

Use of clinical practice guidelines to promote best practice when managing clinical interventions for liver transplant candidates

Background—Limited organ availability and an increasing demand for organ transplantation has extended transplant waiting times and thus increased morbidity and mortality for potential recipients on waiting lists. The Queensland Liver Transplant Service identified use of clinical practice guidelines developed from evidence-based practice as a strategic clinical management/workflow tool that could improve clinical outcomes for patients awaiting liver transplant.

Method—An extensive review of publications related to the management of advanced liver disease in potential transplant recipients was undertaken and the supporting evidence was identified. In all stages of development of the guidelines, the multidisciplinary collaborative team of clinicians used recommended principles from The Appraisal of Guidelines, Research and Evaluation collaboration. The liver transplant recipient coordinator acted as facilitator for the project, identifying positive factors and resolving obstacles.

Results—Key focus areas in optimizing medical management before liver transplant were identified with the aim of preventing disease progression and complications that would jeopardize patients' outcome. Clinical practice guidelines were developed for each key area to optimize care by promoting appropriate timing of clinical interventions.

Conclusion—Practices that required change to comply with identified best practice were investigated, and clinical practice for the outpatient medical management of potential liver transplant recipients with chronic liver disease were developed collaboratively. These guidelines have been accepted and are being implemented within the gastroenterology and hepatology department at the Princess Alexandra Hospital. (*Progress in Transplantation*. 2009;19:132-141)

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Notice to CE enrollees:

A closed-book, multiple-choice examination after this article tests your ability to accomplish the following objectives:

1. Describe the factors that contributed to the need for development of clinical practice guidelines for care of liver transplant candidates
2. Identify the key focus areas for optimizing medical management before liver transplant
3. Discuss the principles for establishing effective clinical practice guidelines and evaluate their utilization in this particular project

Liver transplantation is a well-established, effective treatment for end-stage liver disease and some inborn errors of metabolism. The procedure was first performed in 1963, initially with poor results, but better outcomes were achieved in the 1970s thanks to

improvements in operative techniques, anesthetic care, and immunosuppressive medication. The 1980s and 1990s saw steady improvement in outcomes from liver transplantation programs, with a 1-year survival after liver transplantation of 80% to 90% and a rapid increase in the establishment of liver transplantation programs internationally.¹ Liver transplantation in Australia began with the establishment of the Queensland Liver Transplant Service (QLTS) at the Princess Alexandra Hospital in 1985. By December 2006, 2886 liver transplants had been performed in Australia and New Zealand, with the 1-year survival rate improving from 70% (1985-1989) to 90% (2006).² The success of the Queensland program has led to an increased demand for transplantation, without a corresponding increase in the number of available organs. This disparity has led to longer waiting times and a need for strategies to optimize care to prevent clinical deterioration and complications related to advancing liver disease while awaiting a transplant.

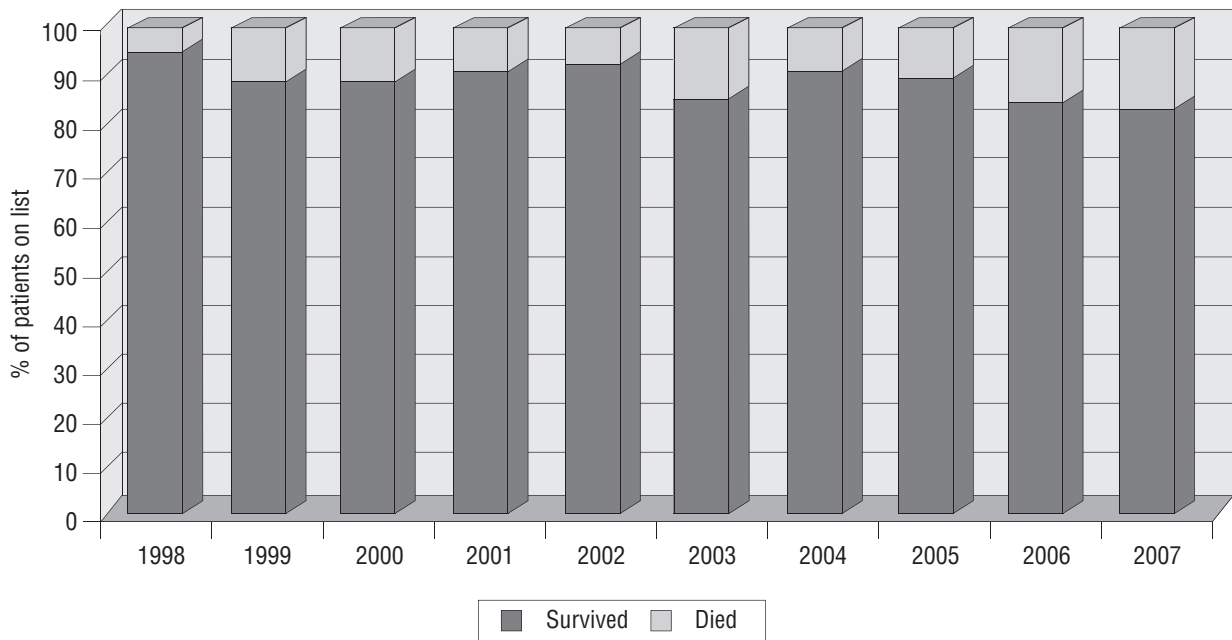


Figure 1 Mortality rates for patients on the Queensland Liver Transplant Service waiting list for 1998 to 2007.

