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Horizon Scanning Technology Prioritising Summary

LifePort® kidney transporter: Portable donor kidney transporter/ perfuser

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Enquiries about the content of the report should be directed to:

HealthPACT Secretariat
Department of Health and Ageing
MDP 106
GPO Box 9848
Canberra ACT 2606
AUSTRALIA

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This Horizon scanning prioritising summary was prepared by Linda Mundy and Professor Janet Hiller from the National Horizon Scanning Unit, Adelaide Health Technology Assessment, Discipline of Public Health, School of Population Health and Clinical Practice, Mail Drop DX 650 545, University of Adelaide, Adelaide, SA, 5005.

PRIORITISING SUMMARY (UPDATE 2009)

REGISTER ID:	**000091**
NAME OF TECHNOLOGY:	**LIFEPORT® KIDNEY TRANSPORTER**
PURPOSE AND TARGET GROUP:	**PORTABLE DONOR KIDNEY TRANSPORTER/ PERFUSER**

NOVEMBER 2009 BACKGROUND

Non-heart beating organ donors (NHBD) are classified according to the Maastricht categories: Category I: dead on arrival

Category II: unsuccessful resuscitation

Category III: awaiting cardiac death

Category IV: cardiac death in a brain dead donor (Doig & Rocker 2003).

Studies describing the success or failure of kidney transplantation will report on the number of human leukocyte antigen (HLA) mismatches between donor and recipient, and the recipient's plasma creatinine levels pre- and post-transplantation. Human leukocyte antigens are cell surface antigens that mediate graft versus host reactions which may result in the rejection of transplanted organs. It is important to minimise the number of HLA mismatches to ensure transplantation success. Creatinine is a breakdown product from muscle which is primarily filtered out of the blood by the kidneys and therefore measuring creatinine levels is an important measure of kidney function. Males tend to have higher levels of creatinine than females due to their higher muscle mass[1].Normal serum creatinine levels are: Male: 60 – 120 μmol/L and female: 40 – 90 μmol/L[2].

NOVEMBER 2009 SAFETY AND EFFECTIVENESS ISSUES

The largest study reported to date is a European multi-centre randomised controlled trial where each pair of kidneys from one donor were divided by the type of preservation with one kidney preserved using conventional cold storage whilst the other was preserved using the LifePort® machine perfusion device (level III-1 intervention evidence) (Moers et al 2009). Donors (n=336) were Maastricht category III or IV with a median age of 51 years (range 16-81). Ninety-four of the donors were expanded criteria donors[3]. There were no significant differences between the characteristics of the recipients in the cold storage or the LifePort® group (Table 1).

[1] http://en.wikipedia.org/wiki/Main_Page
[2] Pathology Service of St Vincent's Hospital, Sydney
[3] Expanded criteria donors: Normally these donors would not meet the criteria for transplantation donors. The extended criteria include kidneys from donors who are either over 60 years, or are over 50 years with at least 2 of the following features: (1) a history of hypertension; (2) death from a cerebral vascular accident; and (3) terminal creatinine levels greater than 133 μmol/L (1.5 mg/ dL). In general,

Table 1 Recipient and transplant characteristics

	Cold storage (n=336)	LifePort® (n=336)	p-value
Recipient			
Median age, yrs (range)	52 (2-79)	53 (11-79)	0.21
Median duration of pre-transplantation dialysis (yr)	4.4 (0.19-24)	4.5 (.015-18)	0.59
Previous transplant	21%	23%	0.38
Transplant			
No HLA mismatches	15%	16%	0.90
Median cold ischemic time (hr)	15.0 (2.5-29.7)	15.0 (3.5-29.7)	0.30

Early post-transplantation outcomes are summarised in Table 2.

