Paper L

University Hospitals of Leicester NHS
NHS Trust

To:	**Trust Board**
From:	Andrew Seddon
Date:	**1st March 2012**
CQC regulation:	N/A

Title:	Charitable Funds Applications

Author/Responsible Director: Director of Finance and Procurement.

Purpose of the Report:
To seek formal approval for a charitable funds application.

The Report is provided to the Board for:

Decision	✓	Discussion	
Assurance		Endorsement	

Summary / Key Points:
Summary of the application and an appendix including the case of need.

Application APP3751 is for £79,950 for a Fibroscan machine, used for the treatment of liver fibrosis using an ultrasound technique. We have confirmed with the Division that a price has been agreed with commissioners for the Fibroscan service.

Recommendations:
The Board is asked to formally approve charitable application APP3751.

Previously considered at another corporate UHL Committee?
This application has been supported in principle by the Charitable Funds Committee which requested confirmation of the agreement of a local price for the Fibroscan service prior to the application being presented to the Trust Board.

Strategic Risk Register N/A	**Performance KPIs year to date** N/A

Resource Implications (eg Financial, HR)
Charity

Assurance Implications
None

Patient and Public Involvement (PPI) Implications
None

Equality Impact
No issues

Information exempt from Disclosure
None

Requirement for further review ?
No

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

REPORT TO: **TRUST BOARD**

DATE: **1st MARCH 2012**

REPORT FROM: **ANDREW SEDDON – DIRECTOR OF FINANCE AND PROCUREMENT**

SUBJECT: **CHARITABLE FUNDS APPLICATION**

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1. Introduction

1.1 This paper seeks formal approval for a charitable funds application which is above the £25k delegated approval limit of the Charitable Funds Committee (the Committee).

1.2 This application was supported in principle by the Committee at its meeting on the 4th November. The Committee asked for further information relating to this application to be presented to the Trust Board.

2. Application

2.1 Application APP3751 is for £79,950 for a Fibroscan machine, used for the treatment of liver fibrosis using an ultrasound technique. We have confirmed with the Division that a price has been agreed with commissioners for the Fibroscan service. This resolves the query raised by the Committee.

3. Recommendation

The Board is asked to:

3.1 Approve application APP3751.

Andrew Seddon
Director of Finance and Procurement

1st March 2012

APPENDIX 1

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

REPORT TO: **CHARITABLE FUNDS COMMITTEE**

DATE: **21st October 2011**

REPORT FROM: **Shirley A Clarke – Acting Medicine CBU Manager**

SUBJECT: SUPPORTING INFORMATION FOR GRANT APPLICATION: 3751

APPLICATION DETAILS

Amount:	£79,950.00 (exc. VAT)
Fund:	P802 General Purposes
Funds available?	Yes
Panel approval received?	Yes – Professor Evans

Executive Summary

- Fibroscan is a non-invasive, painless way of quantifying liver fibrosis using ultrasound technique.
- Fibroscan is more beneficial to patients because
  - it is safe, painless, quick & effective,
  - it has minimal / no clinical risk in comparison with traditional liver biopsy,
  - it may engage vulnerable sections of society in healthcare,
  - it would reduce overall 18-Week Referral to Treatment Target (RTT) waiting time and number of separate attendances per patient.
- Fibroscan costs £79,950.00 for the total package (year 1 capital outlay exc. VAT), with additional yearly revenue costs from year two onward of £4,565.00. exc. VAT
- Fibroscan will save
  - on liver biopsy avoidance,
  - on ultrasound scan avoidance,
  - On follow up appointment avoidance.
  - reduction in Radiologist / nursing time,
  - reduction in Pathologist / technician time,
  - Elective Inpatient to Daycase activity transfer & reduced length of stay (LoS),
  - Reduced 'Did Not Attend' (DNA) rates & increased Outpatient efficiency.
- Fibroscan may also be used to generate private patient income.
- Published evidence exists from The NHS Purchasing and Supply Agency that proves the cost effectiveness of Fibroscan against traditional liver biopsy and biological markers.

