent on the availability of suitable aircraft, flying crews, and safe weather and flight conditions.

Aircraft used by the Air Corps for patient transfers include both fixed wing and rotary wing services. Fixed wing services are provided by the Lear Jet and two CASA aircraft; rotor wing services are provided by AW139 and EC135 helicopters. These services operate from the military airbase at Baldonnel, County Dublin.

3.2.2 Irish Coast Guard (IRCG)

The Irish Coast Guard (IRCG), an internal division of the Department of Transport, Tourism and Sport, discharges the State's responsibility for maritime search and rescue (SAR). The primary function of the IRCG service is the search and rescue of survivors from vessels in distress, persons on the water, coastline, inland waterways and remote areas of Ireland. The service also performs a wide variety of functions to assist other State agencies and emergency services as well as monitoring ship-sourced pollution and providing services to the shipping industry. However, as outlined, the IRCG's principal activity is SAR, with the helicopter emergency medical service (HEMS) as a secondary role.

The search and rescue responsibility of the IRCG was provided by the Air Corps prior to January 2004, when it was awarded to CHC Ireland following a competitive tendering process. The search and rescue service again went out to competitive tender in 2012. A contract was then awarded to CHC Ireland for a 10-year period to 2022, with an option to extend to 2025.

Coast Guard helicopter services are provided under contract by CHC Ireland. The contractor operates four bases (Dublin, Waterford, Shannon and Sligo) with one SAR helicopter (Sikorsky S92A) available on 24/7 basis at each base. In order to achieve this level of serviceability, the operator maintains a pool of five helicopters, all of which are rotatable amongst the four bases. The pilots and aircrew are staff of CHC Ireland.

The IRCG provides reserve capacity to the National Ambulance Service on an "as available" basis through an SLA between the National Ambulance Service and the Department of Transport, Tourism and Sport. Crew operate on a 24 hour roster, with a shift change daily at 1pm. Crews are on 15 minutes notice by day (8.30am to 10pm in June, July and August, and 7.30am to 9pm from September through May) and 45 minutes notice thereafter.

3.2.3 Private air ambulances

Private air ambulance providers can be commissioned on a mission-by-mission basis and are funded through the Treatment Abroad Scheme of the HSE Acute Hospitals Division. The HSE maintains a comprehensive list of these providers, who are available to provide services at short notice on request from the HSE. This list is updated on an ongoing basis. However, all providers currently on this list are based outside the Republic of Ireland (Northern Ireland and England), which means the aircraft must first travel to Ireland before travelling to the UK, with consequences for the timeliness of transfers. It should be noted that, to date, with the exception of one transfer that fortuitously could be undertaken on a commercial flight within the accepted time limit when adverse weather conditions prevented the Air Corps and the IRCG from flying, a private provider has never been used for a Priority 1 transfer of a paediatric patient to the UK.

3.3 Co-ordination of transport logistics

The co-ordination of the transport logistics for paediatric transplant patients from Ireland to the UK rests with the aeromedical desk [2] of the National Emergency Operations Centre (NEOC), which is part of the National Ambulance Service.

The NEOC aeromedical desk is manned 24 hours a day and manages all aero-medical missions. A dedicated aeromedical liaison officer assists in the management of all HSE aeromedical operations and liaises with the families of patients on the UK

[2] The NEOC aeromedical desk was previously known as the National Aeromedical Control Centre prior to the merging of regional control centres

transplant lists on a regular basis so that they are kept informed of any developments.

Time is of the essence when transporting Priority 1 transfer patients to transplant centres. From the time of the receipt of the call from the UK that a suitable organ is available, cardiac patients have four hours to get to the UK hospital, while liver transplant patients have a six hour window available. It is, therefore, critical that careful logistical pre-planning is carried out for patient transfers. When a patient is added to the active transplant list, the NEOC aeromedical desk works closely with the relevant hospital administration to develop a transport logistics plan, individualised for each patient.

This plan has all the information required to execute a Priority 1 transport at short notice including:

- demographic data for the patient and parents/guardians (including passport numbers)
- the indicated transport time frame
- contact number for the nearest Garda Síochána station
- flight times for each provider from the nearest airport, and ground transport time from UK airport to hospital
- the total mission time per provider, that is, how long it will take to transport the patient from their home, or hospital, to the receiving hospital for each of the potential transport providers.

An example of a patient logistics communication checklist is provided in Appendix 2.1. The aeromedical dispatcher has 24/7 awareness of the availability and status of all Irish-based assets. The aeromedical desk uses a traffic light system to indicate availability of Air Corps and IRCG assets:

- green (60 minute activation)
- amber (2–5 hours activation)
- red (>5 hours activation or not available).

Availability is updated twice daily, in the morning between 9.00am and 10.00am and in the afternoon between 4.00pm and 5.00pm. It is standard operating procedure to notify the aeromedical desk if an aircraft changes status during a duty period. The aeromedical desk is also notified once an aircraft is placed back in service.

In 2016, the IRCG bases were generally green 24/7 — an individual aircraft may have been amber or red, but generally there were at least three of the four IRCG bases green at any one time.

When an organ becomes available, the transplant coordinator in the UK contacts the:

- NEOC aeromedical desk
- relevant hospital administration (Our Lady's Children's Hospital, Crumlin, (OLCHC) or Temple Street Children's University Hospital)
- the child's parents.

OLCHC also inform both the NEOC aeromedical desk and the parents of the call to ensure all relevant parties have been contacted. An example of a hospital-level plan outlining the steps and personnel involved in the emergency transfer of a critically ill patient abroad for transplant surgery is provided in Appendix 2.2.

The individualised transport logistics plan is used by the NEOC aeromedical desk to make decisions on the most appropriate transport based on asset availability at that moment in time. The aeromedical dispatcher chooses the most appropriate service provider based on the location of the child, the location of the aircraft, fixed-wing versus rotor wing aircraft, weather conditions and any other considerations pertinent at the time (for example, the level of medical support required — nurse accompaniment for ambulatory patient or a medical team including an intensivist plus nursing support for a ventilated patient).

As a general rule, fixed wing flight speed is double that of rotor wing. This is important given the tight timeframes, particularly for heart transplant patients. Examples of travel times are included in Table 3.1 below.

Table 3.1 Travel times for aircraft between Dublin and London

Service provider	Aircraft type	Travel time from Dublin to London
Air Corps	Learjet	60 minutes
	CASA 295	90 minutes
	AW139 Helicopter	115 minutes
IRCG	S92 Helicopter	108 minutes

These times are indicative and weather-dependent, as prevailing wind speed and direction may alter flight times. Moreover, severe storm conditions, fog, frost or snow could make flight transfers impossible. There was the unprecedented situation on the 22 January 2017 where a liver transplant patient could not be transported to King's College Hospital in London using the Air Corps or IRCG due to severe fog conditions. The transfer was successfully provided via a commercial Aer Lingus flight to London Heathrow.

In general, the preferred option is Air Corps fixed-wing (based on speed), followed by the IRCG or Air Corps helicopter, and then private air ambulance. As the latter are based in Northern Ireland or the UK, they must fly to the Republic of Ireland to collect the patient before flying on to the UK. The absence of de-icing rotor blades on the Air Corps AW 139 generally mitigates against its use for Priority 1 transfers during the winter.

The dispatcher also co-ordinates ground transport in Ireland, advises time of aircraft arrival in the UK airport and alerts the relevant UK ambulance service of same to ensure urgent "blue light" transfer from the airport to the hospital. For transfers to London, the Air Corps and the IRCG have access to the Royal Air Force Northolt airbase, which is accessible Monday to Friday (until 8.00pm), or London Heathrow outside those hours. Most of the commercial providers use London Heathrow. The transfer time from London Heathrow Airport to Great Ormond Street Hospital is calculated at approximately one hour. The transfer time from the Northolt RAF airbase to Great Ormond Street Hospital is calculated at approximately 52 minutes.

Since the NEOC was established in 2012, all Priority 1 patient transfers have been completed by either the Air Corps or the IRCG, with the exception of the one transfer by Aer Lingus in January 2017. Details of the transfers undertaken are provided in Table 3.2.

Table 3.2 Priority 1 transfers by Mission Type and Service Provider (2012–2017 YTD)

Year	Mission type	Patient location	Service provider
2012	Liver x 3	OLCHC x2 Home x1	Air Corps (All)
2013	Liver x 4	OLCH x 3 Home x 1	Air Corps (All)
2014	Kidney x 1 Heart x 2 Liver x 4	Temple St Hosp. x 2 OLCHC x 3 Home x 1 Wexford Hospital x 1	Air Corps (All)
2015	Liver x 1	OLCHC	Air Corps
2016	Liver x 8 Liver & Kidney x 1	OLCHC x 2 Home x 7	Air Corps x 1 IRCG x 8
2017 YTD	Liver x 6 Heart x 2	OLCHC x 2 Home x 6	Air Corps x 3 IRCG x 4 Aer Lingus x 1

Abbreviations: OLCHC, Our Lady's Children's Hospital Crumlin; IRCG, Irish Coast Guard.

Since the NEOC was established in 2012, all Priority 1 liver patients have been transplanted in King's College Hospital. One patient was transferred to Birmingham Children's Hospital for a combined liver and kidney transplant in 2016. As a dedicated national paediatric renal transplant unit is available in Ireland based in Temple Street Children's University Hospital, paediatric kidney transplants are normally completed in Ireland and are not normally considered for Priority 1 transfers. One patient was, however, transferred to Birmingham for a kidney transplant in 2014 due to exceptional circumstances. The notified timeframe for the kidney transplant patient to get to Birmingham was five and a half hours, while the notified timeframe for the liver and kidney transplant patient to get to Birmingham was four and a half hours.

Four cardiac Priority 1 transfers have been undertaken to Great Ormond Street Hospital: two by the Air Corps in 2014 and one in 2017 plus one by the IRCG from Shannon airport in 2017. While other cardiac patients have been transferred to the UK, these missions were scheduled in advance and carried out by the Air Corps. For example, in 2016, there were 12 patients who had consultations and or treatments

relating to their cardiac transplant status at Great Ormond Street Hospital on 15 different dates. These were scheduled transport missions and were not classified as Priority 1 transfers.

3.4 Current situation

3.4.1 Priority 1 transfers by service providers (2012–2017)

Between 2012 and 2015, all of the Priority 1 transfers were undertaken by the Air Corps. Following changes to the rostering of the Air Corps in June 2016, details of which are outlined in Section 3.4.2 below, the majority of the transfers were undertaken by the IRCG. In 2016, eight of nine transfers were provided by the IRCG, comprising seven children transferred for liver transplant and one for a combined liver and kidney transplant. The trend whereby the majority of transfers were undertaken by the IRCG continued until September 2017, with three of the first four transfers in 2017 conducted by the IRCG.

Temporary contingency measures were put in place by the Air Corps to provide night time cover for Priority 1 transfers from 5th September 2017 until 6th November 2017. During this period to the date of this publication, there have been four Priority 1 transfers, three night-time transfers by the Air Corps (two on the same evening, highlighting the unpredictable requirements for the Priority 1 transfer service) and one daytime transfer by the IRCG.

3.4.2 Changes to the availability of Irish Air Corps (IAC)

As with other areas of the public service, challenges have arisen in relation to the recruitment and retention of personnel with specialised and highly marketable skills, including pilots, Air Traffic Control staff and aircraft technicians. The challenges for the Air Corps have been particularly acute. The loss of a number of experienced pilots and air traffic control personnel have impacted on the organisation and limited Air Corps availability for unscheduled air ambulance and other services, such as provision of Top Cover for SAR missions or contingency for security roles. This necessitated the stand-down of the 24 hour roster in June 2016. As a consequence, there was an increased reliance on the IRCG and private providers for air ambulance services.

The impact of the capacity issues on Air Corps asset availability is evident from the data reports for the traffic light system used by the NEOC. In the first months of 2016, the Air Corps fixed wing service was generally amber 24/7. There was some green availability (Monday to Friday 9.00am to 4.30pm), while assets were rarely listed as red. From June 2016 until September 2017, Air Corps assets were amber

roughly 40–50 hours per week (Monday to Friday 9.00am to 4.30pm), and consistently red (indicating non-availability) after 4.30pm as well as all through Saturday and Sunday.

The provision of an inter-hospital service during the daytime by the Air Corps has continued on an "as available" basis despite the staffing challenges. In addition, following a request from the Department of Health, temporary contingency measures were put in place following the suspension of IRCG night time service. This provided the HSE Priority 1 cover at night time from 5 September 2017 allowing some time for the HSE to address the operational challenges. This contingency cover is provided in line with the Service Level Agreement already in place, that is, it is on an "as available" basis. However, it is noted that the Air Corps are not in a position to extend this contingency cover beyond 6 November 2017, for safety and operational reasons.

It is important to note that there is considerable work taking place within the Defence Organisation to address the shortages in experienced personnel in the Air Corps and to improve the retention of experienced personnel. However, this problem will likely take a minimum of two to five years to resolve.

3.4.3 Restriction on IRCG Availability

The Department of Health was advised by the Department of Transport, Tourism and Sport on 31 July 2017 that following a review by the Irish Aviation Authority of existing arrangements for aeromedical services, all patient transfers provided by the IRCG for the NAS must be operated under HEMS rules with effect from 5 Sept 2017. Through the application of European Commission Regulation (EU) No. 965/2012 on Air Operations,[57] Priority 1 transfers by the IRCG are classified as HEMS flights and are subject to commercial air traffic flight rules. These regulations specify a maximum of 12 hour shifts with a minimum of ten hours uninterrupted rest between shifts. This differs from SAR flight rules, which allow for 24 hour rosters. Resulting restrictions to the availability of the IRCG for HEMS and air ambulance activity from 5 September 2017 are outlined in Table 3.3.

Table 3.3 IRCG HEMS/air ambulance availability from 5 September 2017

Time	Availability	Comment
1.00pm–11.00pm	No HEMS/air ambulance restrictions	Flight commander obliged to plan on aircraft being back at base at 11.00pm
9.00pm (10.00pm in the summer)–11.00pm	HEMS requests can be processed with caveat that crew become unavailable for further HEMS during that shift (that is, to 1.00pm on the following day)	Flight commander obliged to plan on aircraft being back at base at 11.00pm
7.30am (8.30am in the summer)–1.00pm	Available for HEMS/air ambulance provided duty crew had 10 hours uninterrupted rest from 9.00pm (10.00pm in the summer)	

While domestic patient transfer services are impacted, in that the National Ambulance Service no longer has 24 hour access to the IRCG for aeromedical services, the most serious impact is on Priority 1 transfers to the UK. Under these restrictions, requests for Priority 1 transfers can only be accepted where a flight commander can plan on a return to base by 11.00pm. Given an estimated four hour return trip for a helicopter transfer from Dublin to London, these restrictions have the effect that the IRCG is no longer available for Priority 1 transfer deployment between the hours of 7.00pm and 7.30am given the arrangements of the current contract with CHC Ireland. However, it is noted that flights could leave Ireland up to 11.00pm for the UK if required, but this would result in an aircrew rest occurring in the UK, leading to potential unavailability of the helicopter and aircrew until 3.00pm the following day impacting on IRCG's primary remit of Search and Rescue.

The restricted availability of air transport at night is a particular concern for patients being transferred for solid organ transplant. As outlined in Chapter 2, due to hospital logistics, notification of an organ becoming available typically occurs at night time. Table 3.4 outlines the times that aircraft were requested for Priority 1 missions to the UK since 2012.

Table 3.4 Time of aircraft requests for Priority 1 transfer missions to the UK (2012–2017 YTD)

Priority 1 Transfer Missions to the UK (2012 – 2017 YTD)			
Time of aircraft request	**Number**	**Mission Types**	**% of total transfers**
7.00am to 7.00pm	8	Liver x 6 Kidney x 1 Heart x 1	25%
7.00pm to 7.00am	24	Liver x 20 Heart x 3 Liver and Kidney x 1	75%
Total	32		100%

More transfers are carried out during the out of cover hours from 7.00pm to 7.00am, with 75% of the missions from 2012 to 2017 YTD occurring at this time. Of the transplant patients transferred during the 7.00pm to 7.00am timeframe, 12.5% needed to be transported within the four hour window. Since 2012, there have been only two Priority 1 transfers that did not meet the transfer time key performance indicator targets by a small margin; neither had clinical consequences for the transplant patients involved.

3.4.4 Financial assistance to families who relocate to the UK

Due to the difficulties that arose with availability for the Priority 1 transfer of patients during 2016, options were explored to mitigate the risk that transport would not be available. In February 2017, the Department of Health requested the HSE to facilitate families, where the clinical recommendation from the NAS was that the child should relocate, by providing a financial contribution to their living costs in the UK. Approval for the financial support is on a case by case basis and relates to those families, for whom there is an identified transfer timeline risk, relocating to the general vicinity of the transplant centre in the UK to mitigate this risk. Under the provisions of the Treatment Abroad Scheme (TAS) which is governed by EU regulation, the HSE covers the cost of the treatment for which the patient has been approved. While the governing regulation does not provide for the cost of travel or subsistence, the HSE introduced a national policy for TAS patients in 2009, whereby the flights of the patient and, in the case of a child, the patient plus one adult are reimbursed by TAS. With the exception of Exceptional Needs Payments through the Department of Social Protection for families experiencing undue hardship, no other financial support is typically provided.

However, the choice to relocate is not available to all patients. As of 31 October 2017, there are three children resident in Ireland listed for heart transplant in the

UK. These patients are in Our Lady's Children's Hospital, Crumlin, and are not well enough to live outside a hospital environment. Children may be transferred for clinical reasons to Great Ormond Street Hospital ahead of an organ becoming available. However, the possibility of transfer is limited to children who deteriorate clinically and for whom a ventricular assist device is an option.

3.5 Factors affecting successful Priority 1 Transfers

The likelihood of successfully transporting a paediatric organ transplant candidate to a UK hospital is dependent on a number of factors:

- location in Ireland and proximity to an airport and air transport provider
- organ transplant type (liver versus heart)
- activation time (day versus night and weekday versus weekend)
- inpatient (usually requiring medical escort etc.) versus resident at home
- fixed wing versus rotor wing air asset
- weather conditions.

The factors that could potentially be controlled from those listed above include:

- The location of the patient in Ireland could be changed to ensure closer proximity to an airport. This may be necessary for patients that are resident at home if their transport logistic plan indicated that there was a risk of missing target transfer times.
- The choice of aircraft could be restricted to fixed wing aircrafts to minimise the transfer times.

The type of organ transplant determines the target transfer time for the mission. For heart transplants, the transfer window is four hours. The actual timeframe and the activation time is determined by the transplant centre in the UK when the donor organ becomes available. The "as available" basis of the transport services does not provide certainty in meeting short time windows at night time.

The weather conditions are an uncontrollable risk factor for air travel.

Overall, the current reduction in Air Corps fixed wing availability reduces the resilience of Priority 1 transfers. Combined with the loss of the IRCG night-time service, this jeopardises the likelihood of successful transport of heart transplant patients.

3.6 Discussion

Whilst acknowledging that the remit of this health technology assessment is to evaluate the transport options for Priority 1 transfer patients, this is just one aspect of all the aeromedical transport services conducted within and from Ireland.

The other aeromedical activities conducted in Ireland include:

- The **Emergency Aeromedical Support (EAS)** service, which was established on a permanent basis in 2015 in the context of the report of the Emergency Aeromedical Support (EAS) service working group. The government agreed that the service model used in the successful pilot since June 2012, which used existing state resources, with aerial support to the National Ambulance Service (NAS) from the Air Corps and reserve support from the IRCG, would continue to be employed. However it was noted that the various options considered in the working group report would be kept under review in the context of ensuring a sustainable long-term service arrangement. The objective of the EAS service is to provide rapid access to appropriate treatment for high acuity patients, specifically where road transit time, given the patient's condition and its severity, would not be clinically acceptable, particularly with regard to HSE clinical care programmes such as Acute Coronary Syndrome, Stroke and Trauma. This service is categorised as a HEMS and is primarily limited to pre-hospital patient transfers. It operates seven days a week in daylight hours from Custume Barracks, Athlone, and has a dedicated two-pilot EW 139 helicopter. The aircraft and crew are provided by the Air Corps, while the NAS provides an advanced paramedic. This service generally operates within the Republic of Ireland with particular emphasis on the west of Ireland. To date, the EAS Service has not been tasked with undertaking a Priority 1 transfer to the UK.
- **Scheduled inter-hospital transfers,** which are conducted by the Air Corps and the IRCG on an "as-available" basis.
- Aeromedical missions conducted on behalf of the **National Transport Medicine Programme (NTMP)**, whose aim is to establish and develop a comprehensive retrieval/transfer system for seriously ill babies, children and adults throughout Ireland. The work of this programme enables the timely retrieval/transfer of critically ill or severely injured patients by appropriately trained and skilled teams of healthcare professionals who get the right patient, to the right care, in the right condition, in the right time. The service operates where patients can be transferred from one hospital to another for specialist treatment and, when appropriate, the patient can be transferred back to the original hospital for on-going care. This ensures the patient gets the most appropriate care to meet their clinical needs.

- **Irish Paediatric Acute Transport Service (IPATS)**, which is part of the NTMP. IPATS is in operation since October 2014 on a 10.00am to 8.00pm, Monday to Friday basis. IPATS is delivered jointly by the two tertiary paedriatic intensive care units (PICUSs) in Dublin (Temple Street Children's University Hospital and Our Lady's Children's Hospital, Crumlin) and provides transport and or logistical support for high risk transfer of critically ill infants, children and adolescents for continuing medical care not available in Ireland (for example, solid organ transplant). It also facilitates the repatriation of critically ill paediatric Irish citizens from institutions outside of the State for continuing medical care in the State. Semi-elective and planned aeromedical evacuations to the UK from the PICUs are typically facilitated by the IPATS or IPATS trained staff during daylight hours. Outside of daylight hours, Priority 1 transfers are facilitated by a team from the referring hospital, which may or may not include IPATS-trained staff.

It is noted that the Priority 1 transfer of transplant patients to the UK can range from an air taxi to a full air ambulance service. While all require expedited transfer to the UK, not all need to be accompanied by medical support. Air ambulance, applies to critically ill patients (for example, heart transplant patients who may require elective intubation and ventilation to travel to the UK) who require specialist equipment for the transfer and must be accompanied by a medical team or IPATS.

3.7 Key points

- The National Emergency Operations Centre is responsible for coordinating the transport logistics for paediatric transplant patients from Ireland to the UK.
- There is no dedicated air ambulance service and all services are provided on an "as available" basis. There have been three providers for Priority 1 transfers — the Air Corps, the Irish Coast Guard (IRCG) and private air ambulance companies.
- Since 2012, there have been 32 Priority 1 transfers for paediatric transplant patients. Missions by transplant type were: liver (n=26), heart (n=4), kidney (n=1) and combined liver and kidney transplant (n=1). Seventy five percent of transfers were conducted between 7.00pm and 7.00am.
- Between 2012 and May 2016, 94% (that is, 15 of 16) of the transfers were conducted by the Air Corps; only one of these 16 missions was conducted by the IRCG in April 2016. However, with services restricted to day time between June 2016 and Sept 2017 due to capacity constraints, the Air Corps only conducted 8% (that is, one of 12) of the Priority 1 transfers. The IRCG

conducted 83% (that is, 10 of 12) of the transfers in this time period. One transfer, in January 2017, was conducted via a commercial Aer Lingus flight due to adverse weather conditions.

- Since 5 September 2017, the availability of IRCG has been limited to 7.30am to 7.00pm cover. The Air Corps resumed stand-by rosters to provide cover for Priority 1 transfers on a temporary basis until 6 November 2017. Since the resumption of the stand-by rosters, there have been three night-time Priority 1 transfers conducted by the Air Corps, with two transfers taking place during the same night. The IRCG has also conducted one daytime transfer from Shannon to London.

- Despite the restricted availability of the Air Corps and IRCG during 2016 and 2017, to date, there has never been a requirement to use a private air ambulance provider for Priority 1 transfers.

4 Overview of services used in the UK for the urgent transfer of patients to specialist transplantation centres

For paediatric heart and liver transplant patients living in the UK and Ireland, surgery is carried out at specialist centres based in England. As with Irish patients, those living in Northern Ireland, Scotland and Wales must also be transferred to English hospitals for surgery. It is, therefore, reasonable to look at the solutions used in those countries to achieve safe and timely transfer of paediatric transplant patients, and to consider if Ireland can learn from or use any of the current models. The purpose of this chapter is to provide an overview of the services in the UK and elsewhere for the transport of patients to transplant centres.

4.1 Transportation of organs in the UK

The majority of liver and heart transplant centres in the UK and Ireland are based in England. For adult liver transplants, there are six centres in England (Birmingham, Cambridge, Kings College Hospital London, Leeds, Newcastle and the Royal Free Hospital in London), there is one centre in Edinburgh, Scotland and one centre in St Vincent's University Hospital, Dublin. For paediatric liver transplants there are only three centres: Leeds, Birmingham and King's College Hospital in London. For adult heart transplants there are five centres in England (Birmingham, Harefield, Manchester, Newcastle and Papworth), one centre in Glasgow, Scotland and one centre in the Mater Misericordiae University Hospital, Dublin. Only two centres carry out paediatric heart transplants: Newcastle and Great Ormond Street Hospital, London. Therefore some areas of the UK face similar difficulties to Ireland in transporting patients, particularly paediatric patients, to the transplant centre within the required timeframes (four hours for a heart transplant and six hours for a liver transplant).

NHS Blood and Transplant manage the NHS Organ Donor Register and the National Transplant Register which allows for the matching of donors with people on the transplant list. In 2010, NHS Blood and Transplant established the National Organ Retrieval Service (NORS) which provides a 24 hour service for retrieving organs from deceased donors across the UK. The NORS teams are made up of highly skilled healthcare professionals, and are surgeon led. It is the responsibility of the recipient centre to arrange transport of retrieved organs from the donor hospital to the recipient transplant centre (with the exception of kidneys).[58, 59] Organs and the transplant recipient are usually transferred separately to the transplant centre.

