Adult-to-Adult Living Donor Liver Transplantation Guidelines

Document Number: GL2008_019
Publication date: 22-Dec-2008
Functional Sub group: Clinical/ Patient Services - Human Tissue

Summary: The purpose of the guideline is to provide guidance to health professionals and additional protection for prospective adult Living Donor Liver Transplantation (LDLT) donors. This guideline is aimed primarily at the jurisdictions that will endorse LDLT, the institutions that will provide LDLT, and the health professionals directly involved in this practice. To the extent that it is adopted by all jurisdictions in line with the particular requirements of their human tissue legislation, and applied in participating liver transplant units, it will promote ethical, lawful and consistent application of quality processes in provision of this complex procedure to donors, recipients and their families.

Author Branch: Research Ethics and Public Health Training
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Audience: All clinical and medical staff involved in transplants

Distributed to: Public Health System, Divisions of General Practice, Government Medical Officers, Health Professional Associations and Related Organisations, NSW Ambulance Service, Ministry of Health, Public Health Units, Public Hospitals, Tertiary Education Institutes

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Review date  22-Dec-2013
Policy Manual  Not applicable

Director-General
Purpose of the Guideline

The LDLT National Policy Framework has been endorsed by the Australian Health Ministers’ Advisory Council (AHMAC). Recognising the clinical need, complexity and risks of the procedure, AHMAC undertook a national development and consultation process in preparing this National Policy Framework. It sets appropriate ethical principles and clinical standards for the practice of adult-to-adult living donor liver transplantation.

Recommended standards

NSW Health has adopted as a guideline for provision of LDLT in the NSW public health system the ‘Adult-to-Adult Living Donor Liver Transplantation (LDLT) National Policy Framework’.

This guideline seeks to promote ethical, lawful and consistent application of quality processes in provision of this complex procedure to donors, recipients and their families; to provide guidance to health professionals; and additional protection for prospective adult Living Donor Liver Transplantation (LDLT) donors. It includes reference to donor selection criteria, necessary consent processes including use of an independent donor advocate, institutional requirements for provision of LDLT, and permissibility of LDLT in the emergency setting.

This guideline should be read in conjunction with: PD2005_406 Consent to Medical Treatment-Patient Information. It should also be read in conjunction with local policy developed by the participating liver transplant unit.

Implementation

Advice is intended for use by clinical and medical staff involved in transplants at institutions that will provide LDLT.

Revision history

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Related documents:
- PD2005_406 Consent to Medical Treatment – Patient Information

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1. Adult-to-Adult Living Donor Liver Transplantation (LDLT) - National Policy Framework
Adult-to-Adult
Living Donor Liver Transplantation (LDLT)

National Policy Framework

Australian Health Ministers Advisory Committee
Technical Advisory Group

March 2007
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1. PREAMBLE

‘Directed’ living donor liver transplantation (LDLT) involves resection of one lobe of a healthy, suitably matched donor’s liver and transplanting it into a recipient with whom the donor has a genetic or close personal relationship. Advances in medical science and clinical practice over the last ten to fifteen years have enabled LDLT to be developed overseas, and more recently introduced in Australia and New Zealand, as a potential treatment of last resort for end-stage liver failure.

In 2005 the Australian Health Ministers’ Advisory Council (AHMAC) commissioned this national policy framework on adult-to-adult living donor liver transplantation (LDLT). AHMAC sought a national policy approach, recognising the clinical need, complexity and risks of the procedure (in particular as in adults the larger liver lobe is resected compared to adult-to-child LDLT), and importantly the ethical risks associated with this procedure. A policy framework was thus seen as desirable to guide further developments in adult-to-adult LDLT, with the risks in mind, and given its infancy in the Australian context.

A specialist, cross-representational LDLT Technical Advisory Group (p.3) appointed by AHMAC, and under the auspice of the Intergovernmental Committee on Organ and Tissue Donation, was charged with drafting policy. National consultation on the draft policy was conducted from May to August 2006 and was funded by the Australian Government Department of Health and Ageing. This process secured advice from a wide range of clinical, jurisdictional and community stakeholders (attachment 1) with public comment invited. The AHMAC LDLT Technical Advisory Group wishes to acknowledge the work of the Transplantation Society of Australia and New Zealand (TSANZ) in developing their guidelines on living donor liver transplantation (2002). The donor selection criteria appearing in this national policy framework have been updated from those original 2002 TSANZ guidelines, in consultation with TSANZ.

LDLT is a challenging and high-risk procedure. To date, approximately 6,000-7,000 living donor liver transplants have been performed worldwide, and the rate of catastrophic complications is estimated to be 0.4-0.6%. Fourteen live donor deaths have occurred, and two donors have needed subsequent liver transplantation. Experience with adult LDLT in Australia is in its infancy with one (emergency) adult LDLT performed in 2002, and ten LDLT performed in New Zealand. Significant experience has however been accumulating in procedures related to donor hepatectomy, such as ablative liver resections, graft reduction for split liver transplantation in children (12 children have received LDLT grafts to date, primarily from a parent), and other hepatobiliary surgery.