Background

Transplant programs worldwide report major shortages of available organs.³ The number of potential recipients listed for liver transplantation is growing while donor rates remain stagnant or are decreasing; as a consequence, waiting times are getting longer and thus pretransplant morbidity and mortality rates are increasing. The mortality rate for patients on the waiting list for a transplant in the United Kingdom is approximately 10%, which is equal to the rates for other programs, but the rate does not include those patients who were taken off the waiting list because of irretrievable deterioration in their clinical condition.¹ A clinical audit revealed a mortality rate of 16.9% for the QLTS in 2007 (Figure 1). This rate includes patients removed from the list because of deterioration in their general medical condition (renal, respiratory, and cardiac complications) and patients with progression of an existing hepatocellular carcinoma.

The need to address the increasing mortality rates for patients on the waiting list is prompting liver transplant institutions to develop strategies to optimize use of this scarce resource. Such strategies include improved organ procurement techniques and use of split liver grafts and live liver donation. For recipients, issues such as timing of referral, rigorous assessment, and aggressive clinical management on the waiting list play an important role in influencing outcome after liver transplantation. With respect to timing and referral, Devlin and O'Grady affirm that pretransplant functional clinical status, age (specifically young children or elderly persons) plus primary liver disease

influence survival, length of hospital stay, and the costs incurred to health facilities.¹ Malnutrition, hepatorenal syndrome and advanced hepatic disease are indicators of late referral and are associated with poor outcomes for patients.¹

Liver transplantation involves considerable operative risks. Therefore a thorough assessment is essential before liver transplantation. The extent of liver disease and the presence of significant comorbid diseases must be determined in order to identify appropriate candidates.³ The evaluation consists of extensive laboratory tests, gastroenterological and radiological procedures, and consultations with other specialists, depending on the patient's individual requirements. Establishing a personal profile of complicating cofactors and calculating prognosis will assist the multidisciplinary team with their decision on the patient's suitability to be placed onto a waiting list for liver transplantation.^{1,3} Killenberg and Clavien³ stress that the management of patients with cirrhosis "has truly become an art and requires more expertise than ever before" to maintain clinical suitability for transplantation. The trend toward increasing morbidity and mortality among patients on the QLTS waiting list (Figure 1) prompted an urgent review of local current clinical practices.

Clinical practice guidelines (CPGs) are systematically developed, evidence-based statements that help practitioners and patients make decisions about appropriate health care for specific circumstances. Development of such guidelines is a strategy that can be used to improve practice and provide optimal management of conditions or procedures.⁴ By developing these

clinically effective evidence-based management tools, best practice can be established and used to prevent clinical complications and increase favorable outcomes.^{1,4,5}

Guidelines go beyond their utility as a clinical management or work flow tool and improve clinical outcomes for patients by implementing evidence-based practice. As a strategy for optimizing care before liver transplantation, this QLTS project was intended to promote appropriate timing of clinical interventions with the development of CPGs for patients who have been accepted onto the QLTS waiting list.

Methods

To identify the best method to use when developing CPGs, we reviewed the published literature by using electronic databases and resources, including the Cochrane Library, MEDLINE, Queensland Health Electronic Publishing Service, and the National Health and Medical Research Council (NHMRC). Systematic review of the literature identified high-quality scientific and supporting evidence for methods of developing and implementing CPGs. Although numerous opinions overlap significantly about the effects that CPGs have on patients, health care professionals, and health care systems, most opinions offer qualified support for the implementation of CPGs into clinical practice.⁴⁻⁷

The evidence supports the belief that guidelines are seen as a tool, not only making care more consistent and efficient, but also bringing together current clinical practice that has been verified with scientific evidence. It was therefore essential that the best documented evidence be reviewed while these CPGs were being developed, ensuring that treatment options implemented are in the best interest of the patient.⁷ A key factor identified was the importance of establishing links with guideline development groups while in the process of developing guidelines.⁸

The Scottish Intercollegiate Guidelines Network (SIGN) has noted that guideline users may fail to understand the importance of the level of scientific evidence used when making recommendations by simply relating to the strength of the supporting evidence and not to the importance of the topic.⁹ Also health care systems often have scientific knowledge about best care, but this knowledge is not always applied systematically or expeditiously to clinical practice.¹⁰ The Appraisal of Guidelines, Research and Evaluation (AGREE) collaboration developed an international network for programs related to guideline development and appraisal.¹¹ The NHMRC is also promoting CPG development based on the initial principles of multidisciplinary involvement, professionals developing recommendations on the basis of systematic review and critical appraisal of the evidence base plus the extended principles that CPGs should be flexible and

adaptable. Information should be “disseminated and implemented with the outcomes evaluated and revised regularly to include current evidence.”⁶