A locally agreed transport company with a service-level agreement (SLA) is used to ensure the conditions for transport of the organ are suitable and the integrity of the organ is maintained and delivered within the required time interval.[60] Amvale Medical has a contract with NHS Blood and Transplant to provide this service and is the biggest supplier of transport to provide a 24/7 transport service to ensure transplant organs, specialist nurses in organ donation, and surgical teams can get to where they need to go in the UK, Ireland or mainland Europe. They have access to a number of land, sea or air transportations options depending on the location of the organ. When air transport is required, they use chartered or scheduled flights for transfer and they arrange all necessary ground transportation. When it is not possible to arrange a commercial flight on time, they have a relationship with Her Majesty's Coastguard and the Royal Air Force (RAF) for the transport of organs and organ retrieval teams.

4.2 Transport of patients from England and Wales

With a population of 55.3 million,[61] England has the majority of specialised transplantation centres. In 2015–2016 there were 5,567 patients on the active transplant waiting list in England and 192 patients in Wales.[62, 63] In the same time period there were 3,808 organ transplants in England and 214 in Wales. Between England and Wales, there were 175 (35 paediatric) heart transplants and 800 (70 paediatric) liver transplant operations in 2015/2016.[62-64]

If the patient is close enough to the hospital, and is well enough, they make their own way to the hospital. However, there are a number of specialised transport services available in England and Wales. These tend to be region specific, but they carry out the transfer of patients out with the region for the purpose of transplant surgery. For example, the North West and North Wales Paediatric Transfer Service (NWTS), has two teams available, the second of which provides long distance transfers to limit interference with regional services.[65] NWTS also has access to air ambulance services for any transfers that are over 90 to 120 minutes in duration (as per national guidelines proposed by Paediatric Intensive Care Society Acute Transport Group). The use of these services are dependant of a number of factors including weather, availability of aircraft and fitness of the patient to fly.[65] The air ambulance service consists of flight teams in the Isle of Man and The Children's Air Ambulance (TCAA). The TCAA is a charity-funded national helicopter service that provides inter-hospital transfer of critically ill children for specialist care and is part of the air ambulance service in England. In England and Wales the air ambulance services are mostly funded through charitable donations.[66]

In the Yorkshire and Humber region, Embrace, which is part of the Sheffield Children's NHS Foundation Trust, provides highly specialised, 24/7 transport service for critically ill infants and children in Yorkshire and Humber who require care in hospital within the region or further afield. As well as road transfers, Embrace has access via private air ambulance services (IAS Medical and Air Alliance) to fixed wing aircraft from within the UK and abroad for the transfer of patients. They also have access to two charity-funded HEMS services, The Children's Air Ambulance (TCAA) service and the Yorkshire Air Ambulance (YAA) service, as well as Bristow Search and Rescue helicopters (UK Coastguard). Embrace is currently the biggest provider of inter-hospital aeromedical transport in England and is accredited by the Commission on Accreditation of Medical Transport Systems (CAMTS).[67] In 2016, Embrace transferred 2,102 children, travelled 170,000 road miles, undertook eight fixed wing missions and 30 helicopter missions.[67]

Transport companies (e.g. Amvale Medical) can be asked to provide transport for transplant patients. The costs involved depend on the type of transport used and the medical personnel and equipment required for transport. For air transport this can vary substantially depending on the aircraft available at the time, where it is located, if a medical team is needed for the transfer and or if the plane needs to be able to take a stretcher and specialised equipment.

4.3 Transport of patients from Northern Ireland

Northern Ireland has a population of 1.9 million,[61] but has no liver or heart transplant programmes. In 2016–2017, 19 (two paediatric) patients requiring a liver transplant and six (two paediatric) patients requiring a heart transplant travelled to either England or Scotland for surgery.[64, 68, 69] Adults most often travel to King's College Hospital in London [70] while children tended to travel to Birmingham Children's hospital for their liver transplant.[68]

4.3.1 Transport

In Northern Ireland there is a specialist paediatric transport service called Northern Ireland Specialist Transport and Retrieval Services (NISTAR); however, this service only covers ground transport and is not involved in transfer of patients to the UK.

The transfer of patients to the UK depends on how fit the patient is to travel and the time at which the patient needs to arrive at the hospital. Patients who are living at home travel to the hospital in the UK via commercial airline when this is possible. For planned procedures travel is arranged by the Patient Travel Team. The cost of accommodation and subsistence for the patient and those travelling with the patient can be reimbursed, subject to approval, at a rate of £85 for a single room (£125 in

London, greater London or Dublin) and £15 for subsistence per adult and £5 per child under 5 years old. Where commercial flights are not available or the timeframe is too short, the Health and Social Care Board (HSCB) in Northern Ireland cover the cost of Woodgate Aviation transferring these patients.

Woodgate Aviation is a private company that has provided the transport of patients to the UK from Northern Ireland for more than 10 years. Woodgate Aviation is under contract with the NHS to ensure a 24/7 service for the transfer of patients to the UK and is based at Belfast International Airport. It is the first point of contact for the transplant coordinator and organises all aspects of the transfer including ground transport to the airport and ground transport from the airport in the UK to the hospital. Ground transport can include a private ambulance or a taxi depending on the medical needs of the patient. If it is outside normal office hours and the patient is well enough to travel by commercial airline and it would be quicker for them to do this, then Woodgate Aviation coordinates the transfer of the patient. That is, Woodgate Aviation:

- arranges for the patient to get to the airport in Belfast
- books the ticket for the patient on the commercial airline
- contacts airport security and the airline to make them aware of the situation and to ensure the patient is fast tracked through security
- arranges ground transportation from the UK airport to the hospital.

As an example, if a patient who is deemed to be well enough to travel by commercial airline needs to be transferred to King's College Hospital and the call comes in after 2am, they might arrange for the patient to get the first commercial flight out of Belfast to London (6.15 am flight arriving in London City airport at 7.30 followed by a 20 minute road transfer to King's College Hospital) if this is within the clinical window given to them by the transplant coordinator.

If the patient is unable to travel by commercial airline or the timeline does not allow it, Woodgate Aviation has two Beech Kingair 200 planes that are fully pressurised and therefore operate at higher altitudes to allow for smoother flying conditions and faster transit times. These aircraft can be used as air ambulances and have LifePort stretcher systems that fit into the planes allowing patients who require ICU care to be transferred safely. Depending on the level of medical care required for the patient, Woodgate Aviation provides a medical team for the transport of the patient. Currently around 60% of their transfers are nurse-led, but a full medical team, including paediatric anaesthetists can be provided when required. For a patient

being transferred to London from Belfast, transit time is approximately one hour and 20 minutes. Woodgate Aviation flies into Stansted airport as it is open 24/7; from Stansted airport there is a 45 minute road journey to King's College Hospital.

In 2016, Woodgate Aviation transferred more than 430 patients to the UK, most of which were planned transfers. Following discontinuation of the paediatric cardiac surgery services for congenital heart disease patients in Northern Ireland in 2015, many of the transfers related to infants requiring cardiac surgery. If itsr own aircraft are not available, Woodgate Aviation will locate and organise for another private plane or air ambulance service to transfer the patient. Woodgate Aviation does not usually arrange for the transfer of patients back to Northern Ireland after a procedure; most of these patients will travel by commercial airline once they are well enough and this will be arranged by the Patient Travel Office.

The cost of Woodgate Aviation transferring a patient to the UK is covered by the Health and Social Care Board in Northern Ireland (HSCB) based on a fixed fee per transfer. The fees are calculated on a combination of the location of the receiving hospital and the category of the patient. The category of the patient is determined by the urgency of the transfer (ranging from a requirement to be bedside to retrieve the patient in 90 minutes to a planned transfer two weeks later) and the level of medical support required during the transfer (ranging from nurse-led to medical team comprising paediatric anaesthetist plus specialist nurse).

The contract between Woodgate Aviation and the NHS was renewed in January 2017 following an open tendering process.

The coastguard and the RAF provide a backup service for Woodgate Aviation; however, to date they have never been used to transfer a patient to the UK from Northern Ireland.

4.3.2 Other air ambulance services

A helicopter air ambulance service has recently been established in Northern Ireland. This service provides an air medical service dedicated to responding to serious trauma emergencies within Northern Ireland and is not used for the transfer of patients to the UK. It is based near Lisburn with a spare aircraft at a secondary base in County Fermanagh. The cost is estimated to be around £2 million a year, half of which is paid by the health service in Northern Ireland and the other half is provided by the charity, Air Ambulance NI. The charity works in partnership with the Northern Ireland Ambulance service to provide a HEMS service.

4.4 Transport of patients from Scotland

Scotland has a population of 5.4 million,[61] and currently has centres that carry out adult heart and liver transplants. Paediatric heart and liver transplants are all carried out in England (liver: Leeds, Birmingham or Kings College London; heart: Newcastle or Great Ormond Street London). In 2016–2017, 116 (14 paediatric) patients from Scotland received liver transplants and 16 (0 paediatric) patients received heart transplants.[64, 71]

4.4.1 Transport

Following a strategic review of Scotland's patient transport arrangements in 2011, it was recommended that specialist retrieval services should be harmonised. ScotSTAR was a result of this recommendation and was formed in 2014. It brings together the Scottish Neonatal Transport Service, the Scottish Paediatric Retrieval Service and the Emergency Medical Retrieval Service and is part of the Scottish Ambulance Service. The base of operations is a purpose-built building at Glasgow Airport with clinical satellite teams in Edinburgh and Aberdeen. Each of the teams is predominantly consultant-lead and supported by trainees, nurses and nurse practitioners. This national service ensures that critically ill patients are transferred within and outside Scotland, this includes the coordination and transfer of transplant patients from the base hospital to the transplant centre (with the exception of extracorporeal membrane oxygenation (ECMO) patients who are transferred by a voluntary team from Glasgow PICU with logistical support from ScotSTAR). In 2015–2016 ScotSTAR completed 2,277 transfers and retrievals (including 235 paediatric transfer and retrievals by road and 88 by air) at a cost of £9.8 million.[72]

When a patient is added to the transplant list, a transportation plan including road and flight times is developed for the recipient by the transplant centre in collaboration with ScotSTAR. When an organ becomes available, the referring clinician contacts ScotSTAR and arranges via conference call with paramedics, local nursing staff and retrieval specialists for the child to be transported to the hospital. ScotSTAR has a number of retrieval specialists on their team including paediatric intensive care unit (PICU), anaesthetic consultants, associate specialists, nurse consultants and a team of band six nurses. All of the specialists are employed by the Scottish Ambulance service which funds ScotSTAR. ScotSTAR does not transfer organs or organ retrieval teams; this is organised separately by other transport providers such as Amvale Medical.

ScotSTAR has access to a number of air ambulance options through the Scottish Ambulance Service's Air Ambulance section. The Air Ambulance service flies over 3,500 missions every year and works closely with Search and Rescue aircraft of the

Ministry of Defence and HM coastguard. It is the only air ambulance service in the UK that is solely funded by the government.[73] The service is operated under contract by Gama Aviation. The service has two new H145 helicopters based at Glasgow and Inverness and two King Air 200c fixed wing aircraft which operate from Glasgow and Aberdeen. The aircraft have been purpose-built for the needs of the air ambulance service. If these aircraft are not available, the Bristow Search and Rescue coastguard helicopters can be requested to help with the transfer of patients.[74]

Following a conference call with the transplant centre and transport team, depending on the needs of the child, the aeromedical transfer can be with a nurse, a medical team or a paramedic.

For a child who is very ill and requires care that is not available to them at their local hospital, they are transferred to the PICU in the quaternary hospital to wait for transplant.

4.4.2 Other air ambulance services

Shetland and Orkney Islands are among the most remote areas of Scotland. In 2015–2016, 280 air ambulance missions were from Shetland and 440 were from Orkney, which accounts for almost 19% of all Scottish air ambulance missions for the year.[74] In Shetland, a private company called Loganair provides scheduled passenger flights and services for the Royal mail. In addition, it has been providing air ambulance services for the Scottish Ambulance service since 1967.[75]

Scotland's Charity Air Ambulance provides a charity funded air ambulance service based in Perth since 2013. The charity received government funding of £3.3m in 2015 to fund a new helicopter, while other costs are met through charitable donations. It operates a Eurocopter E135 helicopter that is staffed by Scottish Ambulance paramedics and receives tasks/missions from the Scottish Ambulance Service ambulance control centre.

4.5 UK Coastguard

The UK Coastguard has recently changed from a military operation to a civilian contract-based service. In 2013, Bristow Helicopters won the contract to deliver search and rescue operation on behalf of the Maritime and Coastguard Agency. Search and rescue is a State activity and is not regulated under EU law; it is regulated by National Aviation Authorities. CAP 999 outlines national approval guidance for SAR in the UK.[76] There are currently ten coastguard helicopters based around the UK, four in Scotland, five in England and one in Wales. Northern Ireland is currently covered by the helicopters based in Scotland. Bristow use two types of

helicopter, the Sikorsky S-92 and Augusta Westland AW189; both these helicopters can fly further and faster than previous models.

The ambulance service works with the Coastguard and the Coastguard can provide transfer of a patient when air ambulance aircraft are not available.

4.6 Royal Air Force (RAF)

In the UK the ambulance service is occasionally supported by the Royal Air Force (RAF). The prime function of the RAF is defence, but in the event that other air ambulance services are not available, the RAF provides help with the urgent transfer of patients if an aircraft is available.

4.7 Other jurisdictions

While reviewing transfer services used across the UK, some additional examples of approaches to the transfer of transplant candidates were identified. This is not intended to be a comprehensive overview, but rather to provide some further illustrative examples.

4.7.1 Isle of Man

The Isle of Man is an island in the Irish Sea between England and Ireland with a population of around 85,000.[77] Under the National Health Services Act 2001 the Department of Health within the Isle of Man must provide health services either locally or if necessary at hospitals in the UK. With medicine becoming more specialised in recent years, the number of NHS patients being transferred to UK hospitals has risen to over 8,000 per year.[78] The island has an Air Ambulance service that is nurse led and which operates 24/7. Patients requiring a scheduled flight or transfer by boat have their transport arrangements organised by the Patient Transfers Section of the Department of Health. The cost of travelling to and from a UK hospital may be met by the Department of Health and includes travel costs of the patient and any escort that is authorised by the consultant. Escorts can be a transfer practitioner, a health care assistant, a voluntary worker and/or a friend or relative. Financial assistance is provided retrospectively towards the cost of accommodation at a rate of £28.00 per person per night outside of London and up to £41.50 per person per night within London.[78]

The Air Ambulance service uses fixed wing aircraft that are dedicated to transferring patients; the service is provided by Woodgate Aviation. The planes include a LifePort stretcher system and are based at Ronaldsway Airport on the Isle of Man. More than 500 patients are transferred by air ambulance each year between the Isle of Man

and the UK.[78]

4.7.2 Norway

Norway has a population of approximately 5.2 million people. Norway has many remote and sparsely populated regions where access to specialist medical care is very limited. Luftambulansetjensesten ANS is the air ambulance service in Norway. The company is owned by the regional health authorities and is fully financed by the public sector at a cost of approximately 870 million NOK (€93 million). Every year around 20,000 patients use air ambulance services, with approximately half transported by fixed wing air ambulances and half transported via helicopters.[79]

The air ambulance fixed wing planes are based at seven airports and are operated by the private company Lufttransport AS, while the helicopters are operated by a combination of Lufttransport AS and Norsk Luftambulanse and are based at 12 bases. Search and Rescue helicopters are also used to provide national coverage and these are operated by the Royal Norwegian air force.[79] Babcock Scandinavian Air Ambulance AB service has recently been awarded the contract by the Norwegian government to supply fixed wing air ambulance services across Norway from 2019. The contract is worth £500 million over 11 years. Babcock will operate 11 fixed wing planes, including Beechcraft King Air B250 and Cessna jet engine planes.

Helicopter ambulance services will be provided in Norway by the airline Norsk Luftambulanse AS from 2018. The operation of air ambulance flights will cost over NOK 500 million (approximately €53 million) annually, a significant increase from current costs.[80]

4.7.3 Denmark

Denmark has a contract with the Norwegian Air Ambulance Foundation for the provision of air ambulances services. They operate three EC135 helicopters and the contract is worth one billion Danish Krone.

4.8 Summary

There are a small number of centres in the UK that perform paediatric heart and liver transplants, and all of these centres are based in England. Other parts of the UK, most notably Northern Ireland and Scotland, face similar logistical challenges to Ireland when it comes to transporting children to these centres within the timeframe of four hours for a heart transplant and six hours for a liver transplant. The different regions of the UK have used different models to overcome the challenges of timely patient transfer. In both Northern Ireland and Scotland, access to a dedicated 24/7, well resourced, air ambulance service has been established. The cost of the services

in these countries may be justified as they are part of a larger transport service. In both cases, transplant patients would only account for a small number of the patients transported each year. The model in Scotland differs from Northern Ireland as they have opted for a national service which is part of the Scottish Ambulance Service with a central base for coordinating the transport. Northern Ireland, on the other hand, has opted to use a private company that coordinates all aspects of the patient transfer.

Other countries such as Denmark and Norway also contract private companies to run their national air ambulance services. These contracts are expensive, but due to the geography of the countries, a number of patients need to be transferred by air ambulance.

4.9 Key points

- Transplant services are centralised in a small number of specialist centres in the UK, with paediatric heart and liver transplant services all located in England.
- In England and Wales, most patients travel to the transplant centre via regional services. Air ambulance services are available through private providers or charity funded air ambulances.
- Northern Ireland and Scotland have access to a dedicated 24/7 service for the transfer of transplant patients. This works in these countries as the service is part of a larger specialised transport service.
- In Northern Ireland a private company provides a dedicated service for the transfer of patients to Great Britain; this includes the transfer of transplant patients, but is part of a larger air ambulance service provided by Woodgate Aviation. Woodgate Aviation is the first point of contact for the transplant coordinator and it organises the entire transfer process. This model is funded by the Health and Social Care Board in Northern Ireland.
- In Scotland, the Scottish Ambulance Service also provides a national, coordinated service. ScotSTAR coordinates the transfer of paediatric heart and liver transplant patients as part of its specialist transport service. This model is government funded.
- In the UK, the Royal Air Force and HM Coastguard are not routine providers of air ambulance. Their use is limited to situations when other air transport is not available.
- Other governments provide for the cost of transfer and for subsistence for both the patient and any authorised escort.

5 Overview of service specifications for the development of a paediatric heart or liver transplantation service in Ireland

This chapter provides a high-level summary of the service specifications for paediatric heart and liver transplantation that would apply to any future service that could be introduced in Ireland.

5.1 Introduction

Heart transplantation is the final treatment option for children in end-stage cardiac failure. While an adult cardiothoracic transplant service is provided by the Mater Misericordiae University Hospital in Dublin, a paediatric cardiothoracic transplantation service does not exist in Ireland. Patients are referred to the UK from Our Lady's Children's Hospital, Crumlin, through a shared care programme to one of two transplant centres: Great Ormond Street Hospital in London or Freeman Hospital, Newcastle. Worldwide, approximately 100 centres perform a total of over 500 pediatric heart transplants yearly.[6]

The liver carries out multiple life-sustaining functions and, despite intensive research efforts, no practical artificial device is yet available to replace a failing liver. Therefore, liver transplantation remains the final treatment modality for many paediatric patients. In the absence of a national paediatric liver transplant service, children from Ireland requiring liver transplantation are transferred to one of three hospitals in the UK, most commonly King's College Hospital in London. Paediatric gastroenterology services located in Ireland have responsibility for the management of disorders of the liver, intestine and pancreas as well as conditions leading to intestinal failure or severe nutritional compromise. It is of note that Ireland's national hepatobiliary surgery service in Our Lady's Children's Hospital, Crumlin, has been effectively suspended since 2012.[81]

Notwithstanding the importance of maintaining sufficient staff with expertise in cardiothoracic or hepatobiliary surgery, many other services would require additional resources if a paediatric heart or liver programme were implemented. These include strengthening immunology, haematology, psychology and social support services and the recruitment of clinical nurse specialists with experience in transplant medicine.

Perhaps the most critical risk attached to the development of an Irish paediatric heart transplantation service is the potential loss of or reduction in access to the UK's larger donor pool. It is also worth noting that many heart transplantations that

take place in the UK originate from mainland European donors. Both maintaining access to the wider organ network of continental Europe, known as Eurotransplant, and missing the "window of opportunity" due to transport times associated with organ retrieval are of great concern.

5.2 Transplant list — Irish patients

Our Lady's Children's Hospital, Crumlin, kindly provided data on Irish patients on the transplant list. The information included activity since 2014 and was up to date to 31 May 2017. On 31 May 2017, two patients were waiting for liver transplantation and three patients were waiting for heart transplantation, one of whom was listed on the adult heart transplant list in the Mater Misericordiae University Hospital, Dublin. No children awaiting transplant were less than three years. One child was waiting over 3 years since listing for transplant. It is important to note that the list is dynamic and patients can be added or removed from the list at any time. The numbers of patients listed and transplanted each year since 2014 is shown in Table 5.1 and Table 5.2. However, we are also aware of two paediatric liver transplantations and one paediatric heart transplantation that have taken place since 31 May 2017. The number of transplants may be less than the number of Priority 1 transfers reported in Table 3.2 if transplantation did not proceed despite the patient being transported successfully within the required time frame.

Table 5.1 Patients listed for liver transplant and transplanted each year since 2014

Liver	2014	2015	2016	2017 (up to 31 May)
Listed	5	2	8	3
Transplanted	4	3	7	1
Waiting				2

Table 5.2 Patients listed for heart transplant and transplanted each year since 2014

Heart	2014	2015	2016	2017 (up to 31 May)
Assessed	10	5	7	11
Listed	5	3	3*	4
Transplanted	3	1	1	1
Waiting				3*

* This includes one patient listed for transplant at Mater Misericordiae University Hospital, Dublin

Simmonds et al. reported on Irish patients transferred to the UK for heart transplantation prior to 2014.[16] The medical records of all children who were referred to Great Ormond Street Hospital or to the Freeman Hospital from Ireland and underwent cardiac transplantation between January 1990 and September 2013 were retrospectively studied. During the 23-year period between January 1990 and September 2013, 22 patients (16 girls, 6 boys) underwent 23 transplants. The procedures were performed at Great Ormond Street Hospital in London (n = 18) and at the Freeman Hospital, Newcastle upon Tyne (n = 5).

5.2 Organ donor activity — Ireland

Organ Donation and Transplant Ireland (ODTI) is the national office responsible for implementing policy on organ donation and transplant services in Ireland. As part of its remit, it is responsible for compliance with and implementation of assigned functions in the European Directive (2010/52/EC) on standards of quality and safety of human organs intended for transplantation. Specifically this includes:

- data collection in relation to organ donation and transplantation activities
- ensuring appropriate organ exchange agreements and arrangements are in place with other member states.

Organ donation in Ireland is currently based on a voluntary donation system (opt in) and may occur in 36 intensive care units in public and private hospitals in Ireland. Organ transplantation takes place in three national transplant centres. Beaumont hospital is the national centre for kidney transplant and living kidney organ donation. Under its auspices, paediatric kidney transplantation takes place in Temple Street Children's University Hospital. Adult heart and lung transplantation take place in the Mater Misericordiae University Hospital, while St. Vincent's University Hospital

provides liver and pancreas transplantation. Each transplant centre has its own organ retrieval team which provides 24/7 service and which travels nationwide to retrieve organs.

To provide a viable paediatric heart and or liver transplant centre in Ireland, there would need to be sufficient access to suitable donor organs. These would comprise organ donations in Ireland and those sourced through exchange agreements and arrangements with other member states. It has been suggested that national paediatric heart and liver transplant services may increase the level of paediatric organ donation in Ireland due to greater awareness. Table 5.3 reports total deceased organ donation activity in Ireland since 2015.

Table 5.3 Total deceased organ donors in Ireland, 2015 to 2017*

Year	Total	Child (<16 years)
2015	81	3
2016	77	2
2017*	44	4

*To 30 June 2017

A total of 61 adult liver transplants were undertaken in Ireland in 2015, and the median waiting list time was 2.9 months. Sixteen adult heart transplants were undertaken, and the median waiting list time was eight months.

5.3 Transplant activity and caseload — UK

5.3.1 Paediatric heart transplantation

As highlighted in Chapter 2, in the financial year 2014/2015, there were 37 paediatric heart transplants performed in two centres in the UK. These were all "donor brain dead" transplantations.[5]

Most centres in other countries perform far fewer transplants per year. Internationally, 136 centres perform between one and four paediatric heart transplants annually, 28 centres perform between five and nine paediatric heart transplants annually and 22 perform ten or more paediatric heart transplants annually.[8]

As detailed in Chapter 3, there is a growing imbalance between supply and demand

for donor hearts, with the number of children actively waiting for a heart transplant doubling in the UK (from 16 to 37) in recent years.[25] This has also translated to a substantial increase in the number of children on the urgent transplant list, with an average of six children on the list each year.[25] Median waiting times for "deceased donor transplant" was 81 days for those ever registered as urgent; 357 days for those never registered as urgent; and 96 days overall for those registered on the paediatric heart transplant list. Between 2012 and 2013, 62% of children classified as urgent were transplanted while 18% died waiting; no child registered as non-urgent was transplanted while 8% died waiting.[25]

The median total ischaemia time (this encompasses warm and cold ischemia times, or from "cross-clamp to reperfusion") for paediatric "donor brain dead" heart transplants between 1 April 2010 and 31 March 2013 was 3.7 hours (interquartile range: 3.2–4.3 hours).

5.3.2 Paediatric liver transplantation

There were 64 deceased donor paediatric liver transplantations performed at three paediatric centres in the UK during the financial year 2015/2016. Fifty-five of these transplants were for patients on the elective list and nine for patients on the super-urgent list. During the same period, one living-donor transplantation was performed for a recipient on the super urgent list and 16 living-donor transplantations were performed for recipients on the elective list.