The procedure involves a major surgical operation performed on a healthy individual; there is a high degree of technical difficulty to ensure the graft is of sufficient size for an adult recipient; there is ongoing uncertainty about a number of factors including optimal surgical techniques and recipient selection;

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and there is accumulating but still relatively limited data about safety of the procedure, including both long and short-term risks in donors and recipients. Nonetheless, LDLT in a subset of patients with severe liver failure may provide the only alternative to certain death, where timely deceased donation is not available, and given that replacement therapies for liver function do not exist as they do for patients with end-stage renal failure.

LDLT therefore raises a number of significant ethical issues. These include what degree of risk is acceptable for one person to assume for the therapeutic benefit of another, especially where current data about this procedure makes the associated risks difficult to quantify. Related questions include who should determine those margins of acceptable risk, and what bearing does this have on the ethical obligation of health professionals to avoid harming patients. A key concern is how to ensure adequate voluntariness in a donor’s decision where this may be subject to either overt, or subtly coercive influences. These influences may come from family or others close to the recipient, or from within the donor him or herself, stemming from a compelling desire to save the potential recipient’s life when other avenues may seem exhausted. Consideration of these complex ethical issues has informed the requirements of this policy.

This policy has been developed within the statutory framework for organ donation and transplantation prevailing in Australia. Various jurisdictional Human Tissue Acts currently govern this area of clinical practice. Altruistic donation of both regenerative and non-regenerative tissue by legally competent adults is lawful, subject to certain special procedures in relation to consent and other matters specified in the Human Tissue Acts. In order to protect children, the law prohibits removal of non-regenerative tissue from the body of a child in most Australian jurisdictions. The principles at the core of these Human Tissue Acts are that organ donation should be based on consensual and altruistic giving, that it must be free of coercion or any obligation to benefit another, and that it is consented to by the competent adult with full knowledge of what is involved and the risks in doing so, especially given that the prospective LDLT donor is agreeing to undergo a procedure and assume known health risks for the benefit of another, rather than him or herself. These fundamental principles in law, by extension, also underpin this policy. Notwithstanding the general principles underpinning human tissue legislation in all States and Territories, there are some procedural differences in relation to the consent and certification procedures. In implementing this framework, jurisdictions, institutions and clinicians must be aware of the particular rules governing organ donation in their State or Territory.

Demand for adult liver transplantation continues to increase, both overseas and in Australia (attachments 2-5), partly related to steady improvements in the effectiveness of liver transplantation for patients with end-stage liver disease, and partly as prevalence of liver disease increases, in particular prevalence of hepatitis C and associated complications. Recent Australian HCV projections predict that, even with expanded combination antiviral treatment for chronic HCV infection, rates of liver failure, hepatic carcinoma and death are predicted

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3 Transplantation and Anatomy Act 1979 (Qld); Human Tissue Act 1982 (Vic); Human Tissue Act 1985 (Tas); Human Tissue Act (NT); Transplantation and Anatomy Act 1983 (SA); Human Tissue and Transplant Act 1982 (WA); and Human Tissue Act 1983 (NSW).


AHMAC Living Donor Liver Transplantation Policy Framework (March 2007)
to increase by the order of 40% over the next decade. Long-term sustained effort is therefore needed to improve access to, and uptake of hepatitis C treatment to prevent progression to hepatitis C-related cirrhosis, carcinoma and liver failure. Current national data (attachment 2) show increasing exits from the liver transplantation waiting list due to death or deterioration in condition, thus precluding transplantation. These reflect the need for therapeutic options, in addition to deceased donor liver donation in a percentage of cases.

In light of waiting list exit data, it is projected that demand for LDLT may initially be in the order of 10-30 cases annually. This may, in the short term, increase to 50-80 cases, taking into account overall numbers of patients on the liver transplantation waiting list (currently approximately 300 patients) and that typically less than one third of potential recipients are able to find a suitable and willing living donor.

No single intervention however, whether it is LDLT, education campaigns to improve deceased donation rates, expanded deceased donation practices, or improved supportive extra-corporeal techniques in the critically ill is likely, in isolation, to resolve the significant current and future unmet demand for effective treatment of end-stage liver disease. Given the inherent donor risks in LDLT, continuing to search for safer alternatives will remain a priority after introduction of LDLT.

The purpose of the policy is to provide guidance to health professionals and additional protection for prospective adult LDLT donors, while operating within the current law. This policy is aimed primarily at the jurisdictions that will endorse LDLT, the institutions that will provide LDLT, and the health professionals directly involved in this practice. To the extent that it is adopted by all jurisdictions in line with the particular requirements of their human tissue legislation, and applied in participating liver transplant units, it will promote ethical, lawful and consistent application of quality processes in provision of this complex procedure to donors, recipients and their families.

2. GUIDING PRINCIPLES

The practice of living donor liver transplantation should proceed on the basis of the following principles:

2.1 The donor has an altruistic desire to assist the recipient generally, and not for any pecuniary or other self-interested purpose.

2.2 The donor must have capacity for informed consent and be of sound mind.

2.3 Donor consent is voluntary and non-coerced. The potential donor is under no obligation to proceed with donation once donor assessment has begun.

2.4 The competent donor provides consent. Substitute consent to donation is not permissible.

2.5 The consent process involves independent donor advocacy.

2.6 Recognising the relative limitations of international evidence, the donor and the recipient are provided with the best available evidence about, and
understand the ramifications of the procedure, its material risks and benefits, and the range of possible outcomes.