These principles have been used as a basis for the development of the QLTS CPG development project. The QLTS has also incorporated the advice of Scott et al,⁵ that CPGs should not only be grounded in theory but also in “real world experience,” and that clinical decisions should be available “at the point of care.”⁵

Method of Guideline Development

- A systematic review of published literature related to the management of advanced liver disease in potential transplant recipients was undertaken by using electronic databases including the Cochrane Library and MEDLINE plus printed texts such as Medical Care of the Liver Transplant Patient³ and British Society of Gastroenterology: Guidelines in Gastroenterology,¹ with the evidence extracted and the findings summarized.
- The scope of the guideline was identified and refined in order to develop effective guidelines in specific medical management areas within the pretransplant program to support change in current practice.⁶
- All persons with a stake in the process who were attached to the QLTS or involved with the management of potential liver transplant recipients were approached to participate in the project. Thus the guideline development group included independent clinician reviewers^{4,12}: director of gastroenterology and hepatology, 2 consultant gastroenterologists, independent consultant gastroenterologist, director of infection management services, consultant interventional radiologist, consultant anesthetist, consultant nephrologist, deputy director of the QLTS (a liver transplant and hepatobiliary surgeon), a clinical nurse consultant who was the liver transplant recipient coordinator, clinical nurses (gastroenterology, infection control, and liver transplant recipient coordinator), and a senior dietician. The medical evidence was reviewed and collated by using the multidisciplinary group approach, promoting higher validity of the guidelines.¹³ Involving expert resource personnel in clinical decision making and people involved at the point of care should make the CPG more readily accepted into practice, as without the support of those persons, the CPG would become ineffective.⁶
- The liver transplant recipient coordinator acted as facilitator for the project development and assisted in expediting the activity in order to achieve the desired time frame.
- Algorithms were developed for complex medical management issues to illustrate the linkages

Table Clinical statements: basic management issues^{1,3}

Management issue	Every month	Every 3 months	Every 6 months	Every year
Cancer general screening				
Mammogram, if >40 years old				X
Pap smear				X
Prostate-specific antigen				X
Skin review			X	
Cancer-specific screening				
Primary sclerosing cholangitis: cholangiography/colorectal cancer				
Carbohydrate antigen 19.9			X	
Carcinoembryonic antigen			X	
Colonoscopy				Every 1-2 years
Cirrhosis: α -Fetoprotein			X	
Dentist				X
Diabetes				
Glycosylated hemoglobin		X		
Endocrine review				As required
Dietician				
Malnourished/obese	X			
All others		X		
General				
Electrocardiography				X
Lipids				X
Vitamin A, D, and E				
Taking replacements	X			
No replacement			X	
Urinalysis			X	
Ischemia—hypertension, diabetes, peripheral vascular disease				
Dobutamine stress echocardiogram				X

between interventions and the intermediate health outcomes that interventions influenced.

- With some of the less complex management issues, statements related to management were used (see Table). Presenting CPG recommendations in this simplified format should make decision points as clear as possible when applied in the clinical practice setting.⁵
- Acceptance and implementation of the CPGs into clinical practice proceeded without impediment. The quality of the evidence, its relevance, and the possible benefits and risks of the guidelines had been addressed in the development phase by the guideline development group. The decision to use clear simple formats such as clinical algorithms and flow charts made decision points as clear as possible and dissemination uncomplicated.^{5,6}
- Potential liver transplant recipients are case managed by the LTRC under the direction of the gastroenterology and liver transplant teams. This arrangement ensures consistent enactment of guideline recommendations and allows point-of-care decisions to be implemented and coordinated.^{5,6}
- Evaluation, revision, and modification of the QLTS CPGs will be undertaken in 3 years;

NHMRC recommends doing so every 3 to 5 years if no rapid change in clinical evidence is occurring. This revision will permit the introduction of new research technologies and adaptation of the guideline after evaluation of outcomes.^{6,14}

Inclusion and Exclusion Criteria

The information gathered in the literature review was used to develop CPGs for the outpatient medical management of potential liver transplant recipients with chronic liver disease, accepted for transplantation by the liver transplant assessment team. Patients placed on the urgent category 1 waiting list (ie, those with acute liver failure) will not use these CPGs because their life expectancy is short unless they receive a transplant quickly.