The number of patients on the active liver only transplant list has ranged between 18 and 42 each year. From 2015 to 2016, the number increased from 36 to 42. As an indication of post-registration outcomes for paediatric patients listed for a liver transplant, the proportion of patients transplanted six months, one year and two years after joining the list was 74%, 85% and 89% between April 2013 and March 2014, respectively.

There are two categories of patient — "elective" and "super urgent" patients, who have sudden liver failure and are likely to die within 48 hours unless transplanted. The median waiting time to transplant for "super-urgent" patients who were registered between 1 April 2010 and 31 March 2013 was four days. Between 1 April 2007 and 31 March 2011, the five-year survival was 73.1% (95% confidence interval (CI): 59.4–82.8) for super-urgent patients. The median waiting time to transplant for elective patients who were registered between 1 April 2010 and 31 March 2013 was 72 days. Between 1 April 2007 and 31 March 2011, the five-year survival was 91.8% (95% CI: 87.0–94.9) for elective patients.

5.4 Paediatric heart transplantation: service specification

5.4.1 Overview

Heart transplantation is a highly specialised procedure. Smaller paediatric cardiology centres traditionally work in collaboration with larger tertiary paediatric centres in listing and bridging patients to cardiac transplantation.

The National Children's Heart Centre is currently based in Our Lady's Children's Hospital, Crumlin.[81] Paediatric heart transplantation is not performed in Ireland; however, Our Lady's Children's Hospital coordinates transfer to one of two specialist referral centres in the UK - Great Ormond Street Hospital, to which most patients are transferred, and Freeman Hospital in Newcastle upon Tyne. No national standards or guidelines exist for the service provision of paediatric heart transplantation in Ireland. However, standards for such a service exist in the UK[82] and internationally.[83] The provision of a paediatric heart transplantation service in Ireland would significantly mitigate the risk associated with the viability of organs and the risks associated with the transport of a paediatric patient. At present, resources for cardiothoracic surgery at Our Lady's Children's Hospital, Crumlin, are directed towards congenital heart disease. While cardiothoracic surgeons with the relevant skills and expertise to perform paediatric heart transplantations exist in Ireland, many issues would need to be carefully considered before investing in a permanent service in Ireland.

At present, there are 23 funded and staffed intensive care unit (ICU) beds in Our Lady's Children's Hospital, Crumlin, of which eight are designated for congenital heart disease patients (cardiothoracic surgery and cardiology, including interventional cardiology). Occupancy rates are in excess of 95% for most of the year. The next phase of the All Island Congenital Heart Disease (CHD) Programme will facilitate surgery for approximately 120 elective CHD patients from Northern Ireland. A further four paediatric intensive care (PICU) beds will be commissioned to accommodate these patients without impacting on the current CHD elective waiting list.

Key elements of a paediatric heart transplantation service

The development of a paediatric heart transplantation service in Ireland would require substantial additional resources and capital investment. At present, three consultant cardiothoracic surgeons who practise in Ireland have the required expertise to carry out paediatric heart transplantations. Recruitment of an additional cardiothoracic surgeon, with expertise in single ventricle physiology as part of his or her routine work, may be necessary.

Beyond the recruitment of trained medical personnel, other resources necessary would include additional operating theatre capacity (including out-of-hours service), funding for a ventricular assist devices (VADs) service and a scale-up of immunological, microbiological and haematological services with specific expertise in the management of paediatric transplantation patients.

In order to have the capacity to manage a heart transplant programme, it is estimated that a minimum of four additional inpatient beds and a further four PICU beds would be required. Additional resources would also be required for immunology services (most likely at Beaumont Hospital).

Clearly, it would take considerable time to develop a paediatric heart transplantation service at Our Lady's Children's Hospital, Crumlin. Given the significant capital and staffing resources that are required it may be more realistic to consider the development of a transplant service in the context of the opening of the new children's hospital rather than in Our Lady's Children's Hospital, Crumlin. The Department of Health would need to develop a policy position in relation to the repatriation of the paediatric cardiac transplant service. Whether the small number of transplants (historically ranging from one to three heart transplants per year) would be sufficient to support a full service should also be considered.

A consensus amongst the consultant group (cardiologists, cardiothoracic surgeons, intensivists and anaesthetists, among others) would be necessary prior to the implementation of any cardiothoracic transplantation service. Additionally, feasibility studies would be required for a paediatric cardiac transplantation service, including artificial heart support (particularly, implantable mechanical heart support such as VADs).

5.4.2 Standards and service requirements — UK

National heart and lung transplant standards for the paediatric patient have been developed in the UK.[82] The *National Heart and Lung Transplant Standards* were first published in September 2002 and subsequently revised by the Standards Development Group in 2005. Beyond the additional resources necessary to support the intraoperative care of a paediatric heart transplant recipients, as outlined below, a scale-up of immunological and haematological services would also be necessary if a paediatric heart transplantation service were to be introduced in Ireland.

Briefly, core standards from the UK that would be applicable to the development of a heart transplantation service in Ireland include:[82]

1. Patients in the transplant service should be managed by a multidisciplinary

specialist team, which may be led by a consultant surgeon or physician. At consultant level the transplant team should include a consultant cardiologist with an interest in heart failure, a consultant respiratory physician with an interest in end stage respiratory disease and a consultant surgeon with an interest in mechanical cardiac support.

2. The transplant service should have consultant paediatric surgeons capable of performing heart and lung transplantation. All should have a high level of skill in congenital heart surgery to enable them to safely perform transplants in patients with complex congenital heart disease.
3. The transplant service would require paediatric anaesthetists whose sole duty is paediatric anaesthesia and have major commitment to paediatric cardiac anaesthesia during their working week.
4. The transplant service would require at least one paediatric respiratory physician and one paediatric heart failure cardiologist, who will be involved in assessment and full management of patients.
5. The transplant service would require histopathologists experienced in the interpretation of endomyocardial and transbronchial biopsies.
6. The transplant service would require a microbiologist with experience in the management of immunosuppressed patients.
7. The following paediatric services should be available immediately to the transplant service: senior and junior medical staff, nursing staff and technical support: dialysis, paediatric neurology, paediatric endocrinology, histopathology, tissue typing and microbiology, immunology, 24 hour paediatric bronchoscopy, paediatric intensive care, child psychiatry and psychology, social worker (children's trained) general paediatric surgery, paediatric infectious diseases, paediatric gastroenterology, nutrition and dietetics, chemical pathology and haematology staff with experience in the use of paediatric sampling.

5.4.3 Standards for heart transplantation — International

The International Society for Heart and Lung Transplantation (ISHLT) convened experts in all areas of heart transplantation to develop practice guidelines for the care of heart transplant recipients.[83] Their practice guidelines are broadly consistent with the standards followed in the UK. Detailed descriptions of paediatric care pathways are included and serve as an international evidence base to support heart transplantation centres.

5.4.4 Service configuration — UK

As highlighted in Chapter 2, comprehensive transplantation service for infants and children referred with cardiac failure who have not responded to maximum conventional treatment exists in the UK.[5] While there are seven licensed heart transplant centres in the UK, only two provide paediatric heart transplants: Freeman Hospital in Newcastle upon Tyne, which transplants adult and paediatric patients, and Great Ormond Street Hospital, which transplants paediatric patients only. Patients are listed for heart transplant if there are no contraindications and when their quality of life and or survival are likely to be improved by a transplant. Patients are categorised as urgent or non-urgent. The service in the UK integrates with NHS services for heart failure, cystic fibrosis/respiratory medicine and pulmonary hypertension. It also closely integrates with the Ventricular Assist Devices (VADs) for Children as a Bridge to Heart Transplant service, which due to the small number of paediatric thoracic transplants each year is limited to two centres to ensure expertise is maintained.

The use of VADs has enabled some people with end-stage heart failure to be supported until such time as a suitable donor heart is identified. VADs may also be used to treat reversible complications of heart failure that are potential contraindications to heart transplantation. Due to the availability of this technology, the demand for heart transplantation is likely to increase.[5] Globally, almost 30% of paediatric heart transplants are bridged with mechanical circulatory support, most commonly with a left ventricular assist device (LVAD), which is used in 17.5% of transplants, followed by biventricular devices (BiVADs), which are used in 5.9% of transplants, and extracorporeal membrane oxygenation (ECMO), which is used in 4.1% of transplants.[8]

Clinical outcomes for the transplant services are monitored by NHS England in collaboration with NHS Blood and Transplant (NHSBT).

The acceptable cold ischemic time for donated hearts is short compared to most other donated organs. This currently makes long-distance transport of hearts undesirable, although organ retrieval from Europe is occasionally necessary because of limited paediatric organ supply in the UK.[5]

It is notable that paediatric patients waiting for a suitable heart can be roughly divided into three categories. Those who are well enough to stay at home but who cannot engage in activities appropriate to their age, those children who remain on the ward on inotropic support until they are placed on mechanical support or transplant, and those children who are too ill to wait at home or on the ward and whose heart disease requires mechanical support such as VAD to maintain their

heart function. Those children requiring VAD are always maintained in ICU pending the availability of a suitable organ for transplant.

5.4.5 Provision of a paediatric VADs service

A paediatric VADs service, which is a necessary component of any paediatric heart transplantation service, does not exist in Ireland. At present, paediatric patients requiring VADs mechanical support prior to transplantation are transferred to Great Ormond Street Hospital, London.

In general, VADs are indicated in cases of acute cardiac failure in children who are listed for heart transplantation and whose condition necessitates the use of additional mechanical support. As the native heart fails, cardiac output deteriorates, resulting in inadequate kidney perfusion and liver congestion. Significant renal and hepatic dysfunction results in renal failure, liver failure and coagulopathy, and patients may become too high a risk for transplantation.

LVADs augment the circulation in these patients, not only saving their lives but also improving secondary organ function for transplantation, reducing pulmonary hypertension and allowing for improvement of nutritional status. The ultimate goal in these patients is to support the contractile function of the failing heart until a donor heart becomes available for transplantation — a technique known as "bridge to transplant". Of note is that there are very limited data to support use of VADs in patients with single-ventricle heart anomalies. While there is evidence that VAD placement can be successfully performed in these patients, outcomes are worse that in patients with biventricular physiology and are associated with lower survival rate.

VADs were originally developed using cardiac ECMO.[84] ECMO can only be used for about one month and using the ECMO pump only extends its usage for another month. This time is insufficient for many patients awaiting heart transplantation due to the limited availability of donor hearts. Many forms of VADs exist. The Berlin Heart devices were introduced to extend the period for which a patient could be bridged to transplant. Berlin Hearts are used for all heart transplant patients who are likely to wait longer than one month for a donor heart. Heartware devices are used in teenagers when possible as the risk of cerebral infarction is significantly less.

Three generations of VADs exist, and the choice of VAD is at the discretion of the clinician and should be evidence based. More than 80% of children who are bridged to transplant, survive and receive a heart in the UK.[84] A small number of children who are bridged to transplant make an unanticipated recovery, such that a heart transplant is no longer required and the VAD can be explanted (unintended bridge to recovery).

Bridge to heart transplant in the UK

The NHS provides a VADs service 365 days a year, 24 hours a day.[84] Bridging to transplant involves the:

1. operative insertion of the LVAD/BiVad or provision of ECMO support depending on clinical assessment and intensive care
2. immediate post-insertion care and management of LVAD, BiVad or ECMO
3. long-term care and management of LVAD and BiVad on the cardiology ward until transplantation
4. support services for the child and family, including psychosocial, school, dieticians and play therapists.

Patients with a VAD remain under the care of the specialist centre for the period of time spent awaiting a heart transplant. There is a dedicated multi-professional paediatric team skilled in the management of patients requiring bridging to heart transplantation. Clinical nurse specialists are also available to prepare the patient and family for bridging to heart transplantation and heart transplantation. The service is delivered in the cardiac intensive care unit, and the child requires intensive care support. Once support has been established, the patient is transferred to the high dependency unit on the cardiology ward.

The bridge to heart transplant service in the UK demonstrates that a similar VADs service in Ireland would require highly-skilled staff and significant resources and investment.

5.4.6 Strengthening of immunology, microbiology and haematology services

Children who are referred for heart transplantation to the UK are sometimes transferred back to Our Lady's Children's Hospital, Crumlin, as early as two weeks post-operatively, at which point they are followed by a multidisciplinary team including management of their immunosuppression.[16] While there are existing immunological, microbiological and haematological services in place at Our Lady's Children's Hospital, Crumlin, and Beaumont Hospital that care for the paediatric heart transplant patient pre- and post-operatively, expansion of their services would be necessary if a paediatric heart transplantation service were to begin in Ireland.

Simmonds et al. outline the immunosuppression regimen and cytomegalovirus (CMV) prophylaxis used in the shared care programme between Our Lady's Children's Hospital, Crumlin, and Great Ormond Street Hospital.[16] Induction

immunosuppression regimens vary and typically begin at the transplant centre.[16] In the longer term, all patients in the UK receive tacrolimus-based immunosuppression. Maintenance immunotherapy is managed in Ireland, with close coordination with Great Ormond Street Hospital.

Transplant centres in the UK use pre-emptive treatment for CMV rather than prophylaxis.[16] Patients also receive antimicrobial prophylaxis after transplant, including nystatin, cotrimoxazole and acyclovir, for three months. Biopsy regimens vary slightly in the transplant centres, but return for biopsy at three and six months is arranged for most patients.

It is likely that an Irish heart transplantation service would follow a similar immunosuppression and antimicrobial prophylaxis protocol as the UK. Follow-up care for transplant recipients is already in place at Our Lady's Children's Hospital, Crumlin. Following return to Ireland, patients are seen in the outpatient transplant clinic weekly for the first three months, every two months for one year, every three months for the second year, and every six months thereafter. Drug levels are checked weekly for the first three months, monthly for the first year, every two months for the second year, and every three months after the second year. Angiography to assess the coronary arteries is performed at one year and then biannually after transplant on the follow-up visit at the specialist transplant centre.[16]

5.4.7 Professional competency

Ongoing education and training of medical staff would be necessary at the transplantation centre, as would active research and development in the area of paediatric heart transplantation. However, as Our Lady's Children's Hospital, Crumlin, already cares for pre- and post-operative paediatric cardiac transplantations, it is likely that many of these activities already take place. At present, none of the Royal Colleges in Ireland or the UK have published professional standards relating to paediatric cardiothoracic transplantation.

At a minimum, continuous professional development would include regular educational meetings and transplantation teaching as a part of the core curriculum for paediatric cardiologists in training. Consultant attendance at regular national and international meetings in transplantation management, management of heart failure and respiratory failure and mechanical support should take place, as appropriate to the specialty.

As part of a National Children's Heart Centre, Our Lady's Children's Hospital, Crumlin, is developing a training programme through the Royal College of Physicians of

Ireland for paediatric cardiology fellows, capitalising on the broad range of tertiary centre experience that can be provided in Ireland.[85] The proposed duration of training is over five years, one of which may be spent in full-time research.

5.4.8 Access to donor pool

The most critical risk attached to the development of an Irish paediatric heart transplantation service is the potential loss of or reduction in access to the UK's larger donor pool. It is also worth noting that many heart transplantations that take place in the UK originate from mainland European donors. Accessing European donors may pose additional problems due to transfer times. Any potential reduction in the pool of donors available to Irish recipients would have severely negative consequences.

5.4.9 Feasibility of carrying out paediatric heart transplantation in Ireland — Our Lady's Children's Hospital, Crumlin

In May 2017, Our Lady's Children's Hospital, Crumlin, responded to a question from the Department of Health related to the feasibility of setting up of a paediatric heart transplant centre in Ireland. Following discussion with key staff in the area, they note that a new transplant service would require the following resources:

1. competent surgeons
2. sufficient surgeons to cover a round-the-clock on-call roster
3. round-the-clock theatre availability
4. a paediatric transplant cardiologist
5. ICU beds for the management of patients waiting for a suitable organ
6. ICU beds for post-operative care
7. a quality manager to ensure compliance with transplant quality management system *(as required under S.I. 325 2012)*
8. immunology services
9. nurse specialists for transplant programme
10. transplant co-ordinator(s)
11. psychological and social supports.

They highlighted that resources for cardiothoracic surgery at Our Lady's Children's Hospital, Crumlin, are directed towards congenital heart disease. If a paediatric heart transplant programme was to be set up and resourced, then additional resources for emergency, out-of-hours surgery (staffing for theatre and possibly an additional surgeon) would be required. Additional information provided by Our Lady's Children's Hospital, Crumlin, included the following, which reflect issues previously discussed in

Section 5.4.1:

- As of May 2017 there were 23 funded and staffed ICU beds in Our Lady's Children's Hospital, Crumlin, of which eight are designated for congenital heart disease patients (cardiothoracic surgery and cardiology, including interventional cardiology). A further five PICU beds are to be commissioned (two in 2017) to accommodate children from Northern Ireland as part of the All Island CHD Programme
- In order to have the capacity to manage a heart transplant programme, a further four PICU beds would be required.
- Four further cardiac inpatient beds will be commissioned as part of the All-Island CHD Programme. At least an additional four inpatient beds would be required and would have to be built in order to accommodate a heart transplant programme.
- Additional immunology resources would be required to service a paediatric heart transplant; however, it may be preferable to add to exisiting resources in Beaumont Hospital rather than setting up a separate paediatric service in Our Lady's Children's Hospital, Crumliln.
- The other resources listed are of equal importance to the commencement of a new transplant programme.

5.5 Liver transplantation: service specification

5.5.1 Current service delivery — Ireland

Paediatric liver transplantation is not performed in Ireland; however a shared care pathway exists with King's College Hospital, London, for the referral of suitable patients. Paediatric gastroenterology services located in Ireland have responsibility for the management of disorders of the liver, intestine and pancreas as well as conditions leading to intestinal failure/severe nutritional compromise. Tertiary paediatric gastroenterology, hepatology and nutrition services for Ireland are provided in one centre, Our Lady's Children's Hospital, Crumlin, and will move to the new children's hospital when it is built.[81] This is in line with international recommendations that specialised services should be delivered in tertiary care centres of excellence.

The Health Service Executive, in conjunction with the Royal College of Physicians of Ireland, have published a draft model of care for paediatric healthcare services in Ireland specific to gastroenterology, which highlights current service provision and

recommendations for a future national model of care for paediatric patients.[81]

The diagnosis and management of the following tertiary conditions are included among the national model of care for paediatric gastroenterology services that relate to hepatic disease:

1. Neonatal-/infancy-onset liver diseases, including neonatal cholestasis, biliary atresia, Alagille syndrome, alpha 1 antitrypsin deficiency, giant cell hepatitis, familial intrahepatic cholestasis syndromes, neonatal sclerosing cholangitis, neonatal haemochromatosis, hepatic vascular anomalies and fulminant acute liver failure

2. Non-neonatal onset liver diseases, including autoimmune hepatitis, Wilson disease, cystic fibrosis-associated liver disease, portal hypertension, extrahepatic portal venous obstruction, chronic liver disease/failure, refractory ascites and acute and fulminant liver failure

3. Infectious hepatitis, including hepatitis B and C treated in conjunction with paediatric infectious disease team

4. Transplantation, including whole or split donor liver transplantation, live related liver transplantation, intestinal transplantation and combined multi-visceral organ transplantation

5. Hepatobiliary surgery, including choledochal cyst, bile duct anomalies, Kasai procedure, intra-operative cholangiography, porto-systemic shunt surgery.

The report highlights deficiencies in the current service related to hepatobiliary disease:[81]

- The national hepatobiliary surgery service at Our Lady's Children's Hospital, Crumlin has been effectively suspended since 2012. As a result, children who now require surgery for biliary atresia, choledochal cyst repair and lobar resection are being referred to UK centres. This situation has potentially led to a deskilling of ward and theatre staff and a lack of national specialist surgical expertise and opinion. Additionally, patients travelling to the UK require significant financial and psycho-social support from social work services.

- Survival pre- and post liver transplant has improved dramatically in recent years for patients in Our Lady's Children's Hospital, Crumlin. However, there is an ongoing need to strengthen shared care practices, develop educational material and deliver education sessions in the community.

The restoration of hepatobiliary surgery services would be necessary prior to the development of a future liver transplantation service. Such a decision would require careful consideration, both in terms of staffing capabilities and any changes to the current access to the UK donor pool. If a paediatric liver transplant programme were to be set up and resourced then additional resources for emergency, out-of-hours surgery, including staffing for theatre, would also be required. Additional information provided by clinical staff in Our Lady's Children's Hospital, Crumlin, regarding the resources required indicated that the following extra resources would be needed:

- three paediatric hepatobiliary surgeons
- three paediatric hepatologists
- an interventional radiologist (half-time equivalent)
- an infectious disease specialist
- two paediatric anaesthetists
- a transplant coordinator
- additional nephrology, cardiology and diagnostic radiology support
- a radiographer
- clinical nurse specialists
- a dedicated theatre, fully staffed and resourced
- two additional PICU beds
- additional laboratory support (blood bank and chimerisation, and immunology).

It is worth noting that if a paediatric heart transplantation service were implemented, as discussed previously, many of the services would overlap with a liver transplantation service and roles could be optimised to maximise the efficiency of both services.

5.5.2 Standards and service requirements for paediatric liver transplantation — UK

Paediatric liver transplantation in the UK is underpinned by the National Standards for Liver Transplantation (2005). The standards outlined pertain to the adult population; however, many of the standards would also apply to the paediatric setting. They include the following:

1. Specialist liver transplant centres will have a process/system in place to ensure patients are added to the transplant waiting list based on the Liver Advisory Group agreed minimal listing criteria and registered with NHS Blood and Transplant (NHSBT). In addition, they will ensure that the list is regularly reviewed and updated and prioritisation is carried out weekly at a

multidisciplinary team (MDT) meeting based on the Model of End-stage Liver Disease/UK Model of End-Stage Liver Disease score. Liver offers must be received and assessed from NHSBT in a timely manner, and the requirements of the EU Organ Donation Directive must be met. In accordance with the EU Organ Donation Directive, written information relating to organ offers should be reviewed prior to the acceptance or decline of offers. Allocation to a particular recipient of an individual donor liver will depend upon a number of factors.

2. The transplant centre should have at least five **consultant surgeons** capable of undertaking liver transplantation. All should be members of the MDT. Robust, published duty rotas should be in place to provide continuing consultant cover for surgical transplant activity. Duty rota arrangements should incorporate sufficient flexibility to allow appropriate rest whilst maintaining continuity of care. Operating theatres should always be available for emergency liver transplantation to ensure there is the capability to accept organs when they become available. Sufficient surgical support staff (surgical trainees and or trust grade doctors) and operating department staff should be rostered to allow for liver transplant activity out of hours and at weekends but including compliance with the working time directive. There should be explicit consultant involvement in the educational aspects of the retrieval program.

3. A **consultant hepatologist** should be available at all times to advise on management of patients with fulminant hepatic failure and those who develop problems whilst on the waiting list or following transplantation. Long-term transplant care should be provided by consultant hepatologists, supported by junior medical staff, in specialist wards and outpatient clinics. Transplant and non-transplant hepatology centres should share responsibility and arrangements for training junior staff in hepatology according to nationally agreed guidelines.

4. **Anaesthesia and intensive care consultants** experienced in the management of liver transplant patients should supervise anaesthesia and intensive care. These consultants should be supported by junior medical staff and be represented on the MDT. Sufficient critical care facilities and nursing staff should be available to support the transplant programme and allow emergency admission of patients with fulminant hepatic failure.

5. The MDT should include a named **consultant radiologist** with a specific interest in liver imaging and interventional procedures. There should be access to a range of diagnostic imaging on a seven-day basis, including ultrasound, CT (computed tomography) and MRI (magnetic resonance

imaging, and to interventional radiology, including biliary and vascular interventions. There should be robust, published consultant duty rotas to provide for emergency imaging and radiological interventions in liver transplant patients.

5.5.3 Standards for liver transplantation — International

No international standards for paediatric liver transplantation services were identified as part of this report.

5.5.4 Service configuration — UK

In the absence of a national paediatric liver transplant service, children from Ireland requiring liver transplantation are transferred to one of three hospitals in the UK, most commonly King's College Hospital in London. The indications for paediatric liver transplantation contrast strongly with those for adults. In the adult population, the commonest reasons among transplanted patients are alcoholic liver disease, hepatitis from viral infections (hepatitis B and C) and fatty liver disease. The predominant conditions in children are biliary atresia (a neonatal biliary disease resulting in 40-70% of primary transplants), congenital metabolic conditions including alpha-1-antitrypsin deficiency, tumours and acute liver failure. Also of note is that paracetamol toxicity, the commonest cause of acute liver failure necessitating transplant in adult patients, is an uncommon indication for transplantation in children.

The Liver Advisory Group, on behalf of NHS Blood and Transplant (NHSBT), outlines referral pathways to the UK national transplant list and most recently updated its policy for the selection of patients for liver transplantation in April 2017.[4] These are discussed in more detail in Chapter 2. The criteria agreed by consensus at the Liver Advisory Group are intended to match overall patient numbers to the availability of donated organs.

5.5.5 Living donor and split-liver transplantation

As mentioned previously, children can benefit from part of an adult donor organ, either reduced or split between two recipients. A healthy adult may also donate part of their liver to a patient in need of a liver transplant; the procedure is called a donor hepatectomy. Living donor transplantation and split-liver transplantation are available in the UK. The NHS has published service specifications for these services.[52]

A paediatric liver transplantation programme in Ireland would require access to split livers and living related donors. The development of a national paediatric liver

transplantation service in their absence would reduce the size of the donor pool for the paediatric population compared with what is currently available in the UK. The development of a living adult donor programme in Ireland would require significant resources and planning. The adult liver transplantation programme is currently located at Saint Vincent's University Hospital. Significant logistical challenges would emerge if the location of the living-donor and split-liver transplantation programmes was different to the location of the paediatric transplantation programme, as ideally all would be located in the same hospital.

5.5.6 Strengthening of immunology, microbiology and haematology services

As discussed in Section 5.1.2.6, strengthening of immunology, microbiology and haematology services would also be necessary for the development of a paediatric liver transplantation service in Ireland.