- Risks exist in not purchasing a Fibroscan:
    - opportunity missed to improve the patient experience,
    - opportunity missed to reduce health community cost,
    - implications of potential litigation comparing Fibroscan with liver biopsy,
    - difficulty in maintaining 18-week RTT compliance,
    - Loss of UHL / Leicester, Leicestershire & Rutland (LLR) market share.

1. Introduction

The Hepatology service within UHL requests the Trust Charitable Funds Committee considers investment in a Fibroscan on the basis of the case of need presented below. The case of need outlines the background to the requirement for a Fibroscan and presents the benefits to patients of developing a Fibroscan service. The financial benefits of developing a Fibroscan service are stated along with the reasons why funding through Trust capital / revenue budgets is not appropriate. The risks inherent in not investing are presented, with a concluding summary recommendation.

2. Background

Within Hepatology, the liver biopsy has been used for many decades as a tool to aid in diagnosing liver diseases. With the advent of new blood tests and new technologies however, fewer and fewer liver biopsies are being performed. As well as using liver biopsy to help in diagnosis, it is used to assess the stage of a particular chronic disease i.e. the degree of scarring, fibrosis or cirrhosis that the patient suffers. A particular patient with chronic liver disease may therefore undergo a number of liver biopsies over their lifetime and each of these liver biopsies is not without risk of morbidity (up to 30%) or mortality (0.33%) (BSG Liver Biopsy Guidelines 2004).

Not unreasonably a number of patients often refuse to have liver biopsies because they are worried about the potential morbidity / mortality and these patients therefore probably receive sub-optimal care. Recently there have been significant developments in non-invasive markers of liver fibrosis. The Fibroscan is a non-invasive, painless way of quantifying hepatic fibrosis. A mechanical pulse is generated at the skin surface, which is propagated through the liver. The velocity of the wave is measured using an ultrasound technique and the velocity of this wave is correlated with the degree of liver stiffness which in turn reflects the degree of liver fibrosis, the stiffer the liver the greater the degree of fibrosis. As a result of its non-invasive nature, there is no restriction on the frequency of its use and therefore Fibroscan can be used safely to monitor the progression of an individual's liver disease, or even the regression of that liver disease in response to therapy.

It is estimated that 4% of the UK population have abnormal Liver Function Tests (LFTs) and with the ever-growing problem with alcohol and obesity this figure is undoubtedly going to rise (c.f. United States of America 10%). It would be foolhardy to believe the capability exists to biopsy all of these patients to assess their degree of liver fibrosis, however the Fibroscan would enable us to non-invasively and quickly measure whether a patient has fibrosis in the outpatient department. This would improve decision making in terms of deciding whether certain patients required follow up by UHL or their GP. In addition we will get more information on the natural history of liver diseases by monitoring the progress of people's fibrosis in clinic and because of its lack of

associated mortality it would certainly be more acceptable for patients, allowing us to tailor treatment to the individual patient's needs.

3. Development of a Fibroscan Service - Patient Benefits

- Fibroscan is safe and painless for patients, quick to perform (10 mins) and effective in distinguishing normal liver / minimal fibrosis (score F0/F1) from cirrhotic livers (F4). It is a portable machine that can be used in a number of clinics (Hepatology / Gastroenterology and the Hepatitis Clinic in Infectious Disease) or the Hepatology inpatient ward / Infectious Disease Unit and therefore transportable to suit the needs of the patient. It is easy to use, enabling Nurse Practitioners / Hepatitis Specialist Nurses and clinicians to be trained in its operation.

- Unlike with a needle biopsy of the liver, no anaesthetic is needed with FibroScan and the patient can be discharged immediately. For this reason Fibroscan is much more acceptable to the patient than a percutaneous liver biopsy. In addition there are well publicised risks with liver biopsy and from a clinical governance perspective, if a Fibroscan result can give the same information as is being sought by a liver biopsy, then it would be difficult to justify doing the biopsy if there were a major complication. This has led to dilemmas in managing patients and the Hepatologists have been contacted and had conversations with patients on more than one occasion about why this technology is not available locally.