2.7 The donor is 18 to 60 years of age. Children are explicitly excluded as donors of liver tissue under the requirements of this policy.

2.8 The donor consent process involves a ‘cooling off’ period.

2.9 The donor may withdraw at any time before surgery without the need to give a reason.

2.10 The donor and recipient are genetically related, are family members or have a genuine close and (typically) longstanding social relationship.

2.11 It is reasonably expected that the donor will not suffer significant psychological and/or emotional harm by the donation process.

2.12 The donor principally determines the acceptability of the potential risks or harms to him or herself, providing there is understanding of risks and no contraindications. However, the donor surgeon also has a duty of care to the donor and must also agree with their decision to proceed with donation.

2.13 The donor meets all stipulated criteria for medical suitability.

2.14 The donor has the willingness and ability, at least at the outset, to comply with long-term follow up, understanding what this is likely to entail. However, in practice, follow-up is ultimately unenforceable.

2.15 The anticipated survival prospects for the individual recipient are good, for example a 50% chance of survival at 5 years. A transplant surgeon may refuse a willing donor and recipient on the basis that the likely recipient outcome is, in his or her opinion, too poor to justify the donor and recipient procedures.

2.16 Recipient consent is voluntary and non-coerced. The potential recipient is under no obligation to proceed with donation once donor assessment has begun.

2.17 Provision of the highest quality of treatment and care for both LDLT donor and recipient, before and after surgery, is of utmost importance.

2.18 Donation must not result from any unlawful conduct, for example “trading” in tissue (including offering to buy or sell human tissue), consistent with the requirements and prohibitions of jurisdictional Human Tissue Acts in Australia.

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5 If, and/or when consideration of minor/child involvement as donors is contemplated in the future, then other ethical and policy issues would require consideration and documentation, either as a separate policy or addendum to the current document.
3. **Recipient Assessment and Informed Consent**

3.1 Information about deceased donor and living donor liver transplantation should be made available to potential recipients, their families or those close to them during the recipient’s transplantation assessment period. This should be available in a ‘plain language’ patient information booklet or given in another appropriate form. Attention should be paid to ensuring adequate understanding in the recipient consistent with informed consent standards, and may require interpreter assistance in some cases.

3.2 The recipient must fulfil the same eligibility criteria as for deceased donor liver transplantation (see attachment 8), and the same guidelines for suitability for transplantation in hepatocellular cancer, other liver tumours and alcoholic hepatitis shall be applied.

3.3 Conventional medical/surgical therapeutic alternatives should be exhausted before LDLT is considered. Other experimental therapies may also be considered, in accordance with applicable research regulatory requirements, for those in whom LDLT is not indicated, including those whose condition is too poor for LDLT.

3.4 The recipient should agree to liver transplantation generally, and must expressly consent to receiving a directed donation of a partial liver from a relative or close friend following all appropriate information and discussion.

3.5 The recipient must be provided with information regarding the following matters prior to giving consent for receipt of a donation from a living person:

- The material risks to the donor, including death;
- The surgical and other risks to them as recipient, including surgical risks specific to living donor graft, for example that living donation involves receiving a portion of, rather than a whole liver (as provided by deceased donation) and that this may pose some risks in the short-term, or the greater incidence of biliary complications related to cutting the liver lobes and tissue;
- The complex potential psychosocial changes for donor and recipient, including, but not limited to:
  - Feelings the donor or recipient may encounter if the donation fails, or the donor ultimately refuses donation;
  - Possible changes in donor-recipient relationships;
  - Possible feelings of ownership towards the recipient by the donor and the possibility of demands made by the donor;
  - Possible debt of gratitude or feelings of obligation felt by the recipient towards the donor; or
  - Possible psychological consequences if donation has a harmful effect on the donor.
- The right of the donor to withdraw at any time, without the provision of a reason for doing so, and the possible cancellation of the procedure.

3.6 Any decision by a potential recipient not to accept a living donor’s organ, or where a potential donor ultimately declines donation, shall not prejudice
the recipient’s place on the deceased donor waiting list, or affect provision of any other treatment or care.

4. DONOR ASSESSMENT AND INFORMED CONSENT

Assessment of the donor and obtaining their informed consent should be completed through the **3-phase process** as follows:

4.1 Phase One - Preliminary identification of suitable donors

4.1.1 Written material (as referred to in 3.1) should be made available to recipients and families about liver transplantation, including the possibility of living donor transplantation. It must then up to an interested potential donor to indicate their willingness to begin an assessment process. The transplant team should not initiate discussion with potential donors, regardless of whether it is an elective or emergency situation.

4.1.2 If an interested individual wishes to be considered, they should then be provided with more detailed information regarding living donation prior to choosing to donate (such as in 4.1.1, 4.1.4, 4.2.3, 4.3.5).

4.1.3 Involvement of an *independent donor advocate* is mandatory in LDLT. Use of an independent donor advocate aims to avoid potential conflict of interest or coercive influence on a donor, in particular where a single team assesses both donor and recipient. The potential donor should be specifically informed that the donor advocate is independent to management of the recipient and that they consider only the donor’s interests.