5.5.7 Professional competency

As discussed in Section 4.1.2.7, ongoing education and training of medical staff would be necessary at the transplantation centre, as would active research and development in the area of paediatric liver transplantation. At a minimum, continuous professional development would include regular educational meetings and transplantation teaching as a part of the core curriculum.

5.5.8 Access to donor pool

As previously discussed, the most critical risk attached to the development of an Irish paediatric liver transplantation service is the potential loss of or reduction in access to the UK's larger donor pool. It is also worth noting that many liver transplantations that take place in the UK originate from mainland European donors. Any potential reduction in the pool of donors available to Irish recipients would have severely negative consequences. Additionally, transport times associated with organ retrieval from European donors would pose additional challenges.

5.5.9 Future technologies

Liver machine perfusion is a promising new method to improve organ viability prior to transplantation and is being used in various clinical trials worldwide.[86, 87] Machine perfusion is a platform that provides continuous circulation of nutrients and metabolic substrates and oxygen to the liver while ex-vivo (outside the body). Potential advantages of this technology, compared to static cold storage, include the following:

- Prolonged preservation times
- Reduction in ischemia / reperfusion injury
- Better ex situ assessment of graft viability
- Potential to restore / regenerate damaged tissue
- Increase in numbers and quality of donor organs.

Ravikumar et al., 2016, reports on the first patients transplanted using a normothermic machine perfusion device that transports and stores an organ in a fully functioning state at 37°C.[88] Adult patients with end-stage liver disease on the King's College Hospital and University Hospital Birmingham liver transplant waiting list were enrolled in the study. Thirty-day graft survival was similar between machine perfusion and control (static cold storage). The study demonstrated the safety and feasibility of using this technology from retrieval to transplantation, including transportation.

Disadvantages, however, are that liver machine perfusion is much more expensive and complex than conventional cold storage. However, it is possible that if this technology were adopted in the future, the prolonged storage capability of the donated liver may extend the six-hour transfer requirement for Priority 1 transfer patients.

5.6 Discussion

A paediatric heart or liver transplantation service does not exist in Ireland. Therefore, children are assessed for and listed on the NHSBT transplant list in the UK. Since 2014, seven Irish paediatric patients underwent heart transplantation and seventeen underwent liver transplantation in the UK. On 31 May 2017, there were two children (less than 16 years) listed for liver transplant and two listed for heart transplant on the UK's NHSBT transplant list. Organ Donation and Transplant Ireland (ODTI) is the national office responsible for planning and setting direction for organ donation and transplant services in Ireland. Organ donation in Ireland is currently based on a voluntary donation system (opt in) and occurs in 33 intensive care units in Ireland.

The provision of a paediatric heart or liver transplantation service in Ireland could potentially mitigate the risk associated with the viability of organs and the risks associated with the transport of a paediatric patient.

At present, resources for cardiothoracic surgery at OLCHC are directed towards congenital heart disease. The development of a paediatric heart transplantation service in Ireland would require substantial additional resources and capital investment. A paediatric VADs service, which is a necessary component of any

paediatric heart transplantation service, does not exist in Ireland. The feasibility of providing artificial heart support (particularly implantable mechanical heart support) would need to be confirmed prior to the introduction of a paediatric heart transplantation service.

The national hepatobiliary surgery service at Our Lady's Children's Hospital, Crumlin, has been effectively suspended since 2012. As a result, children who now require many forms of hepatobiliary surgery are referred to UK centres. This service should be reinstated prior to the development of a paediatric liver transplantation service.

Beyond the recruitment of trained medical personnel for a future paediatric heart or liver transplantation service, other resources necessary would include additional operating theatre capacity (including out-of-hours service) and a scale-up of immunological, microbiological and haematological services with specific expertise in the management of paediatric transplantation patients.

Given the significant capital and staffing resources that are required, it may be more realistic to consider the development of a transplant service in the context of the opening of the new children's hospital rather than in Our Lady's Children's Hospital, Crumlin. A consensus amongst the consultant group would be necessary prior to the implementation of any transplantation service.

A highly important consideration in the development of an Irish paediatric transplantation service is the potential loss of or reduction in access to the UK's larger donor pool. In addition, many transplantations that take place in the UK originate from mainland European donors; maintaining access to the wider organ network of continental Europe is of great concern. Retrieval of organs from European donors may pose additional problems due to transfer times, similar to current Priority 1 transfer issues.

5.7 Key points

- A paediatric heart or liver transplantation service does not exist in Ireland. Therefore, children are assessed for and listed on the NHSBT transplant list in the UK.
- Organ Donation and Transplant Ireland (ODTI) is the national office responsible for implementing policy on organ donation and transplant services in Ireland. Organ donation in Ireland is currently based on a voluntary donation system (opt in) and occurs in 36 intensive care units in public and private hospitals in Ireland.
- The provision of a paediatric heart or liver transplantation service in Ireland could potentially mitigate the risk associated with the viability of organs and the risks

associated with the transport of a paediatric patient.

- At present, resources for cardiothoracic surgery at Our Lady's Children's Hospital, Crumlin, are directed towards congenital heart disease. The development of a paediatric heart transplantation service in Ireland would require substantial additional resources and capital investment.
- A paediatric VADs service, which is a necessary component of any paediatric heart transplantation service, does not exist in Ireland. The feasibility of providing artificial heart support (particularly implantable mechanical heart support) would need to be confirmed prior to the introduction of a paediatric heart transplantation service.
- The national hepatobiliary surgery service at Our Lady's Children's Hospital, Crumlin, has been effectively suspended since 2012. As a result, children who now require many forms of hepatobiliary surgery are referred to UK centres. This service should be reinstated prior to the development of a paediatric liver transplantation service.
- Living donor transplantation and split-liver transplantation are not available in Ireland. Without these services, the donor pool available to a national paediatric liver transplant service would be reduced compared with what is currently available to Irish children listed for transplant in the UK. Logistical challenges would likely arise if these services were to be provided to facilitate a national paediatric liver transplant programme, as the adult and paediatric liver transplant programmes would not be co-located on the one site.
- Beyond the recruitment of trained medical personnel, other resources necessary would include additional operating theatre capacity (including out-of-hours service) and a scale-up of immunological, microbiological and haematological services with specific expertise in the management of paediatric transplantation patients.
- Given the significant capital and staffing resources that are required, it may be more realistic to consider the development of a transplant service in the context of the opening of the new children's hospital rather than in Our Lady's Children's Hospital, Crumlin.
- A consensus amongst the consultant group would be necessary prior to the implementation of any transplantation service.
- Consideration should be given to whether the expected number of transplants anticipated to take place in Ireland would be sufficient to ensure a safe and effective service.
- Ongoing education and training of medical staff would be necessary at the

transplantation centre to maintain professional competence as would active research and development in the area of paediatric transplantation.

- A highly important consideration in the development of an Irish paediatric transplantation service is the potential loss of or reduction in access to the UK's larger donor pool. In addition, many transplantations that take place in the UK originate from mainland European donors. Retrieval of organs from European donors may pose additional problems due to transfer times, similar to current Priority 1 transfer issues.
- In the future, new organ preservation technologies, such as ex-vivo liver machine perfusion, may prolong the duration a donor organ is viable prior to transplantation.

6 Alternative approaches for providing efficient and sustainable treatment or transport of Priority 1 transfer patients

The purpose of this chapter is to outline a range of alternative approaches for providing efficient and sustainable treatment of transport of patients that currently meet the requirement for Priority 1 transfers

6.1 Introduction

As detailed in Chapter 2, the majority of patients fulfilling the criteria for Priority 1 transfer are children resident in Ireland who require urgent transport to the UK upon notification that a suitable donor organ has become available. As detailed in Chapter 3, the Health Service Executive (HSE) does not have a dedicated air ambulance service. Current transport arrangements for Priority 1 transfer patients are facilitated through service-level agreements (SLAs) with the Departments of Defence (for the Air Corps) and the Department of Transport, Tourism and Sport (for the Irish Coast Guard [IRCG]) and through potential commissioning of private air ambulances. These elements are provided on an "as-available" basis. However, as highlighted in Chapter 3, restrictions to the availability of the Air Corps and the IRCG mean that as of 6 November 2017, there will be no night-time availability from either of these services.

A range of approaches that reflect potential immediate and short term alternatives for the treatment or transfer of these patients as well as the longer term solutions that aim to improve the efficiency, resilience and sustainability of the service provided are outlined in this Chapter. The immediate approaches explore alternatives to mitigate the risk of a failed transfer effective from 6 November 2017. Short term alternatives are those that would take up to six months to implement while longer term alternatives are those that could take two to five years to develop and implement. Those alternatives identified as plausible will then be assessed against a range of criteria in Chapter 8.

6.2 Immediate alternatives

Six alternative approaches were identified as being available to the Department of Health and HSE effective from 6 November 2017. These ranged from different commissioning models for air ambulance to transfer patients within the time window, facilitating patients to relocate to the UK to mitigate the risk of a failed transfer, and continuing with the "as is" approach which accepts the known

restrictions of the services currently provided. These options are outlined in more detail below.

6.2.1 Dedicated aircraft and aircrew from commercial provider

The HSE has received estimates of the cost of a dedicated air ambulance from commercial providers. However, these quotations were subject to significant price and specification variation, depending on whether they were:

- Dublin-based or UK-based
- a 24/7 service for 365 days/year a 7.00pm–7.00am service for 365 days/year.

Costs exceeding €700,000 per annum were quoted by private providers for a fixed wing aircraft with dedicated pilots 24/7/365 days a year, based in the UK, These costs were inclusive of VAT, but excluded certain other charges that would be associated with the specific flights). This service would have a turnaround time from time of notification to arrival of the patient at the UK hospital of five and a half hours. It would therefore not meet the requirements for transfer of heart transplant patients, and there would be a risk that a UK-based aircraft may also not meet a six-hour time window for Priority 1 liver transfers. In order to mitigate this risk, a Dublin-based dedicated aircraft should be considered a pre-requisite for any potential private air ambulance service provider.

Quotes for an aircraft with dedicated pilots on either 7.00pm-07.00am standby or permanent 24 hour standby and, based at Dublin airport ranged from €900,000 to €3.7 million per annum. The service costs quoted do not include the charge per flight which would comprise airport landing and handling charges and hourly flight costs. As these costs encompass different service specifications they are not directly comparable.

Short term nightly bookings of private air ambulance providers with the requirement to base in Dublin range in price from €15,000 to over €30,000 depending on the availability of aircraft and length of the notice period.

6.2.2 Dedicated IRCG aircrew operating "as-available" S92 helicopter

As highlighted in Chapter 3, the primary remit of the IRCG is Search and Rescue (SAR); helicopter emergency medical service (HEMS) activity is a secondary remit defined through a service level agreement between the Department of Health and the Department of Transport, Tourism and Sport, and is provided as a concurrent activity on an "as available" basis.

The Irish Coast Guard (IRCG) helicopter services are provided under contract by CHC Ireland. The contactor operates four bases with one SAR helicopter available on a 24 hour basis at each base. In order to achieve this level of serviceability, the operator maintains a pool of five helicopters, all of which are rotatable across the four bases.

Due to the existing commercial agreement between the Department of Transport, Tourism and Sport and CHC Ireland for the provision of coast guard activities, it would be challenging to negotiate immediate amendments to the working rosters, and the terms and conditions for existing air crew and support staff. These were specified in the current 10 year contract signed in 2012. Any material changes to this contract would have to be negotiated and agreed between the Department of Transport, Tourism and Sport and CHC Ireland. This alternative is explored in Section 6.3.4. The only available immediate option for extending the Irish Coast Guard remit, to include 24 hour HEMS, would be to pay CHC Ireland to recruit an additional aircrew that would provide cover from 19.00 to 07.30, thereby restoring the level of service available to the HSE from the IRCG prior to September 2017.

CHC has provided a price to the HSE to place an aircrew on standby in Dublin airport to fly one of the IRCG helicopters (subject to aircraft availability). This quote for two specialist pilots available on a 12 hour service basis (from 7.00pm to 7.00am) was similar to quotes from other commercial services providing a dedicated night time service, as described in 6.2.1. Consistent with other IRCG flights, additional charges per flight taken would accrue comprising airport landing and handling charges as well as hourly flight costs. These averaged €6,000 per flight in 2016. This potential solution still involves using "as-available" aircraft.

To consider IRCG as a solution for all Priority 1 transfers it would be advisable to seek assurance that relevant equipment to support critically ill patients can be safely accommodated on the S92.

6.2.3 Charter aircraft "as needed"

This option involves working with either an online aircraft charter booking portal (for example, Avinode) or aircraft charter broker (for example, FlyMeNow, European Air Charter or Flightserve) on an "as needed" basis for Priority 1 transfers.

Avinode operates a real-time online database of available charter aircrafts. This enables commercial purchasers to find and compare the real-time availability of aircraft, best flight options and prices. Avinode charge a monthly fee for a member subscription which provides access to their database. The cost of any flight chartered would also then be accrued. For example, flying from Dublin to Luton

airport, London at 9.00am on a weekday, a search indicted over 500 charter options available. When the air ambulance option was specified, the number of available charter options decreased to 44. The air ambulance option on the booking portal is a tick box, which provides no minimum requirements regarding service and equipment expectations on board the aircraft. For those missions that require a high level of air ambulance specifications, this is a major limitation if using the Avinode portal.

FlyMeNow specialises in non-scheduled passenger transport. This broker of charter aircraft operates from Farnborough, England. It has been used by the Commercial Unit of the HSE to charter aircraft for patient transfers to the UK. The majority of these aircraft are based in the UK. The cost of using an air charter broker can range from €1,000 to €7,000, depending on the pre-planning, flight destination, lead-times, aircraft availability and various other factors. To date, the HSE has used only two charter brokers – FlyMeNow and European Air Charter (an Irish-based air charter broker).

Flightserve provides a medical aircraft charter service to the UK Organ Transplant Programme. The list of services include: transporting critically ill patients, transporting organs and transporting medical teams on demand and with very little notice. Flightserve has access to aircraft operators that supplying both Medevac and private aircraft.

Chartering an aircraft as required is a high-risk option, as there is no guarantee that a suitable aircraft would be available at short notice when requested by the NEOC.

6.2.4 Relocation to the UK –financial assistance to patients and families

If a child is added to a UK paediatric organ transplant list, the HSE may need to consider advising all families that the only means to guarantee access to transplant surgery is to relocate to the vicinity of the receiving hospital in the UK.

Due to the difficulties that arose with availability for the Priority 1 transfer of patients during 2016, options were explored to mitigate the risk that transport would not be available. In February 2017, the Department of Health requested the HSE to facilitate families, where the clinical recommendation from the NAS was that the child should relocate, by providing a financial contribution to their living costs in the UK. Approval for the financial support is on a case by case basis and relates to those families, for whom there is an identified transfer timeline risk, relocating to the general vicinity of the transplant centre in the UK to mitigate this risk.

It is important that there would be continued transparency about the difficulties faced in meeting the required time windows. Health services need to provide families

with complete information, so that they can make a fully informed decision as to whether to relocate or not.

It is accepted that relocation is extremely disruptive for families. It is also pertinent that in choosing to relocate, the families do not know how long they will need to stay in the UK. As illustrated in Chapter 2, the waiting time for non-urgent transplants can range from weeks to over a year. Relocation removes families from their support networks, and may involve temporarily splitting families, particularly if they have other school-age children. Such disruption is likely to have negative consequences, such as increased stress and uncertainty. Ethical issues in relation to the various alternative options are discussed in detail in Chapter 8

As highlighted in Chapter 3, EU Regulation 883/2004, which governs the Treatment Abroad Scheme (TAS), does not include or place a requirement on health service funders to fund travel or subsistence. However, a national policy was introduced by the HSE in 2009 for TAS to cover the cost of some travel. This provides for the reimbursement of flights for the patient or, where appropriate, the patient and one travelling companion. Given the current difficulties with ensuring timely transport of Priority 1 transfers to the UK, an additional interim arrangement was provided by the HSE in February 2017 to make a financial contribution to families of those listed on the NHSBT transplant list, who are recommended to by the NAS on clinical grounds, and who choose to relocate. It is noted that the cost of living in the London area is substantial, and the current nightly subsistence provided to families may be insufficient to cover the cost of residing there or for the ongoing cost of travelling between Ireland and the UK for family members. Relocating to London is also likely to have consequences for welfare entitlements and employment. The treating consultants might be in a position to give some advice on the timing of the relocation of individual patients, in accordance with their medical needs. It should be noted that relocation may not be an option for patients that require continued specialist medical treatment or who are inpatients at Our Lady's Children's Hospital, Crumlin.

If the difficulties with ensuring reliable transport of Priority 1 transfer patients persist, recommending relocation of all ambulatory patients on the NHS Blood and Transplant (NHSBT) transplant list may need to become a permanent measure. In those circumstances, there is a need to develop a policy position regarding the level of the subsistence allowance, the period of time to be covered and the scope of the funding, rather than the current situation where those listed on the paediatric liver transplant list are considered on a case-by-case basis. It is noted that, in a post-Brexit environment, relocation of families to the UK may be problematic, so the offer of relocation may only provide a temporary solution.

6.2.5 Relocation to the UK – lease or purchase of a property in the UK

Consideration could be given to purchasing a property in the UK to accommodate families rather than offering financial assistance. However, a property could be idle for months in the year, while at other periods, a number of families may require its use. Furthermore, while most children go to London some may need to attend other transplant centres, such as Newcastle or Birmingham. Therefore, the requirement may be for properties to be purchased in multiple locations. Notwithstanding any implications of Brexit, it may not be a feasible alternative to purchase and maintain a property in the U.K for the use of families of patients on the transplant waiting list. While purchasing a property is presented as an immediate option, it is impossible that this could be effected by the 6 November 2017.

The other immediate-term option would be to lease a property for patients and their families in London. This arrangement could be made on an annual lease basis (for example, an average two bed apartment in Bloomsbury, central London has annual lease costs of £57,000 with accompanying fees of £57,200, which gives a total cost of £114,200) or on a short-term leasehold basis (for example, a studio apartment at Citadines Aparthotel Holborn for one adult and a two year old child costs £303.50 per night, which give a total cost for a year of £110,777.50).

The leasehold agreement with the letting agency would need to facilitate use by different children and accompanying adults at different times of the annual arrangement. The need for lift-access to the accommodation also needs to be considered, which may limit the choice of apartments. If there was need for agency nurse support for the patient, this could only be provided in the long-term leasehold accommodation. These potential costs need to be factored into this option.

The offer of financial assistance to families was introduced as an additional interim measure in February 2017 to allow families to make their own accommodation arrangements. However, this places a substantial logistical burden on families, particularly at a time of stress. In addition, the upfront financial burden may make it more difficult for certain families to avail of this solution. Social and ethical issues are discussed in further detail in Chapter 7. An alternative might be to develop a formal model of subsistence, financial and logistical support for the transport, accommodation and living expenses of patients and families, who temporarily relocate to the UK. This could be along the lines of those developed for use by the Health and Social Care Board (HSCB) in Northern Ireland.[5]

The role of a Transplant Liaison Officer could be considered by the HSE to provide a more holistic approach to the management of the patients required to access care in

the UK. This offer would co-ordinate the navigation of these guidelines for families in what is a stressful context. There may be possibilities to achieve economies of scale through direct bookings of flights and accommodation for families by the Transplant Liaison Officer, using a HSE corporate account unique identifier. This would eliminate the need for families to fund flights and accommodation up-front and reduce the financial and administrative burden associated with retrospective reimbursement.

6.2.6 Work with the Air Corps and Irish Coast Guard from 6 November 2017 (the "as-is approach")

This option continues to rely on the "as-available" service provision from the Air Corps and the IRCG from 6 November 2017 with no change in the arrangements for the sourcing of private air ambulance. In reality, this means that availability for Priority 1 transfers among these service providers for the NEOC, would be as follows:

- The Air Corps will potentially be available on "amber" from 9.00am—4.30pm (that is, available within two to five hours of activation during daytime hours) from Monday to Friday only.
- The IRCG will potentially be available on "green", (that is available within 60 minutes of activation) from 07.30am (08.30am in the summer) to 7.00pm seven days a week, providing that the crews plus aircraft are not otherwise occupied with SAR activities.
- There would be no cover for Priority 1 transfers between the hours of 7.00pm—7.30am unless an aircraft can be chartered at short notice through a broker or commercial provider.

The majority of patients listed on the NHSBT list for heart transplant are hospital inpatients requiring substantial medical support. Medically unstable patients may require elective intubation and ventilation to travel. As such these patients would require air ambulance transfer (as opposed to air taxi) accompanied by a medical team with specialist equipment. Given the four hour time frame for heart transplant patients to arrive in the transplant centre following notification of an organ becoming available, and the limited likelihood of a charter aircraft capable of aeromedical transfer being available at short notice in Ireland or the UK, this option is unlikely to be a viable alternative for these patients. Adoption of the "as is" approach would likely result in patients missing the transfer window and the opportunity to receive a donor organ with a potential impact on patient morbidity and mortality. It may also impact the existing relationship with the transplant centres in the UK, if it is known that there is not a viable transport alternative for these patients available on a 24 hour basis.

6.3 Short-term alternatives

The alternatives discussed below are those that could be used in the short term, but which could take up to six months to implement.

6.3.1 HSE leasing and operating aircraft

The HSE could lease an aircraft to guarantee dedicated aircraft availability. This could be a bespoke aircraft matching the air ambulance specifications determined by the HSE. A finance lease is a way of providing finance, whereby a leasing company (the lessor) buys the aircraft for the HSE (the lessee) and rents it to them for an agreed term. If a fixed wing aircraft was lease financed over a period of 12 to 15 years, it would allow for a structured and manageable repayment schedule for the HSE over the lifetime of the aircraft. However, one aircraft will not be sufficient to provide a dedicated Priority 1 transport solution, as the service would be unavailable during scheduled and essential maintenance work.

To operate an air ambulance service, the HSE would have to become a licensed aviation provider and recruit pilots. Given the current difficulties in the recruitment and retention of pilots within both the Air Corps and the commercial aviation sector (for example, Ryanair), this alternative is unlikely to be a viable short term solution.

Furthermore, the HSE does not currently have the expertise to safely operate an aeromedical service in-house. It would involve acquiring the key personnel and equipment, while also developing the physical infrastructure and organisational competencies, to safely operate such an aeromedical division. It would only work, in the short term, if the responsibility for pilotage, maintenance, flight safety and facilities rested with those with existing expertise in this area, for example the Air Corps. The HSE could continue with co-ordination of the transport logistics through the NEOC aeromedical desk. This would in reality be the Garda Air Support Unit (GASU) model mentioned later in Section 6.4 on the long-term alternatives.

6.3.2 Northern Irish service provider (all-island approach)

Woodgate Aviation provides aeromedical services to the Health and Social Care Board (HSCB) in Northern Ireland and in the Isle of Man. Its contract means it must be available 24/7 to transfer patients to Britain from Northern Ireland. It has two Beech King Air planes, two full-time crews and three freelance captains and currently transfers over 400 patients a year. The company charges a set rate per mission and that is based on a combination of which hospital the patient is travelling to and the category of patient being transferred. Its work load has almost doubled since the closure of cardiac surgery services for congenital heart disease in Belfast in 2015.

Currently, approximately 30% of these patients are now treated in Our Lady's Children's Hospital, Crumlin, with the intention that the service will fully migrate to Dublin over the next few years. In the interim, other children requiring cardiac surgery are transferred to Britain for their care.

Following a tender process a number of years ago, Woodgate Aviation is listed as a private provider on the HSE Air Ambulance Framework, and as a provider of first choice in respect of proximity to Dublin. Woodgate Aviation has confirmed that they are happy to continue to be listed. However, Woodgate is under contract to the NHS and has confirmed that it will only be in a position to offer services on an "as-available" basis. Since the Framework was put in place, it has been the experience of the HSE that Woodgate Aviation has never been in a position to accept an emergency mission from the HSE and it has not had availability in respect of non-emergency missions. Woodgate Aviation is, therefore, unlikely to be a viable alternative for the transfer of Priority 1 transfer patients in the short term. While Woodgate Aviation currently does not have enough planes or crew to provide a guaranteed 24/7 service for the Republic of Ireland, it may be one of the commercial entities who may be interested in tendering for a dedicated private air ambulance solution in the longer term, if tit acquired another plane, or its work load in Northern Ireland decreased.

In the long term, an all-island approach could be explored by the Department of Health with the Health and Social Care Board in Northern Ireland.

6.3.3 Funding of transport resources through philanthropic partnerships

The Department of Health and the HSE are currently in discussions with a registered charity around the possible provision of HEMS in the south of the country. Discussions have recently broadened to include the potential provision of fixed wing support to provide additional capacity for Priority 1 transfers. A written proposal from the charity is awaited.

6.3.4 IRCG – changes to existing arrangements

As referenced in Section 6.2.2, any material changes to the existing contract for provision of coastguard services would have to be negotiated and agreed between the Department of Transport, Tourism and Sport and CHC Ireland. It may be possible to seek agreement on amendments to the current working rosters, and the terms and conditions for the air crew and support staff, in order to modify the shift patterns to operate 12 hour pilot rosters at one or more of the IRCG bases. A 12

hour shift pattern would facilitate IRCG undertaking night-time Priority 1 transfers under HEMS rules.

There is an alternative of the IRCG accepting the risk of a helicopter crew overnighting in UK, with the potential latest time of arrival in UK for an individual flight would be 1.00am (that is, with an approximate departure time of not later than 11.00pm). This alternative does not solve the night time Priority 1 transfer problem, but it would reduce the current time window without cover for Priority 1 transfers by four hours, that is to 11.00pm – 7.30am. It would necessitate the aircrew having their rest period in the UK, and the aircraft being unavailable for SAR missions. Following a night time Priority 1 transfer tasking, the earliest time for this aircraft and aircrew to be available for SAR duty in Ireland would be 3.00pm the following day. This would pose a substantial risk to the primary function of the IRCG and is not considered further as an option.