Key Focus Areas

Areas in which medical management could be optimized through the implementation of CPGs were identified from the literature and from local experience. These areas were based on preventing disease progression and complications that would jeopardize patients' outcomes. (The scope of this project does not include acute medical management issues such as

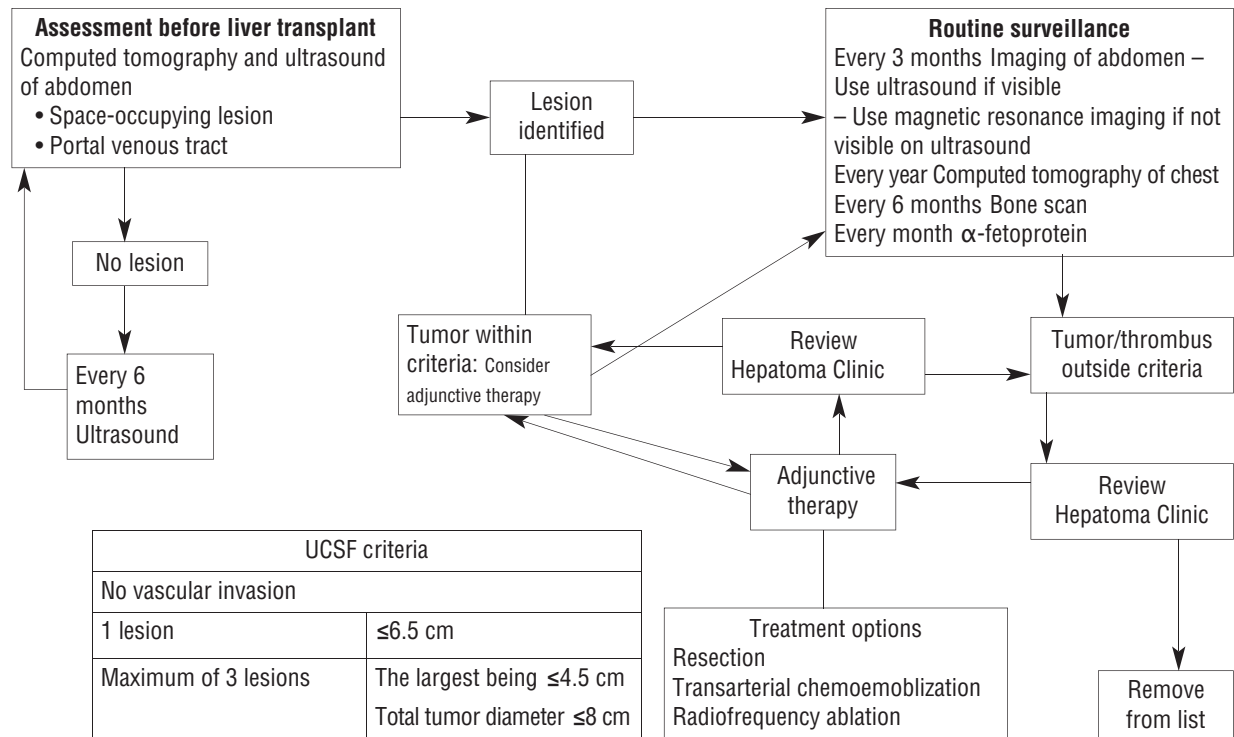


Figure 2 Clinical guideline for hepatocellular carcinoma and vascular patency.^{1,3,15} Cirrhosis increases the risk of hepatocellular carcinoma. Patients with hepatitis C, hepatitis B, and hemochromatosis are at particular risk. Extrahepatic spread and macroscopic vascular invasion preclude liver transplant because of the high incidence of recurrence after transplant. Early stage hepato-cellular carcinoma is acceptable, though, with selection for listing by using University of California, San Francisco (UCSF) criteria, which have a proven patient survival rate of 86% at 2 years. Consideration for extended criteria can be addressed by the liver transplant team, on a case by case basis. Tumor growth varies and fluctuates with the individual, but a median doubling time is estimated at 4 months. Radiological surveillance to identify suspicious lesions and possible adjunctive therapies for hepatocellular carcinomas may be necessary to keep patients within acceptable criteria.

spontaneous bacterial peritonitis, fluid retention [ascites or peripheral edema] or psychosocial issues).

The key focus areas identified were as follows:

- Hepatitis B virus
 - Vaccination—surface antibody–negative patients
 - Antiviral management—surface antigen–positive patients
- Hepatocellular carcinoma and vascular patency
- Portal hypertension
- Portopulmonary hypertension
- Hepatopulmonary syndrome
- Hepatorenal syndrome type II and preexisting renal disease

The rationale for the inclusion of each focus area is that they have been identified in the literature as areas that may adversely affect patients' outcomes.^{1,3} Examples of subordinate documentation for the implementation of treatment within key focus areas are illustrated in Figures 2 through 5. The intervals for clinical interventions required to address these focus areas are identified on the Pre–Liver Transplant Schedule for Implementing Clinical Practice Guidelines (Figure 6).

Discussion

Through this review, we identified unit practices that had to be changed to comply with identified best practice. Changes (in the form of CPGs) were made after current evidence was investigated and documentation was developed within the multidisciplinary team. These CPGs will be implemented and administered by medical and nurse specialists managing the QLTS patients before liver transplantation.