- In addition patients with viral hepatitis and cirrhosis often come from the vulnerable sections of the community (black/ethnic minority, ex-intravenous drug users, patients with mental health issues, alcohol misuse etc). These patients often do not like attending hospital and some of them fall out of the clinics because they do not want to undergo a liver biopsy, subsequently failing to attend for their appointments. The ability to perform a fibroscan on these vulnerable patients would mean avoidance of a liver biopsy and their continued engagement with the service and their diagnosis / treatment. In addition a FibroScan and would facilitate the development of one-stop hepatology and hepatitis clinics for this vulnerable group, thereby minimising and streamlining need for their interaction with the hospital.

- Use of a FibroScan would greatly benefit the 18-week RTT and sustained achievement of this in the Infectious Disease specialty. The Infectious Disease specialty is particularly susceptible to failure against the Non-Admitted RTT target of 95%, given relatively low number of clock stops per month and the difficulties in accommodating diagnosis and treatment of patients from prisons (Sept 09: 94.9%, Nov 09: 94.6%, Dec 09: 94.6%). Hepatitis pathway redesign has already been undertaken to minimise the waiting time associated with diagnosis at the beginning of the pathway, the use of a Fibroscan would vastly reduce the overall journey time by reducing the need for component waiting times for liver biopsy and ultrasound scan (estimated 2-3 weeks). Fibroscan would also enable further moves toward a one-stop hepatitis clinic service, where diagnostic results, discussion regarding treatment and counselling can all be delivered at the same time. Patients would benefit from a reduction in overall journey time and reduced number of attendances along their pathway.

As with many diagnostic tests, it should be recognised that Fibroscan has its limitations:

- Patients who are very obese and who have very inflamed livers cannot be scanned by use of the standard 'M' probe alone (refer to Section 4a below).

- Fibroscan is less good at accurately distinguishing between middle grades of fibrosis. The technology would be mainly used to distinguish patients whose fibrosis lies at either end of the spectrum e.g. cirrhotic patients will get different management in terms of drug treatments and follow up arrangements etc from those who don't and patients with no fibrosis can be confidently discharged back to primary care.

4. **Development of a Fibroscan Service - Financial Benefits**

a. Cost

The capital equipment cost for a Fibroscan is £79,950.00 excluding VAT based on the standard 'M' series probe covering patients with a BMI <30, and including the XL probe for patients with a BMI >30.

This case of need requests funding for the total package of £79,950.00 exc. VAT. We are advised that if the equipment is funded through the Charity that exemption from VAT would apply.

The Fibroscan system is covered by an initial 12-month warranty which includes the necessary probe calibrations at 6 months and 12 months. A second year service contract providing one annual preventive maintenance visit, recommended software updates, any call outs, parts, labour, travel, accommodation and two probe calibrations is available for £4.500 exc. VAT. Neither the warranty or service contract covers accidental or malicious damage to any part of the system, in particular the probe(s). The service contract costs are available for the first five years of the Fibroscan's life, after which it is likely they may increase. Echosens (the supplier) will provide a PPQ indicating that service support should be maintained for a minimum of seven years from the date of last manufacture, beyond that it will depend upon continued availability of parts.

The only consumables used with the Fibroscan are a small amount of ultrasound gel and T-Spray cleaning agent (circa £65 per box of twelve bottles which is likely to be a 12-month supply), plus tissues for removal of the gel at the end of the examination.

b. Financial Benefit

The financial benefits of using a Fibroscan to the health economy are many and as follows:

- Fibroscan saves cost on liver biopsy avoidance, ultrasound scan avoidance and hepatitis clinic follow-up appointment avoidance. As a consequence of using Fibroscan to assess fibrosis in liver disease patients, we would anticipate a reduction of 60 liver biopsies required per annum.

- In the Hepatitis Clinic all new patients undergo an Ultrasound Scan (USS) to identify patients with advanced fibrosis and cirrhosis who need special monitoring during treatment. By using a Fibroscan these new patients would no longer require a routine USS of their liver. Further, the use of a Fibroscan would support delivery of a one-stop Hepatitis outpatient clinic service and reduce follow-up outpatient visits. Utilisation of a Fibroscan would change the patient pathway from one of 'referral-opd-test-opd-treatment' to one of 'referral-one stop opd-treatment'.