At present, the IRCG transport Priority 1 transfer patients to the UK under commercial aviation rules, which require pilots to have at least 10 hours uninterrupted rest and no longer than 12 hour shifts on duty. The Department of Health could explore the scope for the IRCG to fly patients to the UK within the relevant regulatory framework, and whether it may be possible to carry out this function within a 24 hour shift system. This option is speculative and in addition would require a suitable agreement being put in place between the relevant Irish and UK authorities. Notwithstanding the small number of night time Priority 1 transfers likely be undertaken (fewer than four on average per annum) and that all are undertaken as airport to airport missions, consideration of any implications of such an arrangement for the safety of the crew, passengers, and ground staff would be of paramount importance.

6.3.5 Interim transfer of patients to Great Ormond Street Hospital (London) in the UK

Paediatric transplant patients, who may wish to relocate to the UK to mitigate the risk of relying on Priority 1 transfers, are often not well enough to live outside a hospital environment. A number of UK hospitals have been approached by the HSE and the Children's Hospital Group about the possibility of purchasing beds for the three Irish patients on the NHSBT heart transplant list for a period of time. This would be on the understanding that this would be an interim arrangement until a formal transport solution is arranged for Priority 1 transfers.

6.4 Long-term alternatives

The alternatives discussed below are those that could be used in the long term, that is longer than six months and up to two to five years to implement.

6.4.1 Air Corps air ambulance

This would replicate the current approach of the EAS (Emergency Aeromedical Support) service, which is operated by the Air Corps, with support from the National Ambulance Service (NAS), out of Custume Barracks, Athlone. Reserve capacity could be provided by the Irish Coast Guard during daytime. For the Priority 1 transfer service, the aircraft and crew would be located at Casement Aerodrome, Baldonnel, Co. Dublin.

The Air Corps fleet currently contains 17 fixed wing aircraft and 10 rotary wing aircraft.[89] However, there are only two operating fixed-wing aircraft — one Learjet and one CASA CN 235 — suitable for Priority 1 transfers. The CASA is currently designated as the contingency aircraft for Priority 1 Transfers. The second CASA CN 235 aircraft is undergoing essential maintenance in Spain until December 2017. It must be noted that these two CASA CN 235 aircrafts are 24 years old. The Cessna aircraft used by the Air Corps were purchased in 1972, and there is a tender for three replacement customised fixed-wing utility aircraft, which will have surveillance, medevac and air ambulance capabilities. These aircraft would have comparable speed to the Learjet. The lead time for procurement is one to one and a half years. The procured aircraft should have a similar platform to that already operated by the Air Corps. However, this procurement process will not yield a dedicated air ambulance.

For the Air Corps to provide an aircraft dedicated as an air ambulance, at least one additional fixed wing aircraft will be required which would result in additional capital expenditure with associated demands for additional current expenditure. This is due to the many and varied roles already performed by the Air Corps. The existing stock of fixed wing aircraft could not be released in order to be dedicated for inter-hospital transfers off-island. As such, any proposal will need to provide for an aircraft for such service provision with the capital cost of providing such an aircraft met by the exchequer rather than from within current Department of Defence resources. Ideally, a second aircraft would also be required due to maintenance cycles. Other existing Air Corps aircraft could be provided on the usual "as available" basis from the existing assets, subject to agreement.

Assuming an appropriate budget with capital and current allocation is secured by the Department of Health from the Department of Public Expenditure and Reform, the

real challenge is the establishment and staffing up of an Air Corps wing to operate the service given the staffing challenges being faced by the Air Corps at present. The option of a Air Corps air ambulance service would require staff recruitment and retention of pilots and air traffic controllers.

As highlighted in Chapter 3, the Air Corps is experiencing considerable staffing challenges. This reduction in staff resulted in the stand down of the 24 hour rosters in June 2016, which had operated on a standby basis (that is, on-call) for evening and night-time cover from 2011.

The Air Corps has been challenged in retaining pilots as the economy has improved, with the challenge coming primarily from the commercial aviation sector. While there is an ongoing plan to train replacement pilots, it is essential that the Air Corps strives to retain its current cohort of experienced pilots. On previous occasions when there was significant staff attrition, a Service Commitment Scheme was used to retain pilots in the Air Corps; a large number of pilots engaged with this scheme thereby protecting core services. Recruitment and retention issues within the defence sector will be considered by the Public Service Pay Commission as one of their priorities in their next tranche of work. All options to enhance pilot retention should be considered.

Of note, any proposal to recommend the Air Corps as the provider could only be considered as a proposition in the long-term.

6.4.2 HSE and Air Corps replicate the Garda Air Support Unit Model

The Garda Air Service Unit (GASU) is a dedicated air service unit for which the Air Corps provides pilots to operate two helicopters and one fixed wing aircraft for An Garda Siochana, under an SLA, and has been operating since 1997. The Air Corps in conjunction with the Department of Justice and Equality currently operate two EC135 T2 helicopters and one Pilatus Britten Norman Defender 4000 aircraft[(90)] seven days a week in the Garda Air Support role. Operational control of the aircraft remains with the Department of Justice and Equality, while the Air Corps provide pilots and aircraft technicians (for fixed-wing only) to the Garda Air Support Unit (GASU) to fly and maintain the aircraft.

If the HSE was to replicate the GASU model with the Air Corps to obtain a dedicated air ambulance service, the operational control of the aircraft would remain with the HSE. The HSE would provide the necessary investment or financial arrangements for the capital acquisition of an aircraft, and the appropriate ongoing financial support for the service provision by the Air Corps pilots and aircraft technicians.

The establishment of such a service would require the establishment of a Squadron (similar to GASU) and associated crew and support staff, office space etc. In addition, there are a number of sunken costs across the entire Air Corps (such as support operations, air traffic control, security personnel, hangar space and associated costs, airfield fire crews, technicians and air field maintenance) which cannot easily be identified and apportioned to reflect the associated cost to such an inter-hospital service.

At least one dedicated fixed wing aircraft would be required, which would result in additional capital expenditure with associated demands for additional annual current expenditure from Department of Defence resources; however, the acquisition of a platform similar to one in use by the Air Corps would be required to maximise synergies in terms of training, maintenance and logistics support. This would enable the provision of a back-up from existing Air Corps aircraft during maintenance cycles. Other existing Air Corps aircraft could be provided on the usual "as available" basis from the existing assets subject to agreement.

Assuming an appropriate budget with capital and current allocation is secured by the Department of Health from the Department of Public Expenditure and Reform, as noted in Section 6.4.1 above, the real challenge is the establishment and staffing up of an Air Corps Squadron to operate the service given the staffing challenges being faced by the Air Corps at present.

Unless adequately resourced, there may be issues with the long term sustainability of such a service and any proposal to recommend the Air Corps as the provider.

6.4.3 Provision of aircraft and aircrew from within IRCG fleet and staff from 2022

The current contract with CHC Ireland finishes in 2022, with an option to extend for three years to 2025. From a public procurement perspective, in any new contract, the Department of Transport, Tourism and Sport could specify additional requirements to the core search and rescue remit of the service provider. A new contract could extend the remit of the Coast Guard to include HEMS such as Priority 1 transfers and inter-hospital transfers as part of the primary remit. Unlike current arrangements for the IRCG SAR contract, which provide for 24 hour duty rosters, HEMS must be provided under commercial air transport rules and operate on a maximum of 12 hour shift patterns. Any new tender would therefore need to take consideration of this requirement if HEMS were to be specified as a concurrent activity.

The new tender proposal may require additional aircraft (including one dedicated for air ambulance duties) and changes to the current work rosters and practices of pilots.

6.4.4 Tender for dedicated private air ambulance service

The dedicated air ambulance service for the Irish state could be provided by a private operator. The high level of variation in price and service specifications available is outlined in Section 6.2.1. A public tender for a fixed term private air ambulance service contract would be required, conducted in line with best practice public procurement policies. Tenders have been conducted by the States of Guernsey and Jersey,[91] and the Isle of Man for air ambulance services.

6.4.5 Setting up paediatric heart and liver transplantation services in Ireland

The six hour time frame for the transport of liver transplant patients is generally achievable, with one to nine Priority 1 transfers per year. This is in contrast to the four hour window available for cardiac transplants. It has been suggested that paediatric heart and liver transplant services might be developed in Ireland. The availability of such a service could significantly mitigate the risk associated with the viability of organs and the risks associated with transporting paediatric patients. However, establishing such services would not be without risk. Given the limited demand for paediatric heart and liver transplants in Ireland, even when considered on an all-island basis, it is essential that future services would meet the recognised key performance indicators for all clinical outcomes associated with international centres of transplantation excellence.

Service specifications for paediatric heart (including the requirement for a ventricular assist device (VAD) service) and liver transplant programmes were discussed in detail in Chapter 5. These outlined the additional clinical, infrastructure and support services that would be required in line with international specifications to resource dedicated national paediatric transplant services.

During 2017, the second phase of the All Island Congenital Heart Disease (CHD) Programme will see the commissioning of a further two paediatric intensive care unit (PICU) beds. These additional beds will enable urgent patients from Northern Ireland to be treated in Our Lady's Children's Hospital, Crumlin, without impacting on the current CHD elective waiting list. The next phase of the All Island CHD Programme will facilitate surgery for approximately 120 elective CHD patients from Northern Ireland. A further four PICU beds will be built and commissioned to accommodate these patients.

It is clear that it would take considerable time to develop paediatric heart and or liver transplant programmes in Ireland. Given the significant capital and staffing resources that are required, and in light of the current focus and priority to develop the All Island CHD Network, it may be more realistic to consider the development of these transplant services in the context of the opening of the new children's hospital rather than in Our Lady's Children's Hospital, Crumlin.

The Department of Health will need to develop a policy position in relation to the repatriation of the paediatric cardiac and liver transplant services. There is need to consider the impact of the loss of access to the larger donor pool in the UK as well as whether the activity levels at approximately one to three paediatric heart and three to seven paediatric liver transplants per year would be sufficient to support a full service, and to ensure clinical outcomes are consistent with those achieved in centres of excellence internationally.

The development of a domestic paediatric transplant service could only be considered as a partial potential long term solution to the air ambulance difficulties. Given a potential reliance of a national programme on obtaining donor organs from the UK and the rest of Europe, it may necessitate urgent transport of organ retrieval teams abroad to retrieve donor organs and for these teams to be returned to Ireland within the four and six hour time windows.

6.4.6 Development of a national integrated aeromedical transport service

As discussed in Section 3.6, national aeromedical transport activites are not just confined to the air transport of Priority 1 transfer patients. As well as the aeromedical transport services already defined in Section 1.2 of the report, there are also the scheduled inter-hospital transfers conducted by the Air Corps and the IRCG on an "as-available" basis.

The national aeromedical activity for 2016 and 2017 is shown in Tables 6.1 and 6.2.

Note, the figures for 2017 are year-to-date as of 31 August 2017. These figures have been extrapolated pro-rata based on monthly averages to give an indicative annual total for 2017. In addition, the IPATS retrieval and transfers by ground ambulance outside Greater Dublin, which numbered 47 missions by 30 September 2017, have been extrapolated to give a number of 64 missions per annum. Aeromedical transfer may also be relevant for IPATS retrievals depending on the location and transfer requirements for the patient. The 2017 estimate figures do not allow for the seasonal winter peaks in service demands.

Table 6.1 National Aeromedical Statistics for 2016 (Source: NAS NEOC)

Service	Requests	Completed	Stood Down/ In-Flight	Refused
EAS HEMS	880	436	273	171
EAS Inter-Hospital Missions	14	11	2	1
EAS Inter Hospital STEMI Mission	17	10	3	4
IRCG HEMS	161	102	25	34
IRCG Inter-Hospital Missions	55	44	6	5
IRCG Inter-Hospital STEMI	27	21	0	6
Air Corps Air Ambulance	81	64	2	15
Total	1,235	688	311	236

Table 6.2 National Aeromedical Statistics for year-to-date as of 31 August 2017 (Source: NAS NEOC)

Service	Requests	Completed	Stood Down/ In-Flight	Refused	Estd Completed in 2017
EAS HEMS	**487**	237	**180**	**70**	356
EAS Inter-Hospital Missions	**10**	5	**0**	**5**	8
EAS Inter Hospital STEMI Mission	**11**	6	**0**	**5**	9
IRCG HEMS	**89**	48	**23**	**18**	72
IRCG Inter-Hospital Missions	**65**	50	**5**	**10**	75
IRCG Inter-Hospital STEMI	**10**	6	**1**	**3**	9
Air Corps Air Ambulance	**33**	22	**3**	**8**	33
Total	705	374	212	119	562
NTMP IPATS Retrievals/Transfers*					64
Revised Estimate					626

* Outside Greater Dublin area

The EAS provides a dedicated air ambulance service. All IRCG inter-hospital missions and Air Corps air ambulance are undertaken on an "as-available" basis. The inter-hospital missions are often scheduled in advance. For 2016, IRCG plus Air Corps missions (excluding HEMS or Priority 1 transfers) totalled 120. If one includes the estimate of 64 potential IPATS retrievals/transfers and the nine Priority 1

transfers in 2016, there could be almost 200 aeromedical missions falling outside current dedicated services per year.

Given the overall number of aeromedical flights, the long-term approach may be to integrate the existing services under one national specialist transport service for Ireland. A similar approach was taken in Scotland with the establishment of the ScotSTAR (Scottish Specialist Transport and Retrieval) service in April 2014. This approach would require a national planning forum to conduct a strategic review of the existing services to formulate an integrated national approach to aeromedical services. It may allow for the combination of existing logistical and support functions, including co-ordination and dispatch of these resources from a central tasking authority. This approach may require significant organisational changes and resources to fund same, but could deliver efficiencies for the health services.

6.5 Other options explored

6.5.1 Interim transfer of patients to private hospitals in the UK

The possibility of contracting private beds in the UK, as an interim measure, was also explored. Aside from the extremely restricted availability of services with dedicated paediatric cardiology and cardiology ICU beds in the private sector capable of meeting the clinical needs of these patients, current UK legislation does not permit private patients to transfer into the public healthcare system. Similar to the Irish legislation (Department of Health Circular 1/1991), relating to health service eligibility and access to public hospital services, patients on the NHS Blood and Transplant (NHSBT) transplant list can only enter transplant treatment centres from the publicly funded healthcare system. Inpatients in private hospitals would therefore not be offered donor organs from the NHSBT unless permission was granted to so do on the basis that these admissions were being funded by the public purse.

6.5.2 Alternative destination airports in London

Given that 75% of Priority 1 transfers have occurred at night time (7.00am-7.00pm), the night-time landing restrictions at London City Airport, and at RAF Northolt, means that these airports do not offer a solution to improve the flight transfer times at night.

In the event that the first choice airport, London Heathrow, is fog bound, other airports in close proximity to London are considered for night-time landing. These include London Gatwick Airport (approximately 30 miles from central London),

London Stansted Airport (approximately 35 miles from central London) and London Luton Airport (approximately 35 miles from central London).

Appendix 3 outlines further details around the destination airports accessed by service providers when conducting Priority 1 transfers.

6.6 Key Points

- A range of alternative approaches were identified for providing efficient and sustainable treatment or transport of Priority 1 transfer patients. These were divided into immediate, short term and long term alternatives, reflecting the requirement to address an immediate need to have a transport solution for Priority 1 transfer patients in place on the 6 November 2017, whilst also exploring sustainable longer term alternatives that could provide improved efficiency.

- The immediate alternatives identified were:
  - fund a dedicated aircraft and aircrew from a commercial provider
  - fund a dedicated IRCG aircrew operating an "as-available" IRCG helicopter
  - charter aircraft "as needed"
  - provide financial assistance to all patients and families who choose based on clinical advice from the NAS to relocate to the vicinity of the transplant centre in the UK
  - lease or purchase of a property in the UK for patients and families who choose or are advised to relocate to the UK
  - to continue to work with the limited availability of the Air Corps and IRCG from 6 November 2017 (the "as-is approach ").
- The short term alternatives identified were:
  - the HSE leasing and operating aircraft
  - partnering with a Northern Irish service provider (all-island approach)
  - funding of transport resources through philanthropic partnerships
  - renegotiating the existing contractual arrangements with IRCG to allow 12 hour rosters at one or more bases
  - seeking permission to undertake IRCG Priority 1 missions to the UK under SAR rules
  - procuring inpatient beds in the UK for selected patients awaiting transplant.
- The long term alternatives identified were:
  - a 24/7 Air Corps air ambulance to be operated "as available"
  - the HSE and Air Corps replicating the Garda Air Support Unit model
  - extension of IRCG primary remit to include HEMS at contract renewal in 2022
  - tendering for a dedicated private air ambulance service
  - setting up paediatric heart and liver transplantation services in Ireland

- developing a National Integrated Aeromedical Transport Service (NIATS).

- Other potential alternatives explored were:
  - accessing alternative London airports.
  - transferring patients to private hospitals in the UK.

7 Societal and ethical issues

This chapter discusses the wider societal and ethical issues that should be considered in relation to the transport and treatment of Priority 1 transplant patients. This chapter was developed broadly in line with the structure described in the EUnetHTA Core Model. In the context of this chapter, the technology of interest is the transport and treatment of Priority 1 transfer patients. The focus here is on paediatric patients being transferred for heart or liver transplant, although it is acknowledged that they may not comprise all Priority 1 transfer patients. Alternatives to the current standard of care include the potential for the provision of new paediatric transplant services within Ireland.

It is recognised that a child in need of a transplant will be in the care of one or both parents or guardians. For simplicity we refer to parents in the subsequent text, but that can be interpreted as guardians.

7.1 Societal issues

The purpose of considering societal aspects of a technology is to highlight issues that are relevant to patients, individuals and caregivers. In this case, caregiver is an umbrella term that encompasses family, friends and other persons within the patient's social network. For some technologies the "patient" may not be ill, such as in the case of a screening programme, in which case it is more appropriate to refer to the patient as an individual. However, in the context of this project, the persons receiving the technology are primarily children awaiting organ transplant and hence they will be referred to here as patients. Children are by definition a vulnerable cohort as they rely on parents or guardians to provide informed consent on their behalf.

It should also be noted that although many paediatric patients are very young, some are adolescents who will wish to actively participate in the process and exercise some degree of self-determination.

7.1.1 Patients' perspectives

Paediatric organ transplantation is often characterised as a journey, taken by the child and their family, and starting when transplantation is first considered as a treatment option.[92]

The need for organ transplantation and acceptance onto the waiting list implies a certain severity of illness. The conditions necessitating transplant may be congenital or acute onset.[92] In the case of the former, the underlying illness may have been identified at or shortly before birth and may have significant impacts on physical and

cognitive development. For acute onset conditions, children that were healthy require urgent and invasive therapy that may result in a permanent reduction in quality of life. These two scenarios have different implications for how the need for transplantation is experienced by both the child and their family.

At the time of diagnosis of the underlying condition and identification of the need for a transplant, parents typically experience a grief reaction in response to the diagnosis of illness.[93] The grief is associated with the perceived loss of a healthy child and the immediate uncertainty over what will happen. Parents tend to experience high levels of stress, anxiety, and depression.[92, 94]

The process of transplantation is complex and has many strands, including sourcing an organ, the procedure itself, the potential adverse outcomes and post-surgical care. For parents there is a complex vocabulary to come to terms with.[93] Depending on the level of health literacy of the parents, developing an adequate understanding of their child's condition and the implications of transplantation is likely to be challenging. There is also a need to be able to navigate through the health system and understand where to source appropriate information and which healthcare professionals to approach in different situations. This may be compounded by the fact that care is currently delivered across two healthcare systems: the Health Service Executive (HSE) in Ireland and the National Health Service (NHS) in the UK. Developing an understanding of a second system may give rise to further stress and anxiety, and create barriers for accessing relevant information or expertise.

The identification of transplant as a treatment option is likely to give rise to hope. There may be an implicit assumption that a transplant will return a child to full health. Consideration of transplantation may be aimed at achieving close to normal life expectancy; however, it may also be aimed at improving the quality of life and not considered as a means to substantially extend life. It is critical that patients and care-givers have realistic expectations with regard to transplant and the extent to which it may extend and improve life. A full appreciation of the level of post-transplant care required may be difficult to convey, but is critical to ensuring good adherence to medication and follow-up care in the medium- to long-term.

Patients awaiting heart transplant often have to reside in Our Lady's Children's Hospital, Crumlin (OLCHC) until an organ becomes available. In contrast, most children awaiting a liver transplant can live at home until an organ becomes available. Residing in hospital for a protracted period of time has implications for children in terms of access to their family and friends. Children of school age that are hospital-based are unable to attend school as normal. Irrespective of whether a child can remain at home or not, there are physical deficits and a reduction in quality

of life associated with illness.[95] The disruption to family life is significant and can adversely impact family dynamics.

The period from being added to the transplant list and actually receiving a transplant is one of uncertainty.[95] There is no guarantee that a suitable organ will become available, and there is a substantial mortality rate for children on a transplant waiting list.[96] The waiting time can be anything from weeks to years, depending on the organ and the characteristics of the individual (for example, size and blood type). Parents or guardians must be on standby to travel if an organ becomes available, which places many of the activities of normal living on hold for fear of missing out on a transplant opportunity. Children on transplant waiting lists have shown high levels of anxiety and depression,[95] and they have complex emotional needs that must be met by the family.[92] Knowing that their child is ill and in need of a transplant, parents are likely to be very conscious of time passing without resolution, leading to increased anxiety and a perception of "time running out". This feeling will be amplified if their child's health is deteriorating. A parent is also likely to be conscious that, with the exception of living donors, a donor must die for their child to receive a transplant. Equally, parents may get to know other families with children awaiting transplant, and they are aware that, for their child to get a transplant, another child must continue to wait and potentially die before an organ becomes available.

When a donor organ is identified, the patient must be transported to the receiving hospital within a tight time-frame. For heart transplants, the time window is four hours. To date the modes of transport to get a child to the UK have been provided on an "as available" basis, meaning that there was no guarantee that transport was available when required. Other circumstances, such as adverse weather conditions, could also lead to flight cancellation. Since the current transfer protocols were put in place in 2012, all transfers have been completed successfully when weather conditions were amenable. A single transfer could not be completed as planned due to weather, although the patient was successfully accommodated on a commercial carrier. Even after successful transfer to the receiving hospital, surgery may be cancelled for a variety of reasons, necessitating a return journey to Ireland and the impact on morale of having not received a transplant.

For heart transplants, a child must travel from Ireland to Great Ormond Street Hospital in London within a four hour time-frame, and it may not be possible for parents to travel with their child. This may occur because of the capacity constraints of the aircraft used for transfer and depend on the number of medical staff and the amount of equipment that must be brought on the flight to manage the patient. Finding flights at short notice can be challenging, and not all parents will have the

financial resources to pay for flights out of pocket and then await reimbursement from the Treatment Abroad Scheme (TAS). Under the EU regulation that governs TAS, only the cost of treatment for which the patient is approved is mandated; the governing regulation does not provide for the cost of travel or subsistence. The national policy for TAS patients that was introduced by the HSE in 2009 does cover the cost of some travel; however, this is restricted to the reimbursement of flights for the patient or, where appropriate, the patient and one travelling companion. Cost of transport for a second parent must be borne out of pocket. Subsistence costs are not eligible for funding through the TAS, nor are additional transport costs such as transport to and from the airport. For families with other children or dependents, it may not be possible for both parents to travel unless alternative care arrangements can be made. Although the transplant procedure is notionally elective, it takes place under emergency conditions. There may be substantial stress for both child and parents if they cannot be together immediately prior to surgery.

If only one parent can travel, then shared decision making will be hampered, which may be particularly significant in the event of major complications or other unplanned events where care decisions must be taken quickly.

After surgery, a patient may remain in the receiving hospital for a number of weeks before returning to Ireland. It is possible that only one parent will be able to stay with their child during some or all of that period. It is in that post-surgical period that there is a significant risk of graft rejection. Depending on the hospital at which surgery takes place and on capacity, it may be possible for parents to stay in accommodation at the hospital during the recovery period. Ordinarily, it is recommended that during this time parents would make use of their extended families and social networks for psychosocial support.[94] However, as surgery takes place in the UK, many parents find themselves separated from those supports.

Liver transplant patients who have recuperated well after surgery may return to Ireland by a commercial airline. Although the cost of commercial flights is reimbursed through the Treatment Abroad Scheme, parents must purchase the flights themselves. This may be less stressful for the return journey, although it may still have to be organised at short notice. However, it still supposes that parents have the wherewithal and financial means to book flights. If a child has not recuperated well after surgery, then there may be a protracted stay in the receiving hospital followed by elective aero-medical transfer back to Ireland.

Should a patient die while obtaining or awaiting treatment in the UK, the parents are responsible for organising repatriation of the body. Repatriation of the child's remains to Ireland can be a complicated and costly process. A funeral director must be appointed and the coroner in Ireland for the district where the body is being

flown to must be notified. The local hospital may liaise with the family to identify a funeral director. It is typical for funeral directors to require advance payment in this context. It must be noted that there are cultural differences between the UK and Ireland in terms of funeral arrangements. For example, funeral directors in the UK tend to be closed at weekends, delaying the process of repatriation. At present, it is the responsibility of the parents to arrange and fund repatriation, although the cost of transfer is reimbursed afterwards. This places a very substantial emotional and financial burden on the family at a time of deep distress. In this situation, support to families who ordinarily reside in Ireland is provided by the Department of Foreign Affairs and Trade through the local embassy or consular office. Although the Department of Foreign Affairs and Trade cannot pay for repatriation, it can put parents in contact with organisations that may be able to offer financial assistance. Some commercial airlines may also require that the coffin is brought to the airport at least a day before flight, which is likely to cause further distress for families.