*Function:* The independent donor advocate acts as an impartial advisor to the donor, a primary source of information about the procedure, and assists in evaluating the voluntariness and informed nature of the donor’s decision. The donor advocate has responsibility to inform the multidisciplinary donor team (4.2.2), in particular the donor surgeon responsible for taking the donor’s consent, of any concerns related to perceived coercive influences on the donor to donate (should these exist). However, the donor advocate is not a decision-maker on behalf of the donor, and has no single right of veto on the decision to proceed with donation, which must be made by the donor, donor surgeon, the recipient and the multidisciplinary donor team as a whole (see 4.2.2 and 4.3.1). The donor advocate may provide written authority/certification as to the adequacy of donor consent obtained by the donor surgeon, in accordance with jurisdictional human tissue legislation requirements.

*Designation:* The donor advocate should be a senior medical specialist; be very familiar with liver disease, and liver surgery (including transplantation) and the risks involved; not be involved in care of the recipient; and hold the donor’s interests and wellbeing foremost. There should not be a professional relationship involving patient referral between the donor advocate and the transplantation team.
4.1.4 The independent donor advocate is responsible for providing information (verbal and written) to the donor in a balanced way and in a time frame acceptable to the potential donor, although the donor advocate is not responsible for obtaining donor consent (see 4.3.2). Such information should be presented in an honest, understandable and realistic manner. Such information should include:

- Reason for using a live donor as opposed to deceased donation;
- A full description of the procedure;
- Implications of the procedure for the donor, such as preparation for surgery by drugs or diet, hospital admission;
- Risks to the donor inherent in the procedure including:
  - Surgical risks;
  - Risks of anaesthesia and that there is the need for Intensive Care management after anaesthesia;
  - Immediate complications as a result of the procedure including risk of liver failure and potential need for liver transplantation;
  - Risk of death;
  - Long terms risks (including that data about risks is limited); and
  - That there may be risks that are still unknown.
- The process of recovery for the donor, including:
  - Physical rehabilitation and length of expected recovery time;
  - Level of probable pain or discomfort after procedure;
  - Inhibition of normal activity;
  - Time off work required (and related financial impact such as access to life insurance etc.);
  - The level and rate of restoration of their capacity to function after the removal of the liver segment.
- The likely outcomes for the recipient (including possibility of failure of the donation, possible complications, prospects of success);
- The possibility of uncovering hitherto unrecognised serious diseases, such as undiagnosed liver abnormalities or other conditions screened for during the assessment process. The donor should be given an undertaking that such abnormalities will be investigated and treated in order to allay any anxiety in this regard;
- The possible psychological impact on the donor if the donation fails in the recipient or critical illness in the donor occurs;
- Possible changes to the donor/recipient relationship (including possible feelings of ‘ownership’ towards the recipient by the donor, the donor feeling the need or right to make demands upon the recipient, and that the donor may be the object of feelings of gratitude by the recipient);
- The reasons for, and importance of long-term follow up of donors’ clinical outcomes, and that this involves inclusion of their de-identified clinical data in a national data registry; and
- That the donor may choose not to proceed with donation at any time before surgery and that it is not a foregone conclusion that donation will occur once donor assessment has begun.
4.1.5 Attention should be paid to ensuring adequate understanding in the donor, consistent with informed consent standards, and may require interpreter assistance in some cases.

4.1.6 After the potential donor considers the written and verbally discussed information, and if the potential donor wishes to proceed with assessment, an initial screening phase should be undertaken. This includes an interview to establish history, general condition (attachment 7), and to exclude any current condition or past history that indicates the potential for deterioration in the potential donor’s liver function in the future. Height and weight (to ascertain Body Mass Index) should be assessed and blood taken for ABO group early in this assessment phase as unsuitability on the basis of overweight or incompatible blood group is not uncommon, and should be known as soon as possible. A thrombophilia screen should also be undertaken in Phase One assessment.

4.1.7 Discussion with the surgeon who will undertake the donor hepatectomy should then take place. This discussion aims to clarify and provide further information to the potential donor as required.

4.1.8 Donor assessment in all assessment phases must be confidential.

4.2 Phase Two – Comprehensive donor assessment

4.2.1 If a potential donor is identified during Phase One assessment, then full screening should take place. The current standard involves tri-phasic CT scan with selective use of Magnetic Resonance Imaging and potential liver biopsy based on that imaging and other laboratory and demographic factors (past alcohol abuse, BMI > 28, abnormal liver function tests). Some of these procedures pose a risk and require proper consent.

4.2.2 During this assessment phase, further discussion will continue between the potential donor and members of the multi-disciplinary donor team. The multidisciplinary donor team should include the surgeon undertaking the hepatectomy, a liaison psychiatrist (or equivalent), social worker, clinical nurse consultant, and the ‘independent donor advocate’. This team aims to provide for the clinical, psychological, social and informational needs of the donor in the lead up to, and following donation.

4.2.3 A liaison psychiatrist (or equivalent) should undertake independent assessment of donor’s psychological health (to exclude psychopathology) and psychosocial circumstances and report, with the donor’s knowledge, the results to the donor surgeon and multi-disciplinary donor team. This assessment should consider the following issues:

- Competence of the donor to consent;
- Donor understanding of the risks and benefits of the procedure;
- Motivations of the donor;
- Relationship with the recipient and associated family;
• Any undue pressure, or any coercion, threats or inducements potentially affecting the donor’s decision;
• Any mental illness, personality disorder or substance abuse potentially affecting the donor’s decision to donate or potential post-operative outcome;
• The donor’s understanding and acceptance of the principle that no financial or other benefits are to be sought from the recipient, the public health organisation or any other person as a result of the donation; and
• Support mechanisms for the donor during and after the procedure.