- In addition there is a cohort of hepatitis B patients whose liver disease is currently not severe enough to require anti-viral treatment. These patients are kept under regular review and can expect to have more than one liver biopsy (3 to 5 yearly biopsies), generating further cost reduction. The European Association for the Study of Liver has further produced 'Clinical Practice Guidelines: Management of Chronic Hepatitis B' (Journal of Hepatology 50 (2009): 227-242) identifying when patients should be considered for hepatitis treatment. These guidelines indicate the suitability of non-invasive markers (Fibroscan) for identifying moderate to severe necroinflammation and/or fibrosis using a standard scoring system as a pre-cursor to consideration of treatment.

- As all liver biopsies from the medical unit are performed by a Consultant Radiologist under ultrasound guidance, a reduction in the number of biopsies needed would free up Consultant Radiologist time and space on an ultrasound list. There would be further nursing and admin reductions in time / cost associated with this reduction in service delivery. Fibroscan is easy to use which will enable Nurse Practitioners / Hepatitis Specialist Nurses to be trained in its use at no additional cost.

- There would also be an associated reduction in the number of liver biopsies being processed through the pathology labs, thereby reducing Consultant Pathologist & Technician time / cost.

- Reduction in requirement for liver biopsies and therefore daycase unit beds will enable the Medicine CBU to pursue its aim during 2012/13 to transfer the overwhelming majority of its remaining elective inpatient work to daycase, thereby reducing the cost to the health economy. Moreover, this transfer from elective inpatient to daycase will have further benefits in terms of reduced length of stay on the inpatient wards, supporting the Directorate's bed reduction programme in contribution to its Cost Improvement Programme (CIP) delivery.

- It is known that liver biopsy pre-assessment appointments and the diagnostic test itself has an above average DNA rate reflecting the risks associated with the procedure and the client group. Reduction in the need for liver biopsy would reduce the DNA rate, increasing outpatient clinic and Daycase unit efficiency.

- There may be a financial opportunity to bring income into UHL by marketing the use of the Fibroscan to the private sector, this not currently a service being provided by Nuffield or Spire. In addition, the Odames daycase management team are currently looking in to the possibilities of developing and marketing a 'health and wellbeing' fitness assessment incorporating basic diagnostic tests, in direct competition with private providers; Fibroscan will form part of this range of tests. It is anticipated that patients will be interested in the assessment of the degree of fibrosis in their liver, relative to the increasing incidence of alcoholic liver disease in society.

- There is a further argument to suggest Fibroscan could be used to screen all existing patients with liver disease to identify significant fibrosis at an earlier stage before it presents with complications, the aim to try to instigate treatment / health interventions earlier to avoid expensive admissions from complications (some patients with cirrhosis have absolutely normal blood tests). This would be a preventative strategy saving the health economy money in the longer term but not recognised as a quick win. There is also opportunity to screen all elderly diabetics as a proportion of these will have undiagnosed advanced liver disease.

- In addition to all of the above, evidence exists and is developing that proves the cost effectiveness of Fibroscan against traditional liver biopsy and biological markers, recognising

that this is a relatively new diagnostic test. The NHS Purchasing and Supply Agency: Centre for Evidence-Based Purchasing have published 'Evidence Review: Ultrasound Elastography' (Dec 2008) and 'Economic Report: Cost-Effectiveness of Ultrasound Elastography' (Jan 2009) in support of the technique used by a Fibroscan. Summary of these reviews is as follows:

- For a cohort of 1000 patients, Ultrasound Elastography (Fibroscan) correctly diagnosed more patients with significant fibrosis than Fibrotest (a blood test looking at a panel of biological markers), though at a greater total cost. However, for the Cirrhosis (stage F4 only) group of patients, Ultrasound Elastography correctly diagnoses more fibroses and is less costly than Fibrotest.

- For a cohort of 1000 patients, traditional liver biopsy correctly diagnoses more patients with fibrosis than Ultrasound Elastography, though at a greater total cost. For patients with significant fibrosis (stage F2 to F4) the cost per extra Correctly Diagnosed Fibrosis gained with Liver Biopsy is £2627 compared with Ultrasound Elastography. However, for the Cirrhosis (stage F4 only) group of patients, this figure is much higher as the cost per extra CDF is £33,839.