7.1.2 Expectations

After a successful transplant, parents and family may feel that the major bridge has been crossed and that their child will achieve near normal or normal health and life expectancy. As stated previously, transplant is considered a treatment and not a cure. The post-transplant period is one of transition to managing illness in a different way. In the short- to medium-term after transplantation, there is a substantial burden on parents and family in terms of management of medication. Parents and family may not fully appreciate the ongoing potential for complications such as the risk of infection due to being immunocompromised and the risk of graft rejection.[92] Children who receive heart transplants are also at risk of developing vasculopathy of the coronary arteries, potentially necessitating re-transplantation. Children that become depressed while waiting for transplant may take an extended period of time to recover.[94] In addition, transplant recipients often experience reduced exercise tolerance and capacity, weight gain and muscle weakness due to prolonged periods of bed rest, physical inactivity, immunosuppressant use and resultant muscle wasting.[97] Thus, while parents may have a perception or expectation that their child will immediately regain full health, the recuperation period may be lengthy.

The discharge transition has been highlighted as a critical point for ensuring good home-based management of children who have received a transplant.[98] Care coordination is seen as an essential component for safe transition from hospital to home. As the discharging hospital is based in the UK and care is also provided through a paediatric hospital in Ireland, care coordination is more complex and there may be a greater risk for important information to be lost or misunderstood, requiring greater effort to ensure an effective discharge transition.

A significant issue in post-transplant care is non-adherence to medication, most notably in adolescents. Non-adherence increases the risk of graft rejection and the need for re-transplantation, and it also affects suitability for re-transplantation.[99] The medication regimen can be complex and difficult to manage. While adults will manage medicines for infants and small children, once patients are adolescents, they are likely to play an important role in their medication management.[94] There are a variety of factors involved in non-adherence to medication, including medication-related issues, psychological issues, family dysfunction, cognitive function and socio-economics.[99] It is imperative that adherence is kept high to minimise graft failure. Some of the suggested approaches to improve adherence include educational programmes, identifying poor adherence early, simplifying the medication burden, and supervised administration. Some of the medications may not be available in the appropriate paediatric dose; this can lead to pill-splitting being required, which can give rise to dose errors.

In the year after transplant, the child will have to have regular and frequent follow-up visits. The extent to which those can be undertaken in Ireland may depend on the individual patient. Should the visits be to the UK, then TAS will fund flights for the child and one adult. Again, for those who may be constrained financially, there may not be sufficient resources for both parents to travel. There may be a lot of clinical information to take in at a visit. Rather than both parents receiving the information first-hand, one will hear an interpretation by the other.

7.1.3 Burden on care-givers

The primary care-givers are the parents or guardians of the child. They must therefore fulfil a dual-role: parent/guardian and healthcare provider. It is not expected that the two roles can be neatly delineated and separated.

Parental quality of life has been shown to be poor in families of children who have had a transplant.[100] Family functioning may be impaired by the experience of a transplant. Reported functioning issues include marital problems, disagreements over the child's care, spousal disagreements, reduced recreational time, reduced time with spouse, and insufficient time to take care of the practical and emotional needs of siblings.[100] These issues may begin soon after transplant has been identified as a treatment option, and continue after a transplant has been undertaken.[101]

A comparison of families of liver transplant patients and those of chronically ill or disabled children found similar levels of family strain.[102] However, significantly higher financial impact, impact on coping, and impact on siblings for the families of

transplant patients were observed. Family strain and parental quality of life impact on the quality of life and psychosocial functioning of the patient.[103, 104]

As has already been noted, the transplant process may place a significant financial burden on a family. This is particularly true if a parent ceases working in order to act as a full-time carer. Parents who are in receipt of social welfare benefits such as Jobseeker's Allowance who spend extended periods of time in the UK may have their payments suspended due to the usual restrictions that apply to these schemes, placing them at risk of very significant financial hardship. The process for seeking reimbursement can be difficult to complete for some, and the time to obtaining approval under TAS and actually receiving the funds can be very slow, further compounding the financial burden.

7.1.4 Social group aspects

Due to the nature of the service, which requires transfer to a UK hospital, and the limited time-window available for transfers, people living in some parts of the country may be unlikely to achieve transfer within the necessary time-frame. For clinical reasons, many patients awaiting heart transplant are inpatients in OLCHC. Contingent on the availability of an aircraft and crew, they should be able to reach London within the four hour time-frame. Other patients, including the majority of those awaiting liver transplant may be clinically well enough to reside at home. Although the time window from notification to required arrival at the transplant centre is longer for those undergoing liver transplant, it may be challenging to provide timely transfer of patients from some parts of the country. Depending on the status of the donor organ (donor after brain death [DBD] versus donor after circulatory death [DCD]) and the length of the process for the formal declaration of brain stem death and the subsequent retrieval of organs, transplant coordinators may be in a position to alert the various stakeholders as to the likely availability of an organ prior to the organ being retrieved. The process of transferring the patient may, therefore, start at an earlier point, which can give the impression that the notification period is longer for DBD organs. While this practice facilitates the timely transfer and transplantation of patients, there is a risk that the transfer may be stood down in the event of the retrieved organ not being found suitable.

For those whose geographic location may be a significant obstacle to achieving successful transfer, it may be necessary to relocate to Dublin to maximise the likelihood of transfer in the event of a suitable organ becoming available. Relocation is a major undertaking that can split a family for what may be a wait of months or even years.

Those with limited financial resources may find cost is a barrier to accessing the service. It may act as a barrier to relocation, to travel and to providing the level of home-care that may be required. Given the complexity of the procedure and care, a certain level of health literacy may be required to ensure that appropriate decisions are made and care provided.

7.1.5 Communication aspects

Given the complexity of the transplant journey, many different aspects must be communicated to both the child and parents. Thus information has to be pitched at different levels to explain issues such as treatment options, to manage expectations, and to support care in the home.

Given the nature of the conditions for which transplantation is an option, there is likely to be a large amount of information that parents must take in regarding illness management, treatment options and outcomes.

When faced with transplantation as a viable treatment option, an immediate question is whether or not to add the child's name onto the waiting list. Consideration has to be given to the likelihood that it will result in improved outcomes over and above other available therapies. Communication at this point must clearly outline what the treatment involves and how long children typically have to wait for a donor organ to become available. It is important that parents understand that not all children survive to transplant as demand for donor hearts outweighs supply.

Assuming that parents wish to place their child on the waiting list for transplant, information must be communicated on the procedure itself, post-transplant care, transport-related matters and how the service in the UK is delivered. Some of that information will come from the HSE and some from the NHS in the UK. It is essential that the two sources of information are coordinated and that they are appropriate to Irish patients. As the HSE is the provider of healthcare to Irish patients, it is appropriate that the HSE takes responsibility for ensuring that the relevant and appropriate information is communicated.

Some parents may have extensive experience of booking and taking flights to other countries. However, it must be recognised that some may have little or no experience. Particularly in the case of London, there are a number of airports with frequent flights to Ireland. Some airports are closer than others to the centre of London, and some may be easier to reach by public transport than others. The choice of flight times will be different at each airport. For flights taken to return home from the transplant operation, there may be significant stress related to

leaving the hospital after several weeks of care and no longer having immediate access to healthcare professionals if the patient feels unwell. It should be considered how best to provide information on travel options, particularly for those parents with little experience of travel outside of Ireland. Parents must also ensure that they have appropriate and up–to-date identification. Some airlines insist on a passport, although it is not a legal requirement for Irish citizens when travelling between Ireland and the UK as alternative photo identification is acceptable. In the case of children under 16 years of age, photo identification is not required when accompanied by a parent or guardian who is an Irish citizen. Requirements for passports and valid visas are substantially more complicated for children whose parents are not Irish citizens (for example, undocumented foreign nationals) and may represent a significant barrier to travel. The Air Corps requires passengers to have valid passports when transferring patients to the UK.

Parents are likely to need support and assistance in the event that their child dies while in the UK in relation to treatment.

As patient care is split between two jurisdictions, separate patient records will be generated at each hospital. This may affect the ease with which parents can obtain relevant information, particularly once the child has been discharged from the UK hospital. Parents of patients should be provided with clear instructions regarding what information they need to obtain at different visits so that, once home, they are confident providing home-based care.

Given the noted impact on families of the transplant journey, especially in relation to family strain and quality of life, parents should be fully informed of any psychosocial supports available to them. It is in the interests of patients, families and the HSE that supports are availed of to minimise the adverse effects on the family. A better functioning family is likely to lead to better adherence to medication and, therefore, improved longer-term outcomes. Strong consideration should be given to the establishment of a transplant liaison officer for paediatric transplants. The liaison officer could act as a central resource for information regarding the process, how to organise travel to and within the UK, and how to access financial and psychosocial supports if needed. Such a role may act to reduce stress and anxiety for families, and enable them to focus on the care of their child.

7.2 Ethical considerations

This section considers the ethical issues that may be relevant to the transport and treatment of transplant patients for Priority 1 transfer. The issues must be assessed in relation to the prevalent social and moral norms relevant to the technology. This section also examines the ethical issues related to the technology assessment itself.

For the purposes of this section it is assumed that children are only considered for heart or liver transplant if there is a belief that it is clinically necessary and provides a viable treatment to prolong or improve the quality of life of the child. It is further assumed that children are prioritised on the waiting list based on sound clinical criteria that balance need with potential to benefit.

7.2.1 Benefit-harm balance

Depending on the underlying condition, a child awaiting a transplant may have a very short life expectancy and reduced quality of life. Transplant can offer the opportunity of improved life expectancy and quality of life. Short to medium term survival can be high for paediatric transplant recipients. There is, however, an ongoing risk of long-term or late complications due to graft rejection or injury or immuno-suppression-related morbidity.[105] Lifelong and non-specific suppression of the child's immune system is a cause of significant morbidity, including infection, diabetes, and cancer.[106] Given the consequences of not providing a transplant to a child in need, it would not be considered ethical to carry out further studies to accurately determine the treatment and adverse effects of a transplant, as might be carried out through a randomised controlled trial.

While extending life can be measured in terms of post-transplant survival compared to predicted life expectancy without transplant, it is more difficult to measure quality of life. A range of disease-specific quality of life measures have been developed and tailored to the nuances of those conditions. Challenges arise due to the age of the patients. Particularly for heart transplant recipients who may be only one or two years old, it is not possible to administer a typical quality-of-life questionnaire.

For liver transplants the potential long-term benefits are quite considerable. Recipients are likely to experience a range of chronic conditions and post-transplantation complications affecting extrahepatic organs.[107] Survival is high and recipients may have a near normal life expectancy. Patients often achieve a post-transplant quality of life that exceeds that of the pre-transplant period, and those benefits can be sustained up to 20 years post-transplant.[108, 109] Although quality of life may reach levels similar to the general population, physical functioning tends to be poorer and employment levels may be lower.

It is anticipated that the benefits of transplant are likely to outweigh the harms for the average patient. It should be noted that the patients, in this case children, may not be able to appreciate the benefits-to-harms balance. It is, therefore, the parents who must determine whether they perceive the benefits to outweigh the harms on the behalf of their child. Whether or not they can make an informed judgement

depends on the information provided to them and their ability to reasonably understand that information.

While it is ordinarily expected that parents will consent to organ transplant, in some cases they may choose not to.[110] There may be a variety of reasons for making such a choice, such as the perceived benefit in a particular case may be very low. Failure to allow treatment for a child may be considered as negligent if there is a prospect of prolonging life even for a short period. This must be counterbalanced with best use of available donor organs. It is essential that parents are fully cognisant of the range of potential benefits and not just a best or worst case scenario.

An unusual feature of paediatric transplant is that it is both rare and that it is dependent on the availability of an organ. As the demand for organs exceeds the supply, not all patients survive to transplant. When an organ becomes available, depending on the characteristics of the organ and those on the waiting list, several children could potentially be eligible for the one organ. Due to the limited supply, providing an organ to one child may deny an organ to another, potentially exposing the other child to harm. This raises questions about how one child is selected over others and whether consideration is given to which child is likely to benefit most from the transplant. As noted in Section 7.1.2, there are a number of factors associated with adherence, and non-adherence is predictive of graft failure. As stated in 7.3, it is assumed that organs are distributed based on sound clinical grounds that are intended to achieve best outcomes across the cohort and not on the basis of whether patients are at risk of non-adherence. As organs are in short supply, it is imperative that they are used appropriately and on the basis of potential to benefit.

In many cases, a patient's parents and care-givers experience stress and negative impacts on quality of life in the post-transplantation period. These findings should be viewed in the context of what the impacts would be of their child not receiving a transplant. Without a transplant a child's health is likely to deteriorate, and they will experience further reduced quality of life and reduced length of life. It is likely that family and care-giver quality of life and stress would be negatively affected under those circumstances.

7.2.2 Autonomy

The right to autonomy is affected by the fact that the patients of interest are children, and hence the right to decide to receive a transplant is with the parents. Where the patient is an adolescent, it is appropriate to consider using a shared decision making approach. To be fully autonomous, the patient must understand not

just the direct risks of treatment but also the alternatives to treatment and how treatment will affect quality of life.

If parents are unable to be with their child at critical points, for example, if they cannot travel with their child at the point of transfer to the transplant hospital, then they may not be in a position to make decisions for their child.

To exercise autonomy, even via their parents, a patient must be able to make informed consent at each step of the process. While it is unlikely that a child will be able to fully comprehend the impact of their choices, it may also be challenging for parents to make those choices on their behalf. It is likely that parents will put substantial faith into the advice and judgment of the clinical team. Informed consent for transplantation may be requested during a pre-transplant assessment in the UK. Although from a legal perspective only one parent is required, it is not ideal to only support the presence of a single parent and this situation disadvantages those who are financially constrained.

It is important to consider whether a short-term benefit, such as an additional five or ten years of life might be considered differently in children than in another population such as the elderly. There may be a belief that in that time, a new technology or medical advance may take place to further prolong life. For an elderly patient, it may be perceived that they have lived their life and that an additional five years would be of limited value. Furthermore, it may be thought that five years for a child would in some way be more valuable. This perception may impact on the ability to make objective decisions regarding treatment on the part of parents and clinicians.

7.2.3 Respect for persons

A child that has received an organ transplant may feel at risk of being stigmatised or marked out. Due to immuno-suppression, a child must be careful to avoid unnecessary exposure to infection. Parents may feel that their child must be carefully managed to avoid the risk of infection or injury and, therefore, may restrict a child's activities to ensure a safe environment. This can result in a child feeling marked out and excluded from many activities seen as normal for a child of their age. However, the alternative of not having a transplant entails chronic illness that may require similar or much more severe restrictions on activity. Hence transplant is unlikely to violate dignity more than the alternative.

As part of the transplant journey, patient records are initiated by a number of organisations, including the transplant service in the UK, the National Ambulance Service in Ireland, and both the Irish and UK hospitals. Detailed data on the individual and their parents are held by these organisations across two jurisdictions.

It is important that the data are managed in accordance with European data protection legislation and are only shared as appropriate.

One of the potential approaches to addressing the current issue with Priority 1 transfers is to forego a night-time service. In other words, transplants could only be availed of if transport is available through the existing "as available" arrangements with the Air Corps, Irish Coast Guard or private air ambulance, whereby neither the Air Corps (from 6 November 2017) or the IRCG is available at night. Given that the majority of transplants occur at night-time, this would mean that most transplant opportunities would have to be forfeited and mortality on the waiting list would likely increase. This would raise ethical questions about placing children onto a waiting list for a service that they have limited prospect of availing of - not because of the organ donor pool but due to an inability to ensure timely transfer to the UK.

7.2.4 Justice and equity

It is ordinarily expected that donated organs will be allocated in accordance with clinical need. However, an exception may occur where there is a living donor, such as a parent donating a lobe of their liver to their child. In that event, the organ is provided to a selected child and not made available to other children on the waiting list. This situation is not ordinarily considered unethical.

Organ transplant as a treatment is costly. This report does not estimate the cost-effectiveness of paediatric organ transplant, but it does consider the potential costs for different approaches to the transfer of patients to the UK for treatment. As there is uncertainty regarding the number of transfers required in a year, the approach of utilising the Irish Air Corps and Irish Coast Guard has been relatively inexpensive for the HSE as there was no retainer payable and charges were only incurred by the HSE for flights provided by the Irish Coast Guard (airport landing charge plus a cost per hour for the mission). The average cost invoiced to the HSE per Priority 1 transfer to the UK by the Irish Coast Guard is approximately €6,000, generating a total invoiced cost of €48,000 in 2016 for example. Transfers, therefore, capitalise on the availability of crews and aircraft. The cost to the HSE represents only a fraction of the actual opportunity cost to the Air Corps and Irish Coast Guard to provide those flights.

Should the HSE enter into a contract with a private provider to provide a 24/7 or night-time only service, there may be a substantial flat fee in addition to a cost per flight. There is no certainty that the private provider would be called on in a given year, as the timing of transplants may coincide with availability of Air Corps or Irish Coast Guard resources. The cost of a retainer would therefore represent a substantial re-allocation of resources that could usefully and effectively be deployed

in other areas. When the costs are spread over the anticipated small number of transfers in a year, they are likely to add between €200,000 and €1,000,000 to the cost of each transfer realised, depending on the number of transfers that occur. This would impact markedly on any measure of cost-effectiveness for paediatric transplant surgery. However, if paediatric transplants are considered as part of a national transplant service, and the transfer costs are included in that total service, then the impact on cost-effectiveness would be less marked. Hence, the impact on cost-effectiveness is dependent on how the service is characterised.

Utilisation of UK hospitals to deliver the transplant surgery requires frequent travel starting before the surgery even takes place. While flight costs for the child and one adult are reimbursed, they must be paid out-of-pocket by the parents. Families living with limited financial resources may find it difficult to pay for flights. This could, in turn, impact on adherence to follow-up visits. The current structure under which travel is funded may create inequities that disadvantage certain families and adversely impact on access to the transplant service. Alternative funding methods should be considered that may remove or reduce these inequities.

Geographic access must also be considered. Families living in remote areas may be disadvantaged as it may be challenging or highly unlikely that they will be able to transfer to the UK within the necessary timeframe for transplant. Consideration should be given to how these families can be best supported to ensure access to the transplant service is not compromised.

One of the suggested alternatives is for the HSE to purchase bed capacity in Great Ormond Street Hospital (GOSH) for heart transplant patients, thereby enabling patients who would otherwise be inpatients in OLCHC, Dublin to reside in the hospital until a donor heart becomes available. Using bed capacity in this way would reduce capacity for GOSH to admit patients for elective procedures or to take seriously ill UK patients who may be in more urgent need of a transplant. It would therefore create an inequity for non-Irish patients.

If an Irish-based service was set up, it would be likely to take a number of years to become established. There may be learning curves for the clinicians and it would take time to develop experience at an institutional-level. The time taken to develop that knowledge and experience could be long given the low volume of patients that would be treated. It raises questions regarding the efficiency of such an approach given the close proximity to a number of world class centres of excellence in the UK. Given that an Irish-based service may also be restricted by a smaller donor pool reducing the likelihood of being offered a transplant, it may be considered inherently unfair to redirect patients to an Irish-based service unless comparable clinical outcomes can be achieved.

7.2.5 Ethical consequences of the assessment

This assessment has not looked at a number of the domains that are ordinarily considered in a health technology assessment (HTA): clinical effectiveness and safety, and cost-effectiveness. The report does not consider, for example, whether an Irish-based paediatric transplant service would achieve different outcomes to the current utilisation of the UK-based service. The alternative approaches to ensuring patients reach the UK service in a timely manner are considered in Chapter 8 in terms of their logistical feasibility and approximate cost.

A feature of this assessment that is significant is the timing. It is being carried out to support service planning at a time when there is an imminent change. It is apparent that the environment for transport services is dynamic, which provides challenges for maintaining a safe, reliable and sustainable transplant programme. To date, the transplant programme has relied on providers for whom the transfer of patients is not their primary function, and transfers have only been provided on an "as available" basis. This very fact means that if the volume of their primary activity increases, then they will have reduced availability for transfers. The assessment is taking place at a time when there is no agreement with any provider to transfer Priority 1 patients at night from 6 November 2017, and, hence, the decision maker is in a position to choose whether a formal agreement is in the best interests of the transplant service both financially and in terms of ensuring safe and timely transfer of patients to the UK. Had this assessment taken place at a different time, for example three to five years ago, then the changes to staff resources in the Air Corps and ability of the Irish Coast Guard to fly under search and rescue rules might not have been foreseen. An assessment occurs at a point in time and it is important to appreciate that the outcome of the assessment is based on evidence and knowledge at that point in time.

7.3 Discussion

In considering the societal and ethical issues of the transport and treatment of Priority 1 transfer patients, a number of common themes emerged.

The transplant journey is complex and different for each patient. It is important that parents understand the potential benefits and harms of treatment. Depending on the underlying condition and organ being transplanted, post-transplant life expectancy can be almost normal or relatively short. A good understanding of the likely outcomes is important for managing expectations and also to emphasise the importance of adherence.

Following on from an understanding of the benefits and harms is the need to provide informed consent. In this case, the patient is a child and parents must provide informed consent on their behalf. For older children, shared decision making is valuable and important, and can increase adherence.

The transplant journey places a very large burden on parents and families. This burden includes stress, anxiety and depression, linked to uncertainty over whether a donor organ will become available and whether the transplant will be successful, and regarding management of care in the home. The burden can be alleviated through the provision of appropriate supports such as psychosocial support.

Adherence plays an important role in longer-term outcomes. When a child transitions into adolescence they are likely to want to begin to take ownership of their care, such as managing medication, and this should be supported. Adherence needs to be closely monitored so that non-adherence can be identified early.

Although not required to do so under EU Regulations, the Treatment Abroad Scheme doe contribute towards transport costs incurred by families. However, the current structure by which travel is reimbursed may create inequities that disadvantage families with limited financial resources. It does this in two ways: it requires the parents to have sufficient resources to pay out of pocket before seeking reimbursement, and it only provides for a single parent to travel with their child. The system also does not support parents booking flights and transport within the UK, which may be an added source of stress and anxiety. Consideration should be given to how to improve the funding and reimbursement mechanisms to minimise inequities. Such an analysis should extend to also address the situation of a patient dying while in care in the UK and how repatriation is organised and funded. There are some charitable supports in place to offset some of the financial burden, such as the Blue Ribbon Fund managed by Heart Children Ireland on behalf of the Moran family, but reliance on charitable support is unlikely to be sustainable in the longer-term. It is important to recognise that the HSE is responsible for funding treatment and not travel, and reimbursing travel costs may be over and above what patients would receive for example when accessing a tertiary referral hospital in Ireland. However, the distinction between travel within Ireland and to the UK, and the additional burden it creates for families must also be acknowledged. If there are deficits in the support given to patients and those deficits give rise to poorer outcomes for patients and families or inequitable access to care, then these must be taken into consideration.

Finally, a common theme is the need for adequate information to ensure that patients and parents are fully informed at each step of the transplant journey. A lack of information creates uncertainty, which is likely to increase stress and anxiety. These adverse effects are likely to contribute to poorer family function and

diminished support for the patient. Hence, it is critical that adequate information is provided. It is recommended that strong consideration is given to establishing the role of a transplant liaison officer for paediatric transplant patients to ensure parents have a single point of contact for important information and access to necessary supports.

The current approach to providing paediatric heart and liver transplants can be described as a shared care approach, with the HSE facilitating access to the transplant programme in the UK. The HSE takes responsibility for coordinating the patient's placement on the transplant list and transfer to the UK hospital for surgery, while the parents of the child are responsible for getting back to Ireland and many of the other aspects of managing treatment and presentation for follow-up. While this approach enables the provision of access to a safe transplant service, it has the potential to leave gaps in the transition from one location to another. It also requires patients and parents to navigate two healthcare systems and may disadvantage some families that are less well off or who have reduced capacity to cope.

In cases where the patient is in the care of a physician in Ireland, the physician transfers the responsibility of care to an accepting physician in a UK hospital. At discharge from inpatient or outpatient care in the UK, the patient is transferred back into the care of the referring physician. It is important that families understand who has responsibility for care at each point and whom they should contact for support at any given time. This also gives rise to questions regarding who parents should contact in the event of a complaint about the care received in the UK hospital and the extent to which the HSE should take responsibility for unsatisfactory treatment.

In the absence of Irish-based paediatric heart and liver transplant programmes, access to the UK programme ensures the chance of eligible children receiving a transplant. However, this approach may also lead to greater emotional and financial stress than a purely Irish-based programme and places a greater burden on families to manage frequent travel to a foreign country. It is recommended that an appropriate and fair approach to funding is developed, preferably with the participation of the main stakeholders and those with experience of the process.

Despite the burden generated by travel to the UK, the families of some patients have expressed a preference for the current arrangement to continue rather than seek to develop an Irish-based transplant service. The vast experiential knowledge of international centres of excellence has been cited as providing comfort. Paediatric transplant is a rare procedure, as evidenced by the limited number of Irish cases that arise each year. A hospital that treats larger volumes of patients will accrue more experience and will be better able to deal with complications. Having

confidence in the clinical care reduces stress and anxiety for parents, which in turn improves the patient journey.

Depending on how 24/7 cover for Priority 1 patient transfers is achieved, it may come at a substantial cost to the HSE. If the cover requires payment of a retainer to a private company, a large cost may be incurred with no certainty that the service will be availed of in a given year. An alternative is the loss of 24/7 cover and the consequent inability to transfer patients during night-time hours when the majority of transfers occur. The money used to fund transfers could be used elsewhere in the health system, with potentially greater benefit. Consideration should be given to the best use of available resources and whether the provision of a 24/7 service for transfers offers value. In the absence of a cost-effectiveness analysis, it not possible to state whether transplants would be considered cost-effective under the current transfer arrangements, or under alternative arrangements such as private providers.

7.4 Key points

- The vast majority of patients that are categorised as Priority 1 transfers are paediatric transplant patients. They are a highly vulnerable group due to both the severity of their underlying illness and their inability to provide informed consent.
- The benefits and harms may be difficult to comprehend for both patients and parents, given the complexity of the transplant journey and the unique nature of each individual.
- The transplant journey places a very large emotional, logistical and financial burden on the parents and families of transplant candidates. The burden can be alleviated through the provision of appropriate supports such as psychosocial and financial support.
- Adherence is important for achieving the best longer-term outcomes. The complexity of post-transplantation medication regimens means that non-adherence is common. Structures need to be in place to monitor adherence so that non-adherence can be identified early.
- The current approach to reimbursing travel is likely to disadvantage families with limited financial resources by requiring the parents to have sufficient resources to pay out of pocket before seeking reimbursement, and by only covering the cost of flights for a single parent to travel with their child. The funding and reimbursement mechanisms should be revised to minimise

inequity.