The benefits of implementing the CPGs will be evaluated in the future. With multiple variables influencing clinical outcomes, the hard end points of transplantation, death and removal from the list due to clinical deterioration, are not the measurements of choice for evaluating outcomes from applying the guidelines. The evaluation process will initially be used to assess current levels of compliance with best practice guidelines. Reevaluation will be done 3 years after the CPGs are applied to determine if practice has improved and how much the intervention has cost. In addition, the evaluation should include review of guidelines to identify changes in recommended practice. These guidelines have been accepted and implemented within the gastroenterology and hepatology department

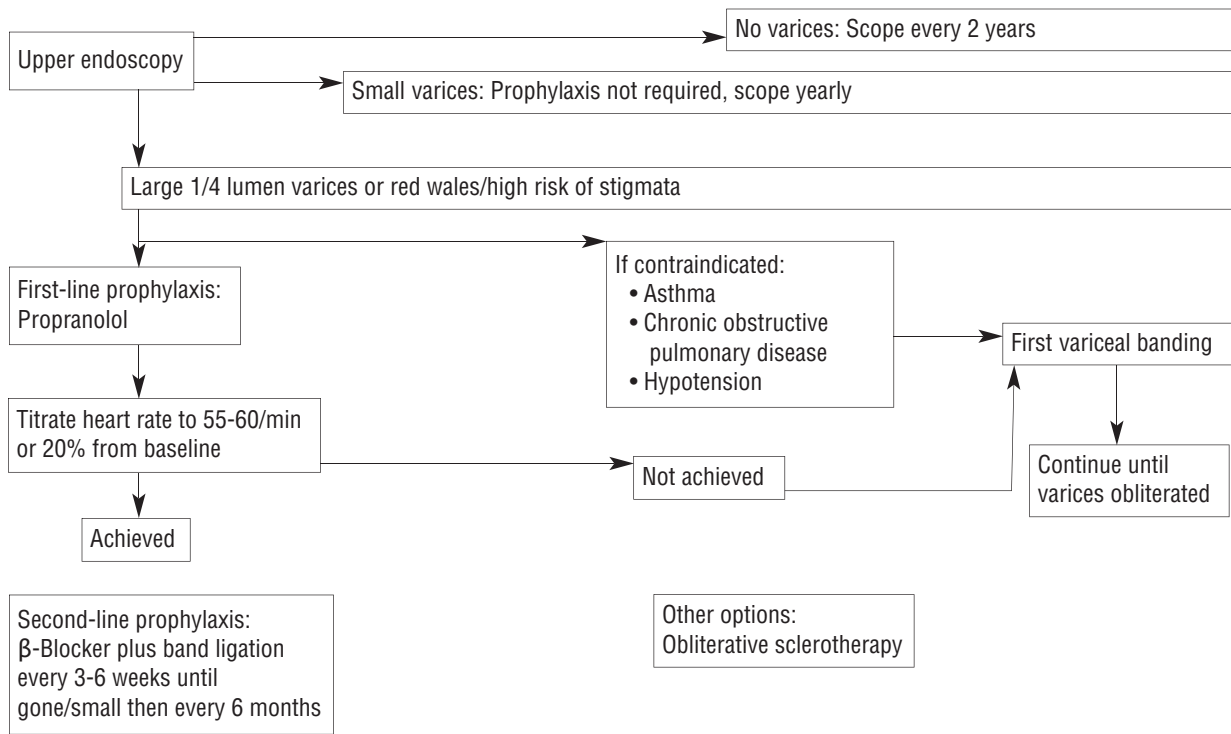


Figure 3 Clinical guideline for first-line prophylaxis of portal hypertension.³ Varices are a common and life-threatening complication in cirrhosis, found in 66% to 85% of patients evaluated for liver transplant, and of these 16% to 46% had bleeding from large varices. β -Blockers are recommended as primary prophylaxis because they reduce portal venous and collateral blood flow. β -Blockers reduce initial bleeding episode by 40% to 50%. The advocated treatment of choice for controlling variceal bleeding is endoscopic variceal ligation rather than sclerotherapy.