- Summary conclusions from the NHS P&SA are that as Ultrasound Elastography is more sensitive than Fibrotest it has the potential to correctly identify more cases of fibrosis than Fibrotest at a small additional cost. For patients with Cirrhosis, Ultrasound Elastography has the potential to correctly identify more cases and to save money.

- The cost of liver biopsy is much greater than for Ultrasound Elastography. The extra cost per correctly diagnosed fibrosis of using biopsy as compared with Ultrasound Elastography is especially high in the sub-group of patients with stage F4 fibrosis i.e. Cirrhosis.

- The evidence supports the use of Ultrasound Elastography in assessing fibrosis, alone or in conjunction with other tests. The performance of Ultrasound Elastography in the assessment of Cirrhosis is generally reported to be excellent, although not as good for less severe fibrosis. The performance of Ultrasound Elastography against other non-invasive tests for liver fibrosis appears to be quite acceptable. Ultrasound Elastography is likely to prove cost-effective as a first stage screening tool for patients with poor liver function and as a tool for follow-up assessment. There is also strong evidence that some patients can benefit from Ultrasound Elastography e.g. patients with bleeding disorders for whom a liver biopsy carries an additional risk of complication.

5. Why Funding through the Trust Revenue / Capital Budgets is not appropriate

A capital equipment case of need for a Fibroscan has been submitted to the UHL Medical Equipment Panel (MEP) both in 2008 and 2009. During the 2009 bidding round, the Medicine and ED Directorate submitted circa 30 bids, of which the Fibroscan bid was ranked 8th in priority order and 'essential'. The prioritisation panel awarded the Fibroscan a 'B' and declined to fund the equipment, requesting specific data on the effectiveness of the equipment against which it can be evaluated e.g. number of relevant liver biopsies currently completed, numbers predicted without a Fibroscan and reduction in numbers with one. The expectation was that any funding award would be based on audit against these numbers in the future, with information available to the MEP at the time of bidding rounds to inform decision making. It is felt that the above case of need addresses these data requirements. Endorsement has subsequently been received from Professor

D Evans (04/12/2009) that this equipment would be worth considering as a possible item for charitable funding.

Funding of a Fibroscan via revenue budgets is simply not possible, given the cost of a Fibroscan relative to the size of the revenue budget. This would create a massive cost pressure in year at a time when significant cost savings are required.

6. Risks in Not Developing a Fibroscan Service

There are inherent risks in not developing a Fibroscan service within UHL, as follows:

- Not investing in Fibroscan would mean an opportunity is missed to increase the quality of the patient experience (with regard to reduction in referral to treatment time, multiple visits to the OPD and the discomfort / potential complications associated with a liver biopsy).

- Not investing in Fibroscan would mean an opportunity is missed to significantly reduce cost across the health community.

- If a single patient who has a liver biopsy for staging of fibrosis dies or has a significant complication as a consequence of a liver biopsy, then this would be difficult to defend in the knowledge of an available alternative test with minimal / no risk.

- Not investing in Fibroscan would mean that it would be difficult to reduce the 18-week Referral to Treatment Target for a significant cohort of patients, jeopardising on-going target delivery.

- Failure to invest in Fibroscan would result in a potential loss of market share for UHL / LLR, as neighbouring providers in Coventry, Nottingham (Queens Medical Centre) and Birmingham (The Queen Elizabeth Hospital) have all invested in Fibroscan. It is further important for UHL's reputation that it remains at the forefront of service development and technological advance.

7. Summary

In conclusion, the Hepatology service within UHL requests the Trust Charitable Funds Committee considers investment in a Fibroscan on the basis of the case of need presented. A Fibroscan has significant benefits for patients in terms of reducing clinical risk and enhancing the overall experience. The financial cost of a Fibroscan is more than offset by the level of savings to the LLR health economy, savings that will be delivered immediately in year one. Published evidence further exists to support the cost effectiveness of Fibroscan. Purchasing a Fibroscan now and developing the service would mitigate against the inherent risks of continuing with the existing diagnostic model of care for hepatology patients.

Shirley A Clarke – Acting Medicine CBU Manager
Dr A Grant, Consultant Hepatologist
Acute Care Division – Medicine CBU
UHL NHS Trust
October 2011