Table 2 Comparison of early post-transplantation outcomes: LifePort® vs cold storage

	Control cold storage (n=336)	LifePort® machine perfusion (n=336)	p value
Primary end-point			
Delayed graft function	26.5%	20.8%	0.05
Secondary end-points			
Functional DGF	30.1%	22.9%	0.03
Primary non-function	4.8%	2.1%	0.08
Median duration of DGF (range)	13 (1-41) days	10 (1-48) days	0.04
Median creatinine clearance at day 14	40 (0-175) ml/min	42 (0-171) ml/min	NS
Acute rejection within 14 days	13.7%	13.1%	NS
Median hospital stay	18 (6-382) days	19 (4-392) days	NS

NS = not significant

At one year post-transplantation, patient survival was 97 per cent in both groups. One-year graft survival was significantly higher in the LifePort® group compared to the cold storage group (94% vs 90%, p=0.04). Logistic regression analysis showed that machine perfusion significantly reduced the odds of delayed graft function (odds ration 0.57, 95% CI [0.36, 0.88], p=0.01). In addition, one-year graft survival was significantly higher in the machine perfusion group with a significant reduction of graft failure (hazard ratio 0.52, 95% CI [0.29, 0.93], *p*=0.03).

An earlier 2007 study by Moustafellos et al, which was not reported in the 2008 summary, transplanted 36 kidneys from class III or IV NHBD over a 3-year period at

kidneys from expanded criteria donors have a lower chance of long-term success and a higher incidence of DGF than those from brain stem dead (BSD) donors (Bond et al 2009).

the Oxford Transplant Unit in the United Kingdom. The first 18 transplantations were performed using conventional cold static perfusion (Group B) and the remaining transplantations were performed using kidneys preserved with the LifePort® machine perfusion device (Group A) (level IV intervention evidence). Both kidneys from one donor were preserved with the same technique. The retrieval technique and organ preparation was identical in all cases with a thrombolytic pre-flush with Ringer's solution containing streptokinase followed by standard perseveration perfusion containing 5,000 IU of heparin/L. The composition of both recipient groups did vary slightly but the differences were not statistically significant. Group A recipients (n=18) consisted of 13 males and five females with an average age of 36.3 years (range 20-66 years). The average number of HLA mismatches for each transplanted kidney was 2.4. Group B recipients (n=18) consisted of 10 males and 8 females with an average age of 54.5 years (range 36-69 years). The average number of HLA mismatches for each transplanted kidney was 2.1.

No grafts were lost in the post-operative period (not stated) and no rejection episodes occurred in either group. Group A recorded one death on the fifth post-operative day due to infection of a working graft. Patient outcomes are summarised in (Table 3). These outcomes are similar to those reported in the 2008 summary and longer-term follow-up is required to ascertain whether improved short-term outcomes translate to long-term patient benefits and graft survival.

Table 3 Comparison of early post-transplantation outcomes: LifePort® vs cold storage

	Control cold storage (n=18)	LifePort® machine perfusion (n=18)	p value
Immediate renal function	2 (11.2%)	13 (72.2%)	
Delayed graft function	16 (88.8%)	5 (28.8%)	0.0002
Mean creatinine at discharge	503.1 μmol/L	385.6 μmol/L	NS
Mean hospital stay	14.1 days	8.1 days	0.001

NS = not significant

A later 2008 study was conducted in the same transplant unit and therefore this study may include transplantations already reported by Moustafellos et al (Plata-Munoz et al 2008). Kidneys were obtained from 30 cardiac dead (Maastrich category III) donors, all aged less than 65 years who had no renal disease, diabetes, systemic sepsis or malignancy. As in the Moustafellos study, kidneys from one donor were not randomised to be preserved using both techniques, rather transplantations were sequential – cold storage transplantations took place first, followed by transplantations using the newer LifePort® technique (level IV intervention evidence). Both kidneys were prepared in the same way as described above. Donor and recipient characteristics are described in Table 4.