4.2.4 At completion of Phase Two assessment, all donor selection criteria (attachment 7) must be met.

4.3 Phase Three – Final decision to proceed

4.3.1 A recommendation to proceed with donation from a living donor may only take place following unanimous agreement between the donor, the surgeon undertaking the hepeatectomy, and others in the multidisciplinary donor team, including the independent donor advocate.

4.3.2 The donor surgeon undertaking the donor hepeatectomy is responsible for obtaining and certifying donor consent, as required by the relevant human tissue legislation. In some jurisdictions, the independent donor advocate may certify consent, although he or she cannot be responsible for obtaining consent.

4.3.3 Following consent to LDLT, a mandatory "cooling off" period of 2 weeks is required.

4.3.4 Potential donors must still be able to decline at any stage before surgery for any, or no reason.

4.3.5 A potential donor may be deemed ‘unsuitable’ for donation according to reasons applicable in one or more of the following broad categories:

• Medical or surgical reasons;
• Infection;
• Biological incompatibility, for example ABO blood group; or
• Psychosocial reasons including the situation where the potential donor declines surgery.

The donor should be informed in confidence of any reason for unsuitability to donate.

4.3.6 The recipient and the donor should be informed at the outset of the assessment process that, as routine practice, any reasons for donor unsuitability are not disclosed to recipients and families by the health care team. Final determination of donor suitability should be provided to the recipient and family but this should not state reason/s (outlined in 4.3.5) where the donor is found ‘unsuitable’.
4.3.7 Disclosure of reasons for unsuitability is solely at the donor’s discretion. Doctors and health professionals should abstain from stating or implying the reason for donor ‘unsuitability’, in order to avoid misrepresenting the reason in any subsequent discussion with the donor, recipient or family.

4.3.8 Rejection of a potential donor on psychological grounds should be handled frankly and compassionately. A decision to refuse a donor on such grounds is at the discretion of the donor surgeon, in consultation with the assessing liaison psychiatrist (or equivalent) and should be conveyed by them to a declined donor.

4.3.9 If a person declines donation, counselling is strongly recommended. A decision to decline donation may potentially be associated with significant guilt or other adverse psychological outcomes and a declining donor should therefore be offered counselling.

5. Institutional requirements for provision of LDLT

LDLT may only be performed in centres with an established adult deceased donor liver transplant program.

Current adult deceased donor liver transplantation centres:
Queensland       Princess Alexandra Hospital
New South Wales   Royal Prince Alfred Hospital
Victoria          Austin Hospital
South Australia   Flinders Medical Centre
Western Australia Sir Charles Gairdner Hospital
New Zealand       Auckland Hospital

An institution wishing to undertake LDLT must be able to demonstrate that they meet the following requirements. Local credentialing of participating institutions, according to the usual process applicable in their jurisdiction, is recommended. A “New Procedures” committee at the institutional level may be appropriate to oversee practical/capability aspects.

5.1 Proven need

An institution must establish sufficient need for LDLT before this procedure is undertaken. Need is reflected in the number and trend of an institution’s liver transplant waiting list exits, including mortality rates and number of patients becoming ineligible for deceased donor liver transplantation because of clinical deterioration.

5.2 Sufficient expertise and experience

5.2.1 Building cumulative organisational case volume in LDLT, while difficult to quantify as an absolute annual case volume requirement, is nonetheless important to develop and maintain expertise in LDLT. The impact of cumulative LDLT case volume on safe and high quality patient care combined with experience in other related procedures (referred to in 5.2.2), and having trained and experienced nursing and allied health staff are determinative of good outcomes in this, as in other surgical procedures.
5.2.2 Significant experience with good outcomes (both mortality and morbidity) is required in other related procedures before LDLT is introduced. Related procedures include hepatic resection (for liver cancer), graft reduction for liver transplantation in children (split liver transplantation), and other hepatobiliary surgery. Institutional criteria for the donor operation should include a sufficient annual and cumulative experience with ablative liver resections; and for the recipient operation, a sufficient annual experience in liver transplants. These criteria should be qualitatively defined and judged, by an external reviewer, in concert with local outcome data from both liver resections and liver transplants.

Reciprocal arrangements between participating institutions for designated surgeons may initially be useful in building surgeon experience.

5.2.3 Surgeons (regardless of clinical specialty) must have clinical privileges delineated for all procedures they undertake, in accordance with prevailing national or local frameworks. Hence, delineation of clinical privileges for surgeons undertaking LDLT should not be exempt from these requirements. There is a need for on-going, independent monitoring of the performance of surgeons; credentialing should therefore be time-limited.

5.2.4 A multi-disciplinary staff including surgeons, hepatologists, anaesthetists, psychiatrists, nursing staff and social workers must exist. Personnel and ancillary support is as required for deceased donor liver transplantation.

5.3 Protocols

5.3.1 Management protocols should be in place for deceased donor and living donor liver transplantation, including post-operative care, before LDLT is embarked upon.