- The complexity of the treatment and post-transplantation care, and the need to navigate two healthcare systems suggest the need to provide substantial amounts of information to support families in providing the best care for their children.

- The alternative approaches to achieving full 24/7 cover for Priority 1 patient transfers may come at a substantial cost to the HSE with no guarantee that those services would even be used in a given year. The money used to fund transfers could be used elsewhere in the health system, with potentially greater benefit. Value for money should be considered when selecting what approach to adopt for patient transfers.

8 Assessment of alternative approaches

In the previous section a range of options for the transfer of paediatric transplant patients were identified. The purpose of this chapter is to outline a set of criteria for evaluating the options and to assess the options against those criteria. The criteria attempt to capture the different elements that are important to the decision process. The analysis is at a high-level and intended to support eliminating options that are clearly unfavourable.

8.1 Criteria for evaluating alternatives

A set of criteria is outlined below that encompass different aspects of the transport and treatment of Priority 1 transfer patients. The criteria are not exhaustive, but are intended to facilitate comparison of alternative service configurations based on key considerations. The six criteria are as follows:

- **Clinical**

  This criterion relates to the access to clinical support, the ability to meet the time window for transplant, and the impact on clinical outcomes. While it is anticipated that the clinical outcomes for surgery should not be impacted by the mode of transfer, an inability to provide timely transfer may result in a missed transport opportunity. Increased waiting time to transplant may impact on outcomes.

- **Economic**

  The cost to the State of providing the service must be considered. This criterion focuses on the budget impact and not the cost-effectiveness or value for money of different options, as that is beyond the scope of this evaluation. Costs accruing to patients and families are not considered here, but fall under societal considerations. It is acknowledged that the HSE does not at present pay the full cost of transfers provided by the Air Corps and Irish Coast Guard.

- **Organisational**

  Human resources and how each alternative would integrate within the current structure of services are considered under this criterion. A change in how the service is delivered can have implications for staff requirements which should be taken into account.

- **Societal**

  The impact of each option on patients and families should be considered. This criterion looks at the financial and psychosocial impact of each option, and how they may change relative to the service provided to date.

- **Time horizon**

  Some options can be implemented rapidly while others have a substantial lead-in time associated with their introduction. Sustainability is also examined under this criterion.

- **Reliability**

  This criterion considers the extent to which the HSE can be confident that the option will ensure the safe and timely transfer of patients for surgery, whether or not that uses the UK-based transplant service.

8.2 Evaluation of alternatives

A set of alternative approaches to the transport and treatment of Priority 1 transfer patients was identified in Chapter 6 and are summarised in Table 8.1. Some of those approaches may only work for a certain number of patients, depending on their mobility and need for clinical support. Here the approaches are considered as solutions for the full patient group, noting where it may only be applicable to some.

Table 8.1 Alternative approaches to the transport and treatment of Priority 1 transfer patients

Term	Option	Description
Immediate	As-is approach (loss of night cover)	Daytime provision of service by the Air Corps and Irish Coast Guard (IRCG). No service between the hours of 7pm and 7.30am.
	Contract with commercial provider	A private provider brings an aircrew and aircraft to Dublin Airport to provide a night-time transfer service.
	Dedicated IRCG aircrew operating S92, if available	The IRCG recruit a dedicated aircrew to be available each evening and provide a night-time transfer service operating an IRCG S92 if it is available.
	Charter aircraft	An aircraft is chartered as and when a Priority 1 call comes through at night-time. This is subject to a charter aircraft being available and able to reach Dublin in time to achieve the necessary transfer time.
	Relocation to the UK: financial assistance	Suitable patients relocate to the UK in the vicinity of the receiving hospital. The HSE provides subsistence to the family.
	Relocation to the UK: lease or purchase property	Suitable patients relocate to the UK in the vicinity of the receiving hospital staying in a property that is owned or leased by the HSE.
Short-term	HSE leases and operates aircraft	The HSE acquires and manages aircraft and aircrews.
	Northern Irish service provider	The HSE contracts the Northern Irish service provider to transport Priority 1 transfer patients at night-time.
	Philanthropy	The HSE enters into an agreement with a registered charity that has leased an air ambulance thereby increasing HEMS capacity and accessing night-time Priority 1 transfers at a reduced cost.
	IRCG – changes to contract	Limited renegotiation of the existing contract to restore capacity for night-time Priority 1 transfers by switching from 24 to 12 hour shifts at one or more bases.
	Permission for IRCG Priority 1 transfers to UK as SAR	Seek permission to undertake night-time IRCG Priority 1 missions to the UK under SAR rules.
	Purchase bed space in UK	The HSE purchases bed capacity in the UK for hospital-based patients who can then have a scheduled daytime transfer to the UK.
Long-term	24/7 Air Corps air ambulance, as available	The Air Corps operates a dedicated air ambulance from Baldonnel with back-up from existing IAC resources on an as available basis.
	HSE plus Air Corps GASU-type model	The HSE implements a Garda Air Support Unit (GASU)-type agreement whereby the HSE owns the aircraft and the Air Corps provides dedicated aircrew and operates the aircraft.
	Extending IRCG remit from 2022	At the end of the current IRCG contract, the new contract includes aircrew and aircraft with HEMS as a primary remit (all bases on 12 hour shift plus additional resources to enable dedicated HEMS).
	Dedicated private air ambulance service	The HSE enters into a contract with a private provider to deliver an integrated air ambulance service including Priority 1 patient transfer capacity. An all island approach could be explored with the Northern Ireland Health and Social Care Board by the Department of Health.
	Irish-based transplant service	A full paediatric heart and liver transplant service is developed in Ireland. The service may or may not be linked in to the UK service. The service would be responsible for retrieving donor organs.

The approaches included are specifically to address the issue of ensuring access to paediatric heart and liver transplants. Although a dedicated air ambulance service that addresses pre-hospital, inter-hospital, and UK transfers may be considered a reasonable long-term goal, it cannot be directly compared to the short-term alternatives as it provides a much wider set of services. The solutions are therefore considered according to immediate, short-term (can be implemented within six months) and long-term time horizons.

8.2.1 Clinical aspects

The main issue identified under clinical aspects was the ability of providers to have a sufficiently rapid turnaround or scramble time to meet the four hour window for heart transplants. This is particularly an issue for charter or private provider flights that might originate in the UK. These flights will have to get to Dublin Airport to collect the patient before returning to the UK, which is challenging to achieve in the four hour window. This may also apply to Irish helicopter-based transfer services that are not based in Dublin.

From a clinical point of view, relocation to the UK is not feasible for inpatient heart transplant patients without access to hospital beds.

Given the experience that the Air Corps and Irish Coast Guard have in aeromedical transport and, more specifically, Priority 1 transfers, they have demonstrated an ability to transfer these patients successfully.

The option of an Irish-based transplant service may have significant clinical consequences if access to donor organs is reduced. Access depends on how the service is structured and whether it is integrated into the UK donor pool. Due to the distances involved, it is unlikely that many organs could be sourced from Europe. Consideration should also be given to whether the expected number of transplants anticipated to take place in Ireland would be sufficient to maintain clinical competency and ensure a safe and effective service.

Table 8.2 Clinical criterion

Term	Option	Pros	Cons
Immediate	As-is approach (loss of night cover)		Missed transplantation opportunity (increased wait time to transplant, potential impact on morbidity and mortality)
	Contract with commercial provider	Likely to accommodate clinical team on aircraft and to be specifically fitted out for the service	Depending on where aircraft is located, service turnaround time could be an issue for heart transplant patients
	Dedicated Irish Coast Guard (IRCG) aircrew operating S92, if available	Experienced in Priority 1 transfers	
	Charter aircraft	Some provide medical team as part of service	Depending on where aircraft is located, service turnaround time could be an issue for heart transplant patients. Appropriate aircraft may not be available
	Relocation to the UK: financial assistance	Timely transfer to hospital	May not be suitable for heart transplant patients
	Relocation to the UK: lease or purchase property	Timely transfer to hospital	May not be suitable for heart transplant patients
Short-term	HSE leases and operates aircraft	Aircraft can be fitted out specifically for the service. Increased HEMS availability for wider system.	
	Northern Irish service provider	Experienced in Priority 1 transfers	Service turnaround time could be an issue for heart transplants
	Philanthropy	Likely to accommodate clinical team on aircraft and to be specifically fitted out for the service	
	IRCG – changes to contract	Experienced in Priority 1 transfers	May only provide partial increase in cover
	Permission for IRCG Priority 1 transfers to UK as SAR	Experienced in Priority 1 transfers	
	Purchase bed space in UK	Timely transfer to hospital	May only be suitable for heart transplant patients.

Table 8.2 continued (Clinical criterion)

Term	Option	Pros	Cons
Long-term	24/7 Air Corps air ambulance, as available	Experienced in Priority 1 transfers.	
	HSE plus Air Corps GASU-type model	Experienced in Priority 1 transfers. Increased HEMS availability for wider system.	
	Extending IRCG remit from 2022	Experienced in Priority 1 transfers. Increased HEMS availability for wider system.	
	Dedicated private air ambulance service	Aircraft can be fitted out specifically for the service. Increased HEMS availability for wider system.	
	Irish-based transplant service	Timely transfer to hospital likely.	Reduced access to donor organ pool Potential challenge to maintain competency due to low volume of activity

8.2.2 Economic aspects

The economic criterion is focused on the budget impact to the State, while costs accruing to patient's families are considered as a societal issue.

Costs can be segregated into up-front costs, such as capital expenditure (for example, on aircraft) or fixed contract, and ongoing costs. It can be anticipated that where there is no flat fee or capital investment, additional costs may accrue on an ongoing basis as a way of balancing how patient transfers are paid for. For example, a provider charging a flat fee is likely to charge less per flight than a provider with no flat fee. As such, over the longer term the cost is likely to be similar. However, if private providers are only intended to act as a short-term solution, then the difference in cost structures may have a large impact on costs for the period they are used.

For any of the flight solutions, ensuring availability comes at a substantial cost. Most of the options should be considered "as available" and not dedicated to Priority 1 transfers. The alternative that in theory ensures availability is contracting a private provider to have a dedicated plane and crew in Dublin Airport every evening. In the event that two transfers are required in the same night, as has happened in the recent past, then a single plane may be insufficient. Doubling the plane and crew capacity has a proportional impact on the cost.

The cost of supporting families that have relocated to the UK depends on how long they are waiting for a transplant. If the wait time is six months, then the aggregate

subsistence payments for living in London is similar to the cost of a private charter flight. Procuring a hospital bed in the UK would enable heart transplant candidates that are hospital inpatients to relocate, mitigating the risk of a failed transfer. While the cost of inpatient care for that patient may not differ substantially between Ireland and the UK, there would be a net increase in the HSE spend as overall bed capacity would increase.

It is difficult to determine the likely economic impact of an Irish-based transplant service. It depends on the extent to which the service could leverage off existing facilities and staff. It also depends on the number of additional services that would need to be established to facilitate a transplant programme, for example the requirement to provide a ventricular assist device service (VADs) as a component of a heart transplantation service.

Table 8.3 Economic criterion

Term	Option	Findings
Immediate	As-is approach (loss of night cover)	Low cost.
	Contract with commercial provider	Costly up-front flat fee. Potentially high per flight cost.
	Dedicated Irish Coast Guard (IRCG) aircrew operating S92, as available	Costly up-front flat fee. Use of existing aircraft reduces per flight cost.
	Charter aircraft	No up-front costs. High per flight cost. Negligible flat fee.
	Relocation to the UK: financial assistance	No up-front costs to HSE. Relatively inexpensive, although dependent on the waiting time.
	Relocation to the UK: lease/purchase property	Up-front costs. Expensive (for property that may be unoccupied most of the time). May also need multiple properties.
Short-term	HSE leases and operates aircraft	Expensive up-front and ongoing.
	Northern Irish service provider	Potentially no up-front costs. Expensive per flight.
	Philanthropy	Lower cost to State.
	IRCG – changes to contract	Uncertain cost.
	Permission for IRCG Priority 1 transfers to UK as SAR	Low cost.
	Purchase bed space in UK	Cost for transferred patient may be similar, but net increase to HSE spend due to increased bed numbers.
Long-term	24/7 Air Corps air ambulance, as available	Low cost to HSE. Costs accrue to Department of Defence (requiring an allocation from the exchequer).
	HSE plus Air Corps GASU-type model	Expensive up-front to acquire aircraft. Expensive ongoing (maintenance of aircraft).
	Extending IRCG remit from 2022	Uncertain cost.
	Dedicated private air ambulance service	Potentially expensive flat fee, but spread over more activity.
	Irish-based transplant service	Low transport cost. Significant investment in staff and facilities.

8.2.3 Organisational aspects

In terms of flight options, approaches that use private providers or the Irish Coast Guard mitigate to some extent against pilot and other staff retention issues. It is likely that demand for pilots will remain high, putting ongoing pressure on the Air Corps in relation to maintaining sufficient staffing levels to offer a 24 hour service. If the HSE took on the role of leasing aircraft and managing crews, then it would be exposed to the same issues. Furthermore, the HSE as a healthcare provider does not currently have competence or experience in managing an aviation service. Depending on the level of funding, a philanthropically-funded air ambulance service may also be exposed to pilot retention problems.

Table 8.4 Organisational criterion

Term	Option	Pros	Cons
Immediate	As-is approach (loss of night cover)	No change to staffing.	
	Contract with commercial provider	No pilot retention issues. Dedicated to Priority 1 at night.	Potential challenges integrating with National Ambulance Service (NAS).
	Dedicated Irish Coast Guard (IRCG) aircrew operating S92, as available	No pilot retention issues. Already integrated with NAS.	
	Charter aircraft	No pilot retention issues.	Potential challenges integrating with NAS.
	Relocation to the UK: financial assistance	Decreases number, but does not remove need for some Priority 1 transfers.	Complex for Treatment Abroad Scheme (TAS) to manage.
	Relocation to the UK: lease or purchase property	Decreases number but does not remove need for some Priority 1 transfers.	Complex for TAS to manage.
Short-term	HSE leases and operates aircraft		Complex to manage. Potential pilot retention issues.
	Northern Irish service provider	No pilot retention issues.	Potential challenges integrating with NAS.
	Philanthropy	No pilot retention issues. Dedicated to Priority 1 at night	Potential challenges integrating with NAS. Not tried and tested.
	IRCG – changes to contract	No pilot retention issues. Already integrated with NAS.	May have implications for IRCG primary functions.
	Permission for IRCG Priority 1 transfers to UK as SAR	No pilot retention issues. Already integrated with NAS.	
	Purchase bed space in the UK	Allows some transfers to occur on scheduled basis.	

Table 8.4 continued (Organisational criterion)

Term	Option	Pros	Cons
Long-term	24/7 Air Corps air ambulance, as available	Already integrated with NAS.	Potential pilot retention issues.
	HSE plus Air Corps GASU-type model	Already integrated with NAS.	Potential pilot retention issues.
	Extending IRCG remit from 2022	No pilot retention issues. Already integrated with NAS.	
	Dedicated private air ambulance service	No pilot retention issues.	Not tried and tested.
	Irish-based transplant service	Single healthcare system to deal with.	Complex to set-up.

Another important issue to consider is how easily different providers can be integrated into the National Emergency Operations Centre (NEOC) in the National Ambulance Service (NAS). The NEOC tasks providers with the missions to transfer patients. Using a charter flight system, either directly or through a broker, does not naturally fit in to the NEOC system. This could potentially create risks for the transfer of critical information or ensuring that the provider follows instructions correctly.

There is little certainty that CHC Ireland would readily agree to the changes in the contract to facilitate the IRCG providing a Priority 1 transfer service in the short term, by introducing a 12 hour shift in one or more bases, or what cost may be associated with such changes. An alternative solution is that the IRCG may be given permission to fly Priority 1 transfers into the UK under SAR flight rules. To explore this possibility further, the Department of Health would have to approach the relevant authorities and initiate discussions. This option is considered highly speculative and, as noted, in Section 6.3.4, consideration of any additional safety concerns for aircrews, passengers or ground staff arising from this arrangement must be paramount.

Relocating patients to the UK creates logistical issues for the Treatment Abroad Scheme due to the need to process reimbursement claims and potentially for the leasing and purchase of properties. While there is extensive experience within the HSE of managing properties within Ireland, managing and maintaining properties in another country may give rise to different issues, particularly if the properties are unoccupied for extended periods of time or require deep cleaning between occupants to mitigate any infection control risks. Furthermore, at certain times, multiple properties may be required. It must be stressed that relocation to the UK is not an option for some patients for clinical or family reasons, and does not negate the need to provide transfer options for those who cannot relocate.

8.2.4 Societal aspects

With the exception of an Irish-based service, all alternatives will continue to place a financial burden on families of transplant patients. This burden arises from the need for up-front payment of travel, accommodation and living expenses while in the UK. In the absence of a change to how reimbursement is organised, that burden would only be alleviated by the establishment of an Irish service.

Relocating families to the UK reduces the anxiety associated with uncertainty regarding successful transfer to the UK. However, it separates a patient and family from their social network and the supports that come with it.

It should be noted that families of patients have an immense respect for the Air Corps and Irish Coast Guard and the manner in which they deal with patients and their families. While that respect may not be there for other providers, it may be rapidly earned if families have good experiences of patient transfer.

The establishment of an Irish-based transplant programme may be welcomed by patients and families on the grounds that it would greatly diminish concerns about timely transfer to the hospital for transplant. However, families are aware of the high standard of care, knowledge and experience in the UK hospitals and may be reticent about entering a newly-established service. While there would be pride in a national service, this may be undermined if there is a belief that access to donor organs has been compromised in any way.

Table 8.5 Societal criterion

Term	Option	Pros	Cons
Immediate	As-is approach (loss of night cover)		Impact of losing out on transplants.
	Contract with commercial provider		Financial burden on family.
	Dedicated Irish Coast Guard (IRCG) aircrew operating S92	Respect for service.	Financial burden on family.
	Charter aircraft		Financial burden on family.
	Relocation to the UK: financial assistance	Reduced anxiety relating to transfer.	Separation from support network and loss of income. Financial burden on family.
	Relocation to the UK: lease or purchase property	Reduced anxiety relating to transfer.	Separation from support network and loss of income. Financial burden on family.

Table 8.5 continued (Societal criterion)

Term	Option	Pros	Cons
Short-term	HSE leases and operates aircraft		Financial burden on family.
	Northern Irish service provider		Financial burden on family.
	Philanthropy		Financial burden on family.
	IRCG – changes to contract	Respect for service.	Financial burden on family.
	Permission for IRCG Priority 1 transfers to UK as SAR	Respect for service.	Financial burden on family.
	Purchase bed space in UK	Reduced anxiety relating to transfer.	Financial burden on family.
Long-term	24/7 Air Corps air ambulance, as available	Respect for service.	Financial burden on family.
	HSE plus Air Corps GASU-type model	Respect for service.	Financial burden on family.
	Extending IRCG remit from 2022	Respect for service.	Financial burden on family.
	Dedicated private air ambulance service		Financial burden on family.
	Irish-based transplant service	Reduced stress and financial burden. Pride for national service.	Need to build confidence

8.2.5 Time horizon

The alternatives have been explicitly grouped in terms of how quickly they can be implemented. Those considered as 'immediate' should be implementable at very short notice, on or soon after 6 November 2017. Short-term solutions are notionally implementable within six months, although there is clearly a major impact for contingency cover whether the solution is realised in one month or five months.

Long-term solutions may require substantial organisational structures or contracts to be put in place that could take two to five years to put in place. Solutions based on the Air Corps are contingent on pilot and technical staff capacity. The lead-in time to train staff is long and it may take a minimum of three to four years for the Air Corps to gain sufficient capacity to provide a night-time service. Substantive changes to the IRCG contract would occur at the end of the current contract, which runs to 2022.

Table 8.6 Time horizon

Term	Option	Findings
Immediate	As-is approach (loss of night cover)	Rapid.
	Contract with commercial provider	Rapid. Sustainable contingent on finances.
	Dedicated Irish Coast Guard (IRCG) aircrew operating S92, as available	Rapid. Sustainable contingent on finances.
	Charter aircraft	Rapid. Unclear sustainability.
	Relocation to the UK: financial assistance	Rapid. Unclear sustainability.
	Relocation to the UK: lease or purchase property	Rapid. Unclear sustainability.
Short-term	HSE leases and operates aircraft	Unclear how quickly it could be put in place. Unclear sustainability.
	Northern Irish service provider	Unclear how quickly they could establish capacity. Unclear sustainability.
	Philanthropy	Unclear how quickly it could be put in place. Unclear sustainability.
	IRCG – changes to contract	Unclear how quickly it could be put in place.
	Permission for IRCG Priority 1 transfers to UK as SAR	Unclear how quickly it could be put in place.
	Purchase bed space in the UK	Possibly rapid. Unclear sustainability
Long-term	24/7 Air Corps air ambulance, as available	Long lead-in. Unclear sustainability.
	HSE plus Air Corps GASU-type model	Long lead-in. Unclear sustainability.
	Extending IRCG remit from 2022	Long lead-in. Sustainable.
	Dedicated private air ambulance service	Potentially shorter lead-in. Sustainable.
	Irish-based transplant service	Long lead-in. Unclear sustainability.

The other issue considered here is sustainability. Some solutions are sustainable, but at a significant economic cost, such as contracting a private provider. While the cost may be affordable over the short-term it is unlikely to be affordable over the longer-term. For a number of options, it is unclear how sustainable they are, as it depends on factors that may be outside the control of the HSE. For example, unless structures to support staff retention are reinstated at the Air Corps, they may continue to be susceptible to loss of pilots and an associated inability to provide a 24/7 service.

8.2.6 Reliability

The criterion of reliability captures whether an option would reliably bring patients to the receiving hospital in time for transplant. A number of the options are considered reliable but with the caveat that they are provided on an "as available" basis. The Irish Coast Guard, for example, may be unavailable if on a mission fulfilling their primary function of search and rescue. Similarly, weather conditions may preclude safe flight.

Relocation to the UK is a reliable option, but only for those who can avail of the option. Thus, these are unreliable options for heart transplant patients.

The reliability of the philanthropic option will depend on the nature of the agreement between the provider and the HSE.

The reliability of a GASU-type model would depend partly on the number of aircraft available. Multiple aircraft would be required to ensure no loss of cover during periods of maintenance or if there are two Priority 1 calls a short time apart, as has happened.

Table 8.7 Reliability

Term	Option	Findings
Immediate	As-is approach (loss of night cover)	Daytime (as available). No night cover.
	Contract with commercial provider	Unclear reliability.
	Dedicated Irish Coast Guard (IRCG) aircrew operating S92, as available	Reliable (as available)
	Charter aircraft	Unreliable.
	Relocation to the UK: financial assistance	Reliable if appropriate
	Relocation to the UK: lease or purchase property	Reliable if appropriate
Short-term	HSE leases and operates aircraft	Unclear reliability.
	Northern Irish service provider	Unclear reliability.
	Philanthropy	Unclear reliability.
	IRCG – changes to contract	Reliable (as available)
	Permission for IRCG Priority 1 transfers to UK as SAR	Reliable (as available)
	Purchase of bed space in the UK	Reliable if appropriate
Long-term	24/7 Air Corps air ambulance, as available	Reliable (as available)
	HSE plus Air Corps GASU-type model	Reliable
	Extending IRCG remit from 2022	Reliable (as available)
	Dedicated private air ambulance service	Reliable
	Irish-based transplant service	Reliable

8.2.7 Ranking of alternative options

To assist in comparing across the criteria, we have ranked options within each criterion, with options grouped by whether they are considered immediate, short- or long-term solutions. We have summed the ranks across the criteria, so that the option with the lowest aggregate score is theoretically the optimal solution. In the absence of a plausible basis for weighting the different criteria, we have given them equal weighting. This is not intended to provide a scientifically rigorous ranking, but rather a means to distinguish between efficient and inefficient options.

In terms of immediate solutions, a contract with a commercial provider was highest

ranked on four criteria, but worst ranked in economic terms. The second best option, with a similar score, was a dedicated IRCG crew operating an S92 helicopter, as available from the Dublin base. These two solutions were consistently better ranked than the other four listed options.

For short-term solutions, it must be acknowledged that a number of the identified options are speculative in nature and subject to further exploration to determine their feasibility. The two options that ranked highest may be considered as speculative: the IRCG operating Priority 1 transfers under SAR rules, and a philanthropic provider. The IRCG option was considered marginally less reliable as the service would be dependent on the availability of the helicopter. However, due to the uncertainty over whether these options could materialise, it would be pragmatic to focus on the alternative of modifying the shift patterns at one or more IRCG bases. The cost of such a change would have to be contrasted with the cost of continued use of contracting a commercial provider or a dedicated IRCG crew as identified in the immediate solutions.

Regarding long-term options, three options had very similar scores: dedicated Air Corps air ambulance, GASU-type model with aircraft provided by the HSE and aircrews provided by the Air Corps, and IRCG aircrew and aircraft with primary remit for HEMS. Both of the Air Corps options carry a risk regarding pilot retention and uncertainty over how long it will take for sufficient staff to be in place to offer a 24/7 service. The option of a GASU-type model creates additional logistical issues for the HSE as it will have to lease aircraft. Although there is uncertainty regarding the IRCG option in terms of potential costs, it carries organizational benefits particularly in relation to ensuring adequate availability of aircrews.

The long-term transport options were identified primarily to address the issue of Priority 1 transfers. However, this fails to consider the requirements for the wider aeromedical service and patient transfers generally. The long-term development of a fully integrated aeromedical service for Ireland has the potential to provide a more sustainable and resilient approach, capitalising on resources more efficiently than can be achieved by a service restricted to a very small number of Priority 1 transfers.