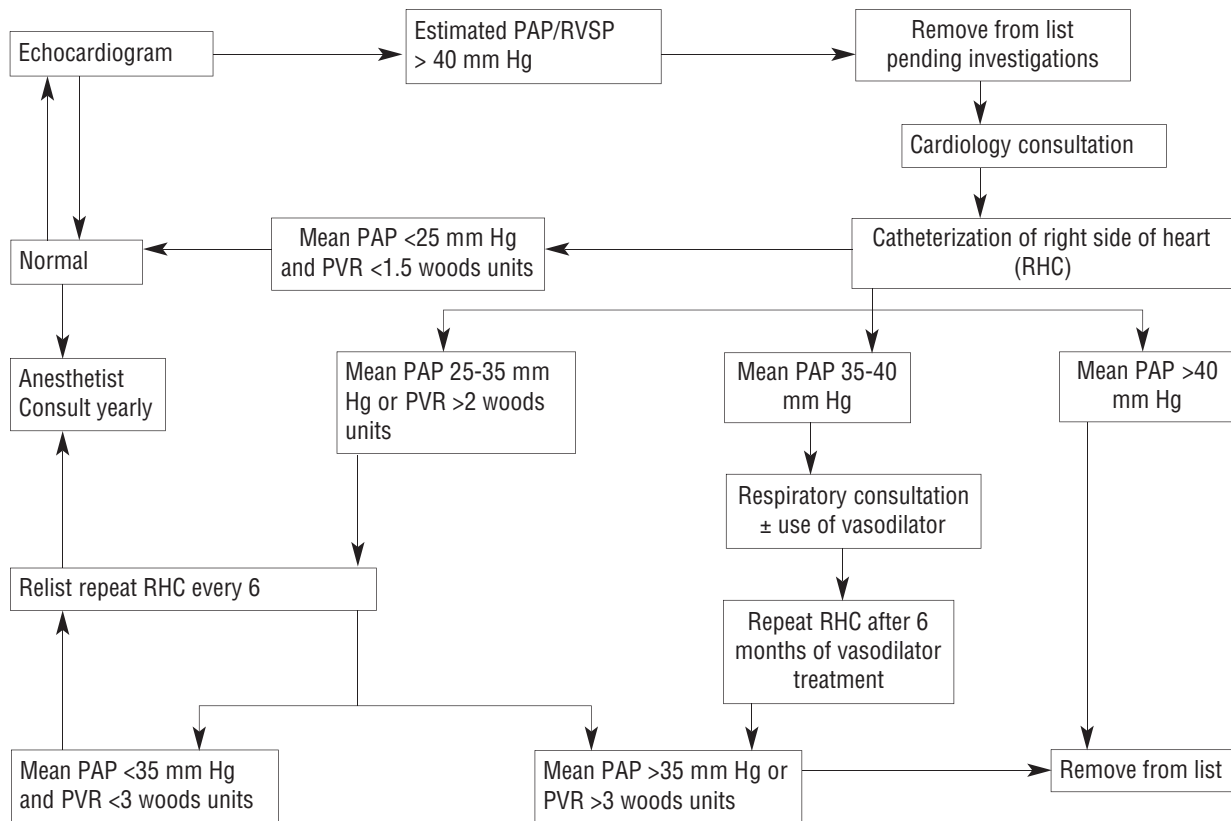


Figure 4 Clinical guideline for portopulmonary hypertension (PPHTN).^{1,3,16} Detection of PPHTN before liver transplantation is extremely important because the presence of PPHTN of any severity increases the perioperative and long-term risks of liver transplantation. The most common symptom is progressive dyspnea, but some patients remain asymptomatic. Echocardiography is the best screening method. Catheterization of the right side of the heart is required to fully describe pulmonary hemodynamics. PPHTN is manifested by an increased pulmonary artery pressure (PAP)/right ventricular systolic pressure (RVSP) (40 mm Hg cutoff) and increased pulmonary vascular resistance (PVR).