5.3.2 Protocols for assessment, consent and management of living donors and transplant recipients should be consistent with this policy.

5.3.3 Adverse events associated with LDLT should be reported to the hospital and competent authorities (such as Health Departments or the Coroner), in line with established reporting mechanisms.

6. NATIONAL DATA registry

6.1 The Australia & NZ Liver Transplant Registry (ANZLTR) currently maintained by the Liver Transplant Unit at Princess Alexandra Hospital, Queensland and funded by Commonwealth Department of Health and Ageing, should be extended to include adult-to-adult LDLT donor and recipient data.

6.2 All institutions undertaking LDLT should contribute de-identified patient data to the national database in order to track short and long term donor and recipient outcomes.
6.3 Current ANZLTR data collection fully complies with prevailing privacy laws. LDLT data should also be collected in accordance with such requirements.

6.4 The addition of LDLT donor/recipient data should be clearly delineated in the database from deceased donor/recipient transplantation data.

6.5 Registry data should be collected in accordance with international data collection systems to facilitate understanding and comparison of population outcomes.

6.6 In addition to physiological data on donors and recipients, the database should allow the opportunity to collect psychological data on donors and recipients following consideration of any relevant privacy and data acquisition issues.

6.7 Both LDLT donors and recipients should be informed of the need for ongoing future contact with the health care institution for the purposes of follow-up and ongoing management of clinical outcomes. In addition, they should be informed of the need for, and importance of, inclusion of their data in the registry. Collection of such data is essential to enable risk of LDLT to be conveyed to future patients, as well as to improve ongoing practice. While participation of donors and recipients in this database cannot currently be mandated under existing legislation, patients should be strongly encouraged to agree to their data being included in the registry for the reasons outlined above.

6.8 Participation in future research on the part of LDLT donors and recipients must be voluntary, with proper consent obtained at the relevant time.

7. Access and equity

7.1 Access to LDLT only in limited centres that meet institutional standards

Liver transplantation generally will remain limited to a select number of centres in Australia with adequate expertise and experience in the procedure. Maintaining optimal safety standards with this higher risk procedure (than deceased donor transplantation) therefore requires that demonstrable expertise before any institution undertakes LDLT, and this will necessarily entail a limited number of appropriately qualified centres in Australia. Owing to the necessarily limited pool of suitable living donors, provision of LDLT will involve fewer cases than deceased donor transplantation. That one participant is healthy and undergoing risky surgery further supports safety considerations being paramount.

7.2 Access to LDLT by foreign nationals

7.2.1 Foreign nationals can apply for a Medical Treatment Visa (MTV). Foreign nationals are eligible as patients for a MTV if they do not have a condition which could be a threat to public health in Australia; arrangements are in place, including an appropriate organ, or an organ donor; arrangements for payment are made; and if no Australian citizen or permanent resident will be disadvantaged by the treatment or consultation.
7.2.2 Foreign nationals wishing to undergo living donor liver transplantation in Australia (because the requisite expertise is not available in the country of origin) must be accompanied to Australia by the potential donor to undergo the same assessment process as applied to Australian nationals. This includes consideration of the veracity of the claimed donor/recipient relationship (2.2) and that all requirements of this policy have been met.

7.2.3 Follow-up care and monitoring on return to country of origin should be through an established liver transplant centre in that country. Appropriate mechanisms for follow up must be considered by the transplanting institution prior to the recipient and donor leaving Australia if the recipient and donor are from a country without liver transplantation services.

8. **Emergency LDLT**

8.1 The potential use of LDLT where there is need for urgent liver transplantation is recognised. LDLT in this setting raises even greater ethical concerns than LDLT in an elective setting. These include greater potential for coercive influence on the donor related to the deteriorating and time critical nature of the recipient’s condition, and inability to provide a ‘cooling off’ period. This is further complicated by less time for information provision to, and assimilation by the donor.

8.2 Therefore in general, emergency LDLT is not recommended because the safeguards/processes described in this policy may be compromised, in particular an adequate ‘cooling off’ period. However, in exceptional circumstances and with all parties understanding the additional risks involved, the treating team may consider LDLT where all requirements of this policy can met (with the exception of a 2 week cooling off period), including that there is unanimous agreement reached between the donor, recipient (where competent) or their substitute decision-maker, donor advocate and multidisciplinary team (4.3.1).

8.3 Individual institutions may wish to consider the appropriateness of ethical advice (e.g. from a clinical ethics committee) in emergency LDLT where such a mechanism with adequate expertise exists, and where circumstances permit.

9. **NON-DIRECTED LDLT**

At this time, non-directed LDLT (that is, donation of a liver lobe to any suitable stranger on the waiting list) is not considered appropriate on the basis that it presents an even more complex, and less persuasive benefit/risk analysis than directed LDLT. The vital emotional relationship that normally exists between the potential live donor and recipient significantly contributes to the context in which the risks taken by the LDLT donor become ethically acceptable. Where there is no such relationship, as in non-directed donation, the psychological benefits accruing to the donor arguably become more tenuous, and largely comprise knowing one has made an altruistic but anonymous gift to society at large. The burdens and risks of LDLT assume greater ethical import when viewed in light of potentially diminished psychological benefits to the donor, and considering the potential for non-directed donors to be motivated by other than altruistic
intentions, for example psychopathology or pecuniary interests. This differs from the ethical acceptability of non-directed kidney donation, permitted in some Australian states, at least in so far as the clinical risks entailed in the donation procedure are significantly less than those incurred in LDLT.