Table 8.8 Ranked options

Term	Option	Clinical	Economic	Organisational	Societal	Time horizon	Reliability	Score (min is best)	Optimal solution
Immediate	As-is approach (loss of night cover)	6	1	1	6	6	4	24	
	Contract with commercial provider	1	6	3	1	1	1	13	**Best option**
	Dedicated Irish Coast Guard (IRCG) aircrew operating S92+C30	2	5	2	2	1	2	14	Second best option
	Charter aircraft	3	4	5	3	3	3	21	
	Relocation to the UK: financial assistance	4	2	4	4	3	5	22	
	Relocation to the UK: lease/purchase property	4	3	6	4	5	5	27	
Short-term	HSE leases and operates aircraft	5	6	6	5	5	5	32	
	Northern Irish service provider	4	4	4	4	4	4	24	
	Philanthropy	1	3	3	1	3	1	12	Second best option
	IRCG – changes to contract	1	5	5	3	2	3	19	
	Permission for IRCG Priority 1 transfers to UK as SAR	1	1	1	1	1	2	7	**Best option**
	Purchase of bed space in UK	6	1	2	6	6	6	27	
Long-term	24/7 Air Corps air ambulance, as available	3	1	2	1	1	4	12	Second best option
	HSE plus Air Corps GASU-type model	1	2	2	1	4	2	12	Second best option
	Extending IRCG remit from 2022	1	4	1	1	1	3	11	**Best option**
	Dedicated private air ambulance service	4	3	4	4	3	5	23	
	Irish-based transplant service	5	5	5	5	5	1	26	

It is important to remember that the analysis of options is not based on a formal scoring system, and that many of the factors are known with a large degree of uncertainty. This is particularly relevant for the economic criterion, where accurate costs cannot be determined without formally seeking tenders for the provision of services. For the long-term solutions which are likely to involve multi-year contracts it will be necessary to examine a number of the options to determine which may be most efficient in relation to costs, and what breadth of services may be delivered beyond Priority 1 transfers.

8.3 Discussion

The IRCG advised that it would no longer be available for transport of Priority 1 transfer patients between the hours of 7.00pm and 7.30am from 5 September 2017. This was to ensure that CHC Ireland remains compliant with the Irish Aviation Authority guidelines. Despite on-going Air Corps capacity constraints, an interim arrangement was made with the Department of Defence for the Air Corps to provide night-time cover for Priority 1 transfers from 5 September 2017 until 6 November 2017. This step up in service was provided by the Air Corps to allow additional time for alternative arrangements to be made by the Department of Health and the HSE, informed by this HTA. The interim arrangements by the Air Corps cannot be continued beyond the 6 November 2017 for safety and operational reasons. Priority 1 transfers constitute the transport by air from Ireland to another country within eight hours for emergent medical or surgical treatment. Therefore, from the 6 November 2017, alternative arrangements will be necessary if Priority 1 transfers are to continue at night.

Assuming the HSE wishes to continue to provide 24/7 Priority 1 transfers, the most comprehensive solution is the provision of a dedicated service for Priority 1 transfer patients. This would confer the greatest certainty that Priority 1 transfers arrive on time to their UK destinations. To maximise the chance that paediatric patients will access transplant within the required time frame, actions to be taken can be considered as immediate, short-term (up to six months) or long-term.

Two immediate solutions were identified as preferred options, both coming at a high, but similar cost. The optimal immediate option would consist of sourcing and paying a private provider to deliver a dedicated night-time service, consisting of an airplane and crew on the ground, located in Dublin Airport. While this provides a dedicated service, it is unlikely that it would be able to deal with two requests for Priority 1 transfer in one night, as has happened recently during the preparation of the report. There may be some challenges in terms of integrating this service within the National Ambulance Service as it is not tried and tested. An alternative immediate option is for the IRCG to recruit a dedicated aircrew, so that it would be

available each evening between 7pm and 7am to operate the Dublin based helicopter. However, in this scenario, availability for Priority 1 transfers would be limited to when the Dublin base is not tasked with a SAR mission. It is noted that the IRCG is experienced in Priority 1 transfers and is already integrated within the National Ambulance Service.

Short-term options can be divided into speculative and available options. Focussing on options that have greatest certainty, the optimal solution may be to explore the logistical potential and cost of modifying IRCG shift periods in order to optimise the availability of the IRCG to fly patients to the UK at night. This would require moving one or more bases from 24 hour to 12 hour shifts. This option would likely come at a substantial cost, would be provided on an "as available" basis, would require contractual changes, and may have some implications for the primary remit of IRCG with regard to SAR. However, as noted, the IRCG is experienced in Priority 1 transfers and already integrated within the National Ambulance Service. The cost of this option would have to be contrasted with the cost associated with the ongoing use of a commercial provider or of a dedicated IRCG crew on standby at the Dublin base. In the short-term it may be possible to identify a commercial provider with more favourable terms than can be achieved as an immediate option.

Two speculative short-term options were identified which should be thoroughly explored, as they may provide less costly, but reliable transport solutions. Firstly, philanthropic options could be pursued, such as a dedicated air ambulance, leased by a registered charity. While this provides a dedicated service, it will likely not be able to deal with two Priority 1 transfer requests in one night as happened recently during the preparation of this report. There may be some challenges to integrating this service within the National Ambulance Service as it is not tried and tested. Although incurring a cost to the HSE, this option would be associated with lower annual costs than the HSE contracting with a private provider in the immediate term. If a 24 hour air ambulance service were provided by philanthropy, it could, in addition, provide daytime HEMS capacity including for Priority 1 transfers.

Secondly, the Department of Health could explore scope for the IRCG to fly Priority 1 transfer patients to the UK within the relevant regulatory framework, and whether it may be possible to carry out this function within a 24 hour shift system. This could require putting in place a suitable agreement between relevant Irish and UK authorities. This would potentially result in a return to the level of service available before 6 September 2017. This option is highly speculative. Its feasibility depends on a number of factors, and, as noted, in Section 6.3.4, consideration of any additional safety concerns from aircrews, passengers or ground staff arising from such an arrangement must be paramount.

When Priority 1 transfers are viewed in isolation, three long-term transfer options which would leverage off existing state resources could be explored. The first option would be to negotiate a contract in 2022 which would extend the primary remit of the IRCG to include HEMS comprising an additional aircraft and crew plus a switch to a 12 hour roster at all bases. The IRCG option carries uncertainty over the cost, which could be substantial. Alternatively, two options based on the Air Corps could be considered. Contingent on the Air Corps rebuilding its staff capacity, there is a track record that provision of 24/7 air ambulance service by the Air Corps on an "as available" basis provides a reliable service. Otherwise, a GASU-type model with HSE control of the aircraft and dedicated aircrews provided by the Air Corps would enable a dedicated HEMS including Priority 1 transfer to be provided. The benefit of the GASU-type model is that there would be ring-fenced crew available and a dedicated aircraft as well as additional day time HEMS capacity. Both the IRCG option and the GASU-type model provide for additional HEMS capacity over and above Priority 1 transfers. The IRCG model is likely more expensive than the Air Corps models. Continued Air Corps, IRCG and or philanthropic air ambulance support on an as available basis could be implemented for any of these options. All three of these long-term options are potentially appropriate to solve the issue of providing Priority 1 transfers, and detailed further exploration and assessment will be required to determine which might be the optimal solution.

However, if Priority 1 transfers are considered as part of the wider patient transport services, then the long-term development of an integrated aeromedical service for Ireland could provide a more sustainable and resilient approach and allow for the more cost-effective use of assets and resources than can be achieved by a service only designed for Priority 1 transfers. An integrated aeromedical service would potentially include pre-hospital, inter-hospital and off-island transfers coordinated by the National Ambulance Service and would integrate the National Transport Medicine Programme's missions including the Irish Paediatric Acute Transport Service where appropriate. It would ideally leverage off existing state resources, provide for a level of dedicated HEMS capacity with resilience provided through access to a range of providers potentially including the Air Corps, IRCG, philanthropy and private providers as available.

For any of the air transfer options to be viable for all patients, it is essential that the aircraft have been tested and certified to carry the necessary equipment to support critically ill patients. This issue is relevant for logistical, clinical and safety reasons.

Non-transfer options are that of (1): relocating the patient to the UK; and (2): developing a paediatric heart and liver transplantation service in Ireland. Both options come with significant risks and challenges. The relocation of children is

neither realistic nor possible in all circumstances. Additionally, relocation to the UK is not feasible for many heart transplant patients without access to hospital beds. Therefore, Priority 1 transfer would still be necessary for those patients who could not relocate to the UK.

The development of an Irish paediatric heart or liver transplantation programme would require substantial resources, capital investment and planning. Eliminating the transport problem to the UK through the development of an Irish transplant programme could create a host of new problems, not least the potential discontinuation of Ireland's enrolment in the UK's NHSBT organ donation network. Indeed, if Ireland was to remain within the UK and or European organ sharing networks, the retrieval of organs would still require Priority 1 transfer capability, to ensure meeting the 'window of opportunity' for organ viability.

While we have not explicitly considered cost-effectiveness, all options are associated with a substantial budget impact. Selection of options for treatment and transport of Priority 1 transfer patients should be guided by consideration of affordability, the opportunity cost for other state services and crucially the requirement to maximise the delivery of safe, effective patient centred care. Consideration should be given to resourcing a paediatric transplant liaison officer to provide comprehensive support to all patients and their families accessing transplant services in the UK and to review how families are reimbursed for the cost of travel and accommodation expenses.

8.4 Key points

- Priority 1 transfers constitute the transfer by air from Ireland to another country within eight hours for emergent medical or surgical treatment. From the 6 November 2017, alternative arrangements will be necessary if Priority 1 transfers are to continue between 7.00pm and 7.30am.
- Immediate options are costly. The optimal immediate option is to pay a private provider to deliver a dedicated night-time service. Alternatively the IRCG may be requested to provide a dedicated aircrew at night to operate the Dublin-based helicopter, when it is available.
- Of short-term options with a high certainty of being feasible, the optimal approach may be to modify the IRCG shift periods at one or more bases from 24 hour to 12 hour rosters in order to optimise the availability of the contracted assets to fly patients to the UK at night. The cost arising from a renegotiation of the contract would have to be contrasted with that of continued use of a

commercial provider or of a dedicated IRCG aircrew at night.

- Two short-term (up to six months) options are speculative in nature but should be explored further:
    - Philanthropic options, such as a dedicated air ambulance, leased by a registered charity delivering HEMS including priority 1 transfers at a lower cost than the HSE could negotiate with a private provider
    - The scope for the IRCG flying patients to the UK within the relevant regulatory framework, and whether it may be possible to carry out this function within a 24 hour shift system having considered any potential safety issues.
- In relation to Priority 1 there are three long-term transfer options which leverage off existing state resources. The first option is to negotiate a contract in 2022 which would extend the primary remit of the IRCG to include HEMS comprising an additional aircraft and crew plus a switch to a 12 hour roster at all bases.
- The second long-term transfer option is the provision of a dedicated air ambulance service by the Air Corps, while maintaining NAS coordination and support.
- The third long-term transfer option is a GASU-type model with HSE control of the aircraft and dedicated aircrews provided by the Air Corp which would enable a dedicated HEMS including Priority 1 transfer to be provided.
- The long-term development of an integrated aeromedical service for Ireland could provide a more sustainable and resilient approach and allow for the more cost-effective use of assets and resources than can be achieved by a service only designed for Priority 1 transfers. It would ideally leverage off existing state resources, provide for a level of dedicated HEMS capacity with resilience provided through access to a range of providers potentially including the Air Corps, IRCG, philanthropy and private providers as available.
- Non-transfer options include relocation to the UK or the establishment of an Irish paediatric heart or liver transplantation service.
- Relocation to the UK is not possible for all patients; therefore, a Priority 1 transfer service would still be necessary.
- Establishing an Irish paediatric heart or liver transplantation programme would

require significant resources and planning, and could threaten Ireland's access to the wider UK and European organ donor pool. Even if access to the wider organ network was maintained, organ retrieval may still necessitate a Priority 1 transfer service.

- While we have not explicitly considered cost-effectiveness, all options are associated with a substantial budget impact. Selection of options for treatment and transport of Priority 1 transfer patients should be guided by consideration of affordability, the opportunity cost for other state services and crucially the requirement to maximise the delivery of safe, effective patient centred care.

- Consideration should be given to resourcing a paediatric transplant liaison officer to provide comprehensive support to all patients and their families accessing transplant services in the UK and to review how families are reimbursed for the cost of travel and accommodation expenses.

Appendix 1 Criteria for 'elective' liver transplantation (Liver Advisory Group on behalf of NHSBT)[4]

1. Chronic liver disease

a. Life expectancy: anticipated length of life <18 months (because of liver disease)

b. Unacceptable quality of life (because of liver disease)

c. Growth failure or impairment due to liver disease

d. Reversible neuro-developmental impairment due to liver disease

2. Likelihood of irreversible end organ damage (which may be renal, respiratory or cardiovascular depending on the underlying disorder) Rarer indications:

A complicating factor in paediatric practice is that many of the conditions affecting children are individually rare and decisions have to be based on general principles rather than condition-specific data. Particular rare indications for liver transplantation that paediatric centres would feel are reasonable, but for which there is limited outcome data, would include the following conditions:

a. Liver transplantation for organic acidaemia

b. Unresectable hepatic malignancies without extra-hepatic spread (to include selected hepatocellular carcinoma and epithelioid haemangioendothelioma)

c. Diffuse hepatic haemangioendothelioma unresponsive to alternative treatments

d. Langerhans cell histiocytosis

e. Mitochondrial respiratory chain disorders with chronic liver disease (selected) but without discernible disabling extrahepatic disease

f. Intestinal failure associated liver disease

g. Hepatoblastoma: children hepatoblastoma should be discussed at a Multi-Disciplinary Team which should include a paediatrician with an interest in liver disease, a paediatric oncologist, a hepatobiliary surgeon and liver transplant surgeon.

Criteria for 'super urgent' liver transplantation (Liver Advisory Group on behalf of NHSBT)[4]

- Category 1

Aetiology: Paracetamol poisoning: pH <7.25 more than 24 hours after overdose and after fluid resuscitation

- Category 2

Aetiology: Paracetamol poisoning: Co-existing prothrombin time >100 seconds or INR >6.5, and serum creatinine >300 µmol/l or anuria, and grade 3–4 encephalopathy

- Category 3

Aetiology: Paracetamol poisoning: Significant liver injury and coagulopathy following exclusion of other causes of hyperlactatemia (e.g. pancreatitis, intestinal ischemia) after adequate fluid resuscitation: arterial lactate >5 mmol/l on admission and >4 mmol/l 24 hours later in the presence of clinical hepatic encephalopathy.

- Category 4

Aetiology: Paracetamol poisoning: Two of the three criteria from category 2 with clinical evidence of deterioration (e.g. increased ICP, FiO_2 >50%, increasing inotrope requirements) in the absence of clinical sepsis

- Category 5

Aetiology: Favourable non-paracetamol aetiologies such as acute viral hepatitis or ecstasy/cocaine induced ALF: the presence of clinical hepatic encephalopathy is mandatory and: prothrombin time >100 seconds, or INR >6.5, or any three from the following: age >40 or <10 years; prothrombin time >50 seconds or INR >3.5; any grade of hepatic encephalopathy with jaundice to encephalopathy time >7 days; serum bilirubin >300 µmol/l.

- Category 6

Aetiology: Unfavourable non-paracetamol aetiologies such as seronegative or idiosyncratic drug reactions: a) prothrombin time >100 seconds, or INR >6.5, or b) in the absence of clinical hepatic encephalopathy then INR >2 after vitamin K repletion is mandatory and any two from the following: age >40 or <10 years; prothrombin time >50 seconds or INR >3.5; if hepatic encephalopathy is present

then jaundice to encephalopathy time >7 days; serum bilirubin >300·mol/l.

- Category 7

Aetiology: Acute presentation of Wilson's disease, or Budd-Chiari syndrome. A combination of coagulopathy, and any grade of encephalopathy

- Category 8

Hepatic artery thrombosis on days 0 to 21 after liver transplantation

- Category 9

Early graft dysfunction on days 0 to 7 after liver transplantation with at least two of the following: AST >10,000, INR >3.0, arterial lactate >3 mmol/l, absence of bile production

- Category 10

The total absence of liver function (e.g. after total hepatectomy)

- Category 11

Any patient who has been a live liver donor (NHS entitled) who develops severe liver failure within 4 weeks of the donor operation

- Category 20

    - Acute liver failure in children under two years of age: INR >4 or grade 3-4 encephalopathy.

    - Definition: Multisystem disorder in which severe acute impairment of liver function with or without encephalopathy occurs in association with hepatocellular necrosis in a child with no recognised underlying chronic liver disease. Children with leukaemia/lymphoma, haemophagocytosis and disseminated intra-vascular coagulopathy are excluded

No other causes of liver failure can be considered appropriate for registration on the super-urgent liver scheme. It is important to note that the MELD (Model of End Stage Liver Disease) allocation system, widely used internationally as a marker of disease severity, cannot be used in paediatric patients due to their special characteristics.

Appendix 2 Patient plans

Figure App2.1: Patient logistics communication plan checklist (Our Lady's Children's Hospital, Crumlin [OLCHC])

Patient Logistics Communication Plan Checklist

1. Patient details	2. Contact details	3. Passport details for parents
Patient: DOB: Transplant: Passport No: Expiry: Place of Birth: Nationality:Irish Address:	Parent/Guardian: name and relationship, – Mother Mobile Number: Land Line Number: Parent/Guardian: name and relationship, - Father Mobile Number: Local Garda Station: Phone:	Mothers Passport Details DOB: Place of Birth: Nationality: Passport: Expires: Dads Passport Details DOB: Place of Birth: Nationality: Passport: Expires:

4. Date placed on Active Transplant list:

5. Latest time patient must arrive to receiving hospital:

6. HSE Aeromedical Dispatch information

Patient transfer estimated travel time in Hrs/mins:

	Aircraft	PT to RV	**Aircraft to RV**	Loading	Flight to UK	Unloading	Land time to Hospital	Total Times
IAC	Lear		-	15 mins		15 mins		
IAC	Casa		-	15 mins		15 mins		
IAC	AW139		-	15 mins		15 mins		
IRCG	R116		-	15 mins		15 mins		
Night	R116		-	15 mins		15 mins		
IRCG	R11	-	-	-	-	-	-	-
Night	R11	-	-	-	-	-	-	-

Notes: ** If necessary
PT to RV includes activation time of aircraft and pts journey to RV point. .
Currently IAC operate Monday to Friday 09.00hrs to 16.00hrs

**Please note up to 3 hours are needed by Irish Air Corps to prepare aircraft / crew etc. Other factors that may affect timings are weather, aircraft availability and patients' condition. This is reflected in PT to RV times*

*** The National Ambulance Service will organise an Ambulance transfer from patients' home to departure airport.*

7. Date and time plan complete:

If completion of plan outside of the 48hours of child placed on the active list please state why:

8. Date and time parents informed:

9. Parents informed by:

10. Signed:

Reviewed by:

Patient Logistics Communication Plan Checklist

1. Patient details	2. Contact details	3. Passport details for parents
Patient: DOB: Transplant: Passport No: Expiry: Place of Birth: Nationality:Irish Address:	Parent/Guardian: name and relationship, – Mother Mobile Number: Land Line Number: Parent/Guardian: name and relationship, - Father Mobile Number: Local Garda Station: Phone:	Mothers Passport Details DOB: Place of Birth: Nationality: Passport: Expires: Dads Passport Details DOB: Place of Birth: Nationality: Passport: Expires:

4. Date placed on Active Transplant list:

5. Latest time patient must arrive to receiving hospital:

6. HSE Aeromedical Dispatch information

Patient transfer estimated travel time in Hrs/mins:

	Aircraft	PT to RV	**Aircraft to RV**	Loading	Flight to UK	Unloading	Land time to Hospital	Total Times
IAC	Lear		-	15 mins		15 mins		
IAC	Casa		-	15 mins		15 mins		
IAC	AW139		-	15 mins		15 mins		
IRCG	R116		-	15 mins		15 mins		
Night	R116		-	15 mins		15 mins		
IRCG	R11	-	-	-	-	-	-	-
Night	R11	-	-	-	-	-	-	-

Notes: ** If necessary
PT to RV includes activation time of aircraft and pts journey to RV point. .
Currently IAC operate Monday to Friday 09.00hrs to 16.00hrs

** Please note up to 3 hours are needed by Irish Air Corps to prepare aircraft / crew etc. Other factors that may affect timings are weather, aircraft availability and patients' condition. This is reflected in PT to RV times*

*** The National Ambulance Service will organise an Ambulance transfer from patients' home to departure airport.*

7. Date and time plan complete:

If completion of plan outside of the 48hours of child placed on the active list please state why:

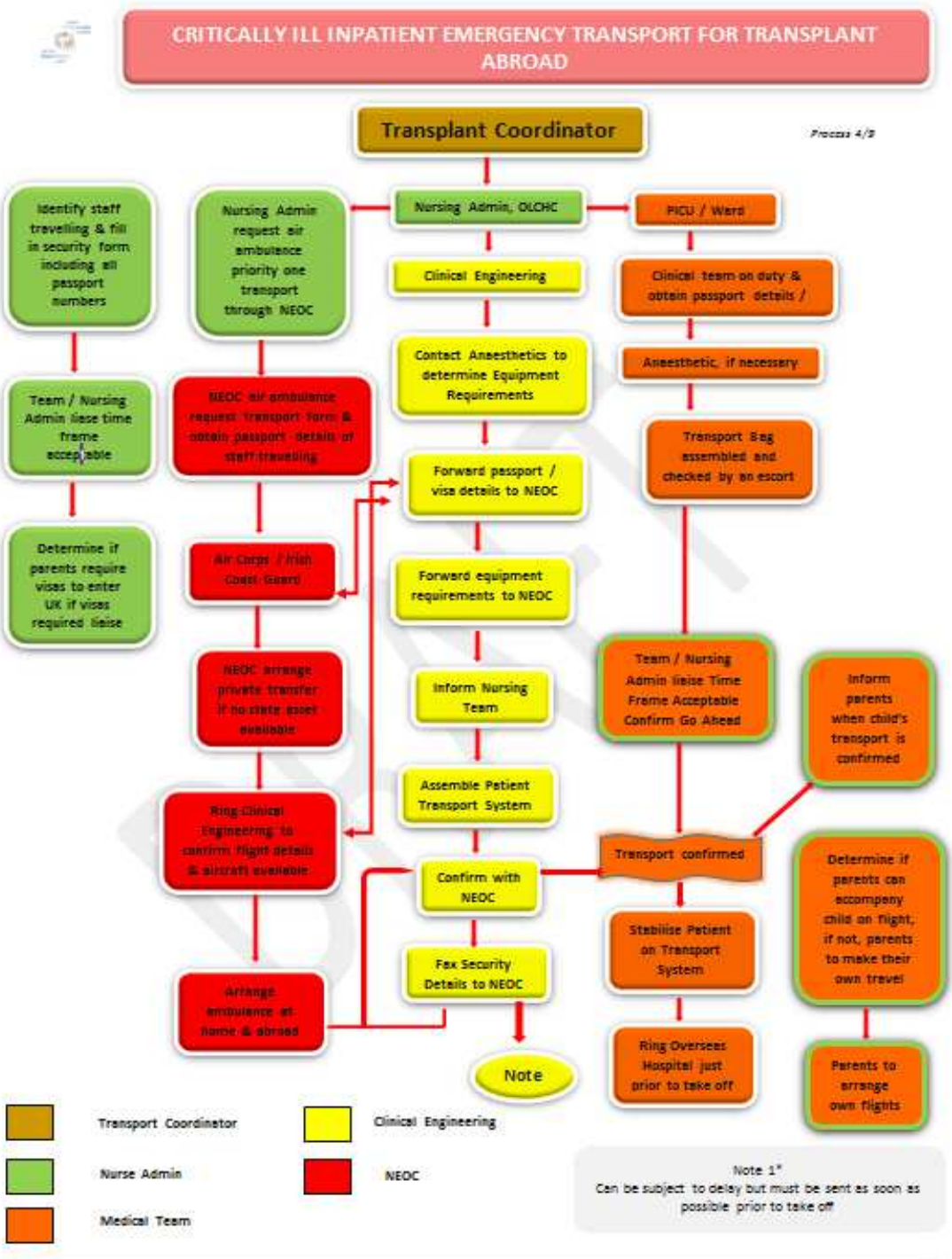
8. Date and time parents informed:

9. Parents informed by:

10. Signed:

Reviewed by:

Figure App2.2: Emergency transport of critically ill in-patient for transplant abroad (Our Lady's Children's Hospital, Crumlin [OLCHC])



Appendix 3 Destination airports accessed by service providers when conducting Priority 1 transfers

The Air Corps fly into RAF Northolt airbase in day light hours. The airport operates private charters and military movements, and is located just 14.9 miles from Central London. The airfield opening hours are listed as:

- Monday-Friday (08.00-20.00)
- Saturday (08.00-15.00) and
- Sunday (12.00-19.00).

Outside of these hours, the Air Corps fly into London Heathrow, which is 19.3 miles from Central London.

The IRCG also has access to Northolt and London Heathrow. The jet centre at Northolt is restricted to a maximum of 40 civilian movements a day for private charters.

London City Airport is not used for Priority 1 transfers. It is located 8.6 miles from Central London, and is the closest airport to Kings College and Great Ormond Street Hospitals. The airport opening hours are listed as:

- Monday-Friday (06.30-22.30)
- Saturday (06.30-13.00) and
- Sunday (12.30-22.30).

Note, the final 30 minutes of operation is solely for flights scheduled earlier which have been unavoidably delayed

Only certain aircraft are allowed to land at the airport. Only aircraft operators, who are able to demonstrate that their aircraft can operate within strict allowable limits, can use London City Airport. This includes noise, weight and other performance restrictions. For the Air Corps fleet, the Learjet is certified to fly into London City Airport, but the CASA aircraft which currently undertakes Priority 1 transfers, is not certified. It should be noted that the crew also need to be certified to fly into the airport.

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