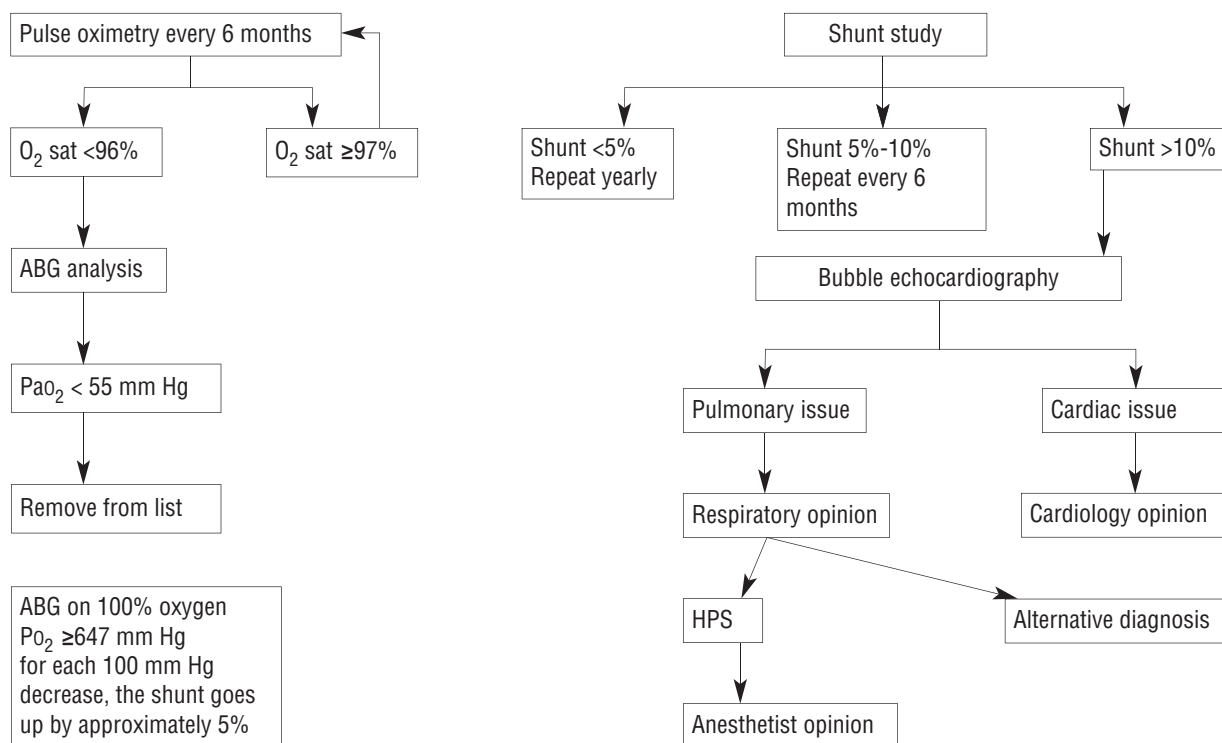


Figure 5 Clinical guideline for hepatopulmonary syndrome (HPS).^{3,17,18} Stringent selection of patients with HPS is essential with a mortality rate of up to 30% after liver transplant, yet liver transplant is still the treatment of choice. HPS is defined as chronic liver disease with hypoxemia ($PaO_2 < 70$ mm Hg) and intrapulmonary arteriovenous dilatation or shunts. The reported incidence of HPS is from 4% to 32% for those with chronic liver disease. Arterial blood gas (ABG) analysis is recommended every 6 to 12 months. A recent study suggests pulse oximetry is effective in detecting arterial hypoxemia and in addition patients with an oxygen saturation (O_2 sat) less than 97% would require the more invasive ABG (in approximately 32% of patients). Normalization of hypoxia is expected within about 15 months after transplant.

at the Princess Alexandra Hospital, and appropriate timing of clinical interventions is being exercised.

Acknowledgment

The author would like to thank Dr Graeme Macdonald, Dr Jonathon Fawcett, and Ms Glenda Balderson for their assistance in reviewing the manuscript and providing advice about document content and presentation.

Author's Note

To limit the size of this article, guidelines for hepatitis B virus—vaccination and antiviral management—and hepatorenal syndrome type 11 have not been included. These clinical practice guidelines may be accessed by contacting the author at maree_jarrett@health.qld.gov.au.

Financial Disclosures

None reported.

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Pre - Liver Transplant

Schedule for Implementing Clinical Practice Guidelines

Evaluation / /

Assessment Committee / /

Test	Frequency				Months											
	Yearly	6 monthly	3 monthly	1 monthly	January	February	March	April	May	June	July	August	September	October	November	December
Alpha - Fetoprotein	Cirrhosis															
	HBV & HCV															
	HCC															
HCC	U/S Abdomen-visible															
	MRI-not visible on U/S															
	CT chest															
	Bone scan															
Ca screening	Mammogram > 40															
	Pap smear															
	PSA															
	Skin															
Cardiac	Echocardiography / DSE	*														
	ECG	*														
Dentist																
Diabetic	HbA1c															
	Endocrine review															
Dietician	Vit A, D, E - on therapy															
	Vit A, D, E															
HBV Pos	HBsAg, aHBcAb, aHBsAb,															
	AHBeAb, HBeAg, HBV-DNA															
Endoscopy																
PSC	Ca 19.9															
	CEA															
	Colonoscopy															
Radiology	Chest	*														
	U/S Abdomen-PV & Liver		*													
Renal	Urinalysis															
	Spot urine prot/creat ratio		*													
	Fasting Ch/Tg/LDL/HDL	*														
	Fasting homocystine	*														
Respiratory	Pulse oximetry >97%															
	Sa O ₂ <97%															
	Shunt studies															
	RFT															
Anaesthetic review																

* If indicated do more frequently

Figure 6 Schedule for implementing clinical practice guidelines before liver transplant.

Abbreviations: aHBcAb, anti-hepatitis B core antibody; aHBeAb, anti-hepatitis B e antibody; aHBsAb, anti-hepatitis B surface antibody; Ca, cancer; CEA, carcinoembryonic antigen; Ch/Tg/LDL/HDL, cholesterol/triglycerides/low-density lipoprotein/high-density lipoprotein; CT, computed tomography; DSE, dobutamine stress echocardiography; ECG, electrocardiography; HbA1c, glycosylated hemoglobin; HBeAg, hepatitis B e antigen; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; HCC, hepatocellular carcinoma; HCV, hepatitis C virus; MRI, magnetic resonance imaging; Pos, positive; prot/creat, protein/creatinine; PSA, prostatic-specific antigen; PSC, primary sclerosing cholangitis; PV, portal vein; RFT, respiratory function test; Sa O₂, oxygen saturation; U/S, ultrasound; Vit, vitamin.