This position may be reconsidered in the future, after more experience with this procedure has been acquired in Australia.
Attachment 1.

POLICY CONSULTATION: CONSULTED AND SUBMITTING STAKEHOLDERS

Government agencies
Ministerial Advisory Committee on AIDS, Sexual Health & Hepatitis (MACASHH), Commonwealth Department of Health and Ageing*

HIV/AIDS and STIs Subcommittee Secretariat (HASTI), Commonwealth Department of Health and Ageing*

Hepatitis C Subcommittee Secretariat, Commonwealth Department of Health and Ageing*

Indigenous Australians' Sexual Health Committee (IASHC), Commonwealth Department of Health and Ageing

Intergovernmental Committee on AIDS, Hepatitis C and Related Diseases (IGCAHRD)

National Health & Medical Research Council, Australian Health Ethics Committee (AHEC)*

Therapeutic Goods Committee

Western Australian Department of Health
New South Wales Department of Health
South Australian Department of Health*
Queensland Department of Health
Tasmanian Department of Health & Human Services
Northern Territory Department of Health & Community Services*
Victorian Department of Human Services*

Health consumer organisations & non-government organisations
ACT Hepatitis C Council*
Alcohol & other Drugs Council of Australia (ADCA)
Australians Donate Inc
Australian Illicit and Injecting Drug Users League (AIVL)
Consumer Health Forum of Australia
Haemophilia Foundation of Australia (HFA)
Hepatitis C Council of Victoria
National Association of People Living with HIV/AIDS
Queenslanders Donate*^
Transplant Australia
Western Australian Network of Alcohol and other Drug Agencies (WANADA)

Professional representative organisations
Aboriginal Health and Medical Research Council of NSW
Australasian Hepatology Association
Australasian Transplant Co-Ordinators Association (ATCA)
Australian and NZ College of Anaesthetists*
Australian and NZ Intensive Care Society (ANZICS)
Australian College of Clinical Psychologists
Australian College of Critical Care Nurses*
Australian College of Critical Care Nurses, Organ Donation and Transplantation Advisory Panel*
Australian Professional Society on Alcohol & other Drugs (APSAD)
Drug & Alcohol Nurses Australasia (DANA)
Gastroenterological Society of Australia*
National Aboriginal Community Control Health Organisation
Royal Australasian College of Surgeons*
Royal Australian & NZ College of Psychiatrists*
Royal Australian College of Physicians*
Royal College of Nursing*
Transplantation Society of Australia & NZ*

Liver transplant units
Austin Hospital, Melbourne*
Flinders Medical Centre, Adelaide*
Princess Alexandra Hospital, Brisbane*^
Royal Prince Alfred Hospital, Sydney*
Royal Adelaide Hospital, Adelaide
Sir Charles Gairdner Hospital, Perth

Other
Australian Health Insurance Association

Notes
* Denotes that this organisation made a submission.
^ Queenslanders Donate and Princess Alexandra Hospital, Brisbane made a joint submission.

Copies of the Report on National Consultation: Adult-to-Adult Living Donor Liver Transplantation National Policy Framework can be obtained by contacting Health Research and Ethics Branch, NSW Health on (02) 9391 9465.
Attachment 2.
Liver Transplantation Waiting List Outcomes (2005)

Source: Australian and New Zealand Liver Transplantation Registry - 17th Report

## Waiting List Activity
(Data 1/1/04 - 31/12/05)

<table>
<thead>
<tr>
<th>Activity 2004</th>
<th>Activity 2005</th>
<th>TOTAL 2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Listed at 31/12/2003</td>
<td>Listed at 31/12/04</td>
<td>117</td>
</tr>
<tr>
<td>Listed in 2004</td>
<td>Listed in 2005</td>
<td>287</td>
</tr>
<tr>
<td>TOTAL</td>
<td>TOTAL</td>
<td>404</td>
</tr>
</tbody>
</table>

### Outcome

<table>
<thead>
<tr>
<th>Transplant in 2004</th>
<th>214 [58%]</th>
<th>Transplant in 2005</th>
<th>76</th>
<th>115</th>
<th>191 [47%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delisted in 2004</td>
<td>41 [10%]</td>
<td>Delisted in 2005</td>
<td>20</td>
<td>52</td>
<td>72 [18%]</td>
</tr>
<tr>
<td>Died on list</td>
<td>6</td>
<td></td>
<td>Died on list</td>
<td>6</td>
<td>20</td>
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<tr>
<td>Too sick</td>
<td>6</td>
<td></td>
<td>Too sick</td>
<td>2</td>
<td>7</td>
</tr>
<tr>
<td>Tumour progression</td>
<td>2</td>
<td></td>
<td>Tumour progression</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>Improved</td>
<td>8</td>
<td></td>
<td>Improved</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>Other</td>
<td>9</td>
<td></td>
<td>Other</td>
<td>6</td>
<td>7</td>
</tr>
</tbody>
</table>

| Still listed at 31/12/2004 | 117 [32%] | Still listed at 31/12/2005 | 21 | 120 | 141 [35%] |
Attachment 3:
Number of Transplants by Year