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CE Test Test ID 4000-J57: Use of clinical practice guidelines to promote best practice when managing clinical interventions for liver transplant candidates. **Learning objectives:** 1. Describe the factors that contributed to the need for development of clinical practice guidelines for care of liver transplant candidates 2. Identify the key focus areas for optimizing medical management before liver transplant 3. Discuss the principles for establishing effective clinical practice guidelines and evaluate their utilization in this particular project

1. Which of the following is associated with poor outcomes in liver transplant patients?

- a. Male sex
- b. Middle age
- c. Inborn metabolism errors
- d. Malnutrition

2. What was the major purpose of the project discussed in this article?

- a. Development of evidence-based criteria for selection of optimal candidates for liver transplantation
- b. Development of clinical practice guidelines for outpatient medical management of potential liver transplant recipients
- c. Extensive review of publications related to the management of advanced liver disease in potential transplant recipients
- d. Reduction in the number of patients requiring liver transplant as a treatment for end-stage liver disease

3. What is the approximate mortality rate for patients on the waiting lists of most liver transplant programs?

- a. 10%
- b. 20%
- c. 25%
- d. 35%

4. Which patients were excluded from the implementation of the outpatient management guidelines identified in this study?

- a. Those with hepatocellular carcinoma
- b. Those with hepatorenal syndrome
- c. Those with acute liver failure
- d. Those who were late referrals to a liver transplantation program

5. The scope of this project included which of these acute medical management issues?

- a. Portal hypertension
- b. Bacterial peritonitis
- c. Fluid retention (ascites and peripheral edema)
- d. Psychosocial issues

6. How many years after implementation will the clinical practice guidelines established by this project be reevaluated?

- a. One year
- b. Two years
- c. Three years
- d. Four years

7. According to the author, which of the following occurred throughout the extensive literature review as an important part of the process?

- a. Identification of unit practices that had to be changed in order to comply with identified best practices
- b. Dissemination of scientific knowledge about best care practices to all persons with a stake in the liver transplantation process
- c. Public education related to the shortage of organs available for transplant
- d. Reevaluation of the criteria used in selecting appropriate liver transplant candidates

8. Who acted as the facilitator for this project's development?

- a. The director of infection management services
- b. The deputy director of the Queensland Liver Transplant Service
- c. The director of gastroenterology and hepatology
- d. The liver transplant recipient coordinator

9. Reevaluation of the clinical practice guidelines established as part of this project will include determination of which of the following?

- a. Medical and nurse specialists' perception of the level of ease or difficulty of guideline implementation
- b. Extent of interdisciplinary acceptance and use of the guidelines
- c. Flexibility and adaptability of the guidelines for systematic application to clinical practice
- d. Cost of application of the intervention(s) into practice

10. Which of the following best describes clinical practice guidelines?

- a. Scientific knowledge that is applied to clinical practice
- b. Clinically effective and evidence-based management and/or work flow tools that improve clinical outcomes for patients
- c. Adaptable and flexible principles that allow for consistent application of patient care methods across a wide variety of situations
- d. Multidisciplinary collaboration tools for use of numerous specialty areas to optimize patient care

11. For this project, how were areas in which medical management could be optimized through the implementation of clinical practice guidelines identified?

- a. Through a national survey of independent clinicians involved in some aspect of liver transplantation
- b. Through collaboration with the Appraisal of Guidelines, Research and Evaluation (AGREE) network
- c. Through a review of related literature
- d. Through recommendations of the National Health and Medical Research Council (NHMRC)

12. Split liver grafts and live liver donations are strategies to optimize which of the following?

- a. Use of a scarce resource
- b. Chances of survival beyond 1 year for liver transplant recipients
- c. Patient survival while awaiting liver transplant
- d. Clinical management of patients with cirrhosis

Test answers: Mark only one box for your answer to each question. You may photocopy this form.

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| Objective 2 was met | <input type="checkbox"/> | <input type="checkbox"/> |
| Objective 3 was met | <input type="checkbox"/> | <input type="checkbox"/> |
| Content was relevant to my nursing practice | <input type="checkbox"/> | <input type="checkbox"/> |
| My expectations were met | <input type="checkbox"/> | <input type="checkbox"/> |
| This method of CE is effective for this content | <input type="checkbox"/> | <input type="checkbox"/> |
| The level of difficulty of this test was: | | |
| <input type="checkbox"/> easy <input type="checkbox"/> medium <input type="checkbox"/> difficult | | |
| To complete this program, it took me _____ hours/minutes. | | |

Name _____

Address _____

City _____ State _____ ZIP _____

Social Security No. _____ P hone () _____

If applicable: State(s) of licensure _____

License number(s) _____

ABTC certification number _____

CPTC, expiration _____

CCTC, expiration _____

I would like to receive my certificate via e-mail.

E-mail address: _____