Source: Australian and New Zealand Liver Transplantation Registry 17th Report, 31/12/2005
Attachment 4:
Primary Liver Diseases of Adult Liver Transplant Recipients

Source: Australian and New Zealand Liver Transplantation Registry 17th Report, 31/12/2005
Explanatory note:

Abbreviations:

BA Biliary atresia
MET Metabolic diseases
ALD Alcoholic liver disease
CC Cryptogenic cirrhosis
PBC Primary biliary cirrhosis
PSC Primary sclerosing cholangitis
MAL Malignancy
FHF Fulminant hepatic failure
OTH Other diseases
CAH: AI Chronic active hepatitis (autoimmune)
CVH Chronic viral hepatitis
Treatment Scenario Projection for Annual Liver Failure in People with Chronic HCV, 2000 - 2025


Explanatory note:
Three modelling treatment scenarios and their impact on projected incidence of HCV related liver failure represented above.

Current: 2,000 people treated with combination antiviral treatment per year since 2000.
Mid 1: Treatment expanded to 6,000 people by 2009 (25% at stage 0/1* liver disease)
Mid 2: Treatment expanded to 6,000 people (50% at stage 0/1 liver disease)
High: Treatment expanded to 10,000 people ((50% at stage 0/1 live disease)

*Stage 0/1 - no or minimal hepatic fibrosis

For discussion see:
Attachment 7.
LDLT Donor Selection Criteria

Adapted from Transplantation Society of Australia and New Zealand (TSANZ) LDLT guidelines (2002) in consultation with TSANZ
(Current at 1 December 2006)

General Criteria

- The donor must have an identical or compatible blood group.
- The upper acceptable age limit for the donor is 60 years old.
- The predicted graft to recipient ratio volume should be > 0.8 (preferably >1.0).
- The donor will have no increased risk factors for anaesthesia such as obesity, (BMI >30) hypertension, diabetes, lung, renal, cardiac disease or be a smoker.
- The donor will have no significant underlying psychiatric or psychological disorder (see 4.2.3 of this policy for more detailed requirements).
- The donor will have no evidence of HIV infection.
- HBC and HCV positive donors may be considered where:
  - Viral loads are undetectable in both donor and recipient; or
  - The donor is HBVc Antibody positive; or
  - HCV+D to HCV+R where there is no evidence of fibrosis in the donor.
- The donor will have no evidence of malignancy with the exception of non-melanoma cancer that is not invasive.
- The donor will have no history of thromboembolisation.
- The donor will have no active ulcer disease.
- The donor will have suitable vascular and biliary anatomy.

Specific Anatomy

- Hepatic arterial anatomy - conventional or replaced RHA. Accessory RHA relative (not absolute) contraindication.
- Portal vein anatomy - Single RPV preferable (double Rt portal vein not a contraindication but requires modified surgical technique).
- Hepatic vein anatomy - Dominant main RHV preferable (dominant MHV with major right lobe sector braches, and/or large IRHV, not contraindications but require modified surgical technique).
- Biliary anatomy More than two biliary anastomoses should, in general, be avoided.
- Macro vesicular steatosis less than 10%.
Attachment 8.
LDLT Recipient Suitability Criteria

As for TSANZ criteria for deceased donor liver transplantation
(Current at 1 December 2006)

LDLT recipients must meet the same criteria, as do deceased donation recipients. These are as follows:

GENERAL: RECIPIENT SUITABILITY CRITERIA
1. Life threatening liver disease not amenable to alternative therapy
2. Accepted onto the deceased donor waiting list by a recognised liver transplant unit
3. Absence of contra-indications, e.g.
   - Life threatening non-hepatic illness considered to preclude successful liver transplantation
   - Persisting alcohol or substance abuse
   - Inability to co-operate with life long medical supervision

Examples of general guidelines for selection for specific disease are:

1. Hepatocellular Cancer
   - Confined to the liver
   - Single tumour  5 cm #
   - Multiple tumours  3 and  3cm #
   - No vascular invasion
     # minor variation on size and number of tumours may occur

2. Cirrhosis (all forms)
   - Decompensated liver disease
   - Correctable extrahepatic manifestations of cirrhosis e.g. hepatopulmonary syndrome, failure of growth neurodevelopment

3. Metabolic disorders
   - Life threatening conditions curable by liver transplantation
   - Severe uncontrolled symptomatic disease

4. Alcoholic Liver Disease
   Liver failure following -
   - 6 months abstinence
   - Considered at low risk for continued alcohol abuse

5. Severe symptomatic liver disease
   e.g. Polycystic liver disease, PBC with severe pruritus, giant haemangioma

6. HIV positive patients
   HIV positive patients acceptable candidates for transplant providing the individual prognosis from HIV infection is acceptable. This usually means a patient with well-controlled HIV on antiviral therapy with undetectable viral load
and with a CD4 count >250. The latter may be lower 2º to cirrhosis.

7. Retransplant
   Is considered only in patients with an acceptable predicted survival (60% one year according to overseas guidelines)

8. Exclusions
   Included
   o Metastatic liver disease (non – neuroendocrine)
   o Post liver resection if not fulfilling original Milan criteria