The LifePort® device significantly reduced the incidence of delayed graft function from 87 to 53 per cent (p<0.000), which was reflected in a significant reduction in the average length of hospital stay from 14 to 10 days (p<0.033) (Table 5). Improvements were also noted in graft function in the LifePort® group compared to conventional cold storage, indicated by a statistically significant decrease in creatinine levels at both seven and 30 days (p<0.000 and p=0.031, respectively). However, these improvements were not reflected in a statistically significant improvement in graft or patient survival in the LifePort® group compared to the cold storage group.

Table 4 Donor and recipient characteristics

	Cold storage (n=30)	LifePort® (n=30)	p-value
Donor			
Mean age, yrs (range)	40.3 ± 2.6 (17-60)	41.6 ± 2.9 (17-61)	NS
Female: Male	12:18	13:17	NS
Creatinine clearance (μmol/L)	103 (range 69-120)	95 (range 65-106)	NS
Recipient			
Mean age, yrs (range)	54.1 ± 2 (34-76)	47.2 ± ? (20-69)	<0.006
Female: Male	11:19	10:20	NS
Mean waiting list time, days (range)	410 (176-683)	493 (291 -1220)	NS
First transplant	29 (97%)	25 (84%)	NS
Number of HLA mismatches			
0	1 (3%)	1 (3%)	NS
1-2	4 (12%)	4 (12%)	NS
3-4	15 (50%)	18 (60%)	NS
5-6	0 (0%)	1 (3%)	NS
Implantation time (min)	40 (32-60)	55 (43-63)	<0.003

NS = not significant, ? = missing value not reported by authors

Table 5 Comparison of post-transplantation outcomes: LifePort® vs cold storage

	Control cold storage (n=30)	LifePort® machine perfusion (n=30)	p value
Post-operative outcomes			
Delayed graft function	25 (86.6%)	16 (53.3%)	<0.000
Mean creatinine 7 days	461 ± 33 μmol/L	259 ± 27 μmol/L	<0.000
Mean creatinine 30 days	282 ± 33 μmol/L	199 ± 20 μmol/L	0.031
Mean hospital stay	14 (9-22) days	10 (6-12) days	<0.033
Clinical follow-up	1021 (840-1180) days	420 (367-516) days	<0.000
Acute rejection	1 (3.5%)	3 (10%)	NS
1 yr graft survival	28 (93%)	30 (100%)	NS
2 yr graft survival	27 (87%)	29 (93%)	NS
1 yr patient survival	28 (93%)	30 (100%)	NS
2 yr patient survival	27 (87%)	29 (93%)	NS

A 2009 study by Kwiatkowski et al reported on the use of the RM3 Renal Preservation System (Waters Medical Systems Inc), which is similar to the LifePort® system with the important exception that it is *non-portable* and could not be used to transport organs between institutions, states or countries. The RM3 gained FDA approval in 2004. Kidneys were obtained from 37, predominantly male (66%) donors with a mean age of 36 years (range 5-70 years). All of the donors were classified as brain dead donors (BSD) and 24 donors were expanded criteria donors. The mean donor serum creatinine level was 124 ± 250 μmol/L (range 44-601 μmol/L). Seventy-four kidneys were obtained and prepared for transplantation according to standard protocol. Paired kidneys from the same donor were randomised, with one preserved using conventional cold storage and the other using the RM3 preservation system (level III-3 intervention evidence).

Although a higher proportion of patients in the cold storage group experienced delayed graft function (50% vs 32.4%, p value not given), this initial difference did not result in improved graft or patient survival (Table 6). However, fewer patients in the RM3 machine perfusion group experienced a return to haemodialysis at 10-year follow-up when compared to patients in the cold storage group.

Table 6 Comparison of post-transplantation outcomes: RM3 vs cold storage

	Control cold storage (n=37)	RM3 machine perfusion (n=37)	p value
Mean recipient age	40 ± 15 years	37 ± 12 years	NS
Post-operative outcomes			
Delayed graft function	17/34 (50%)	11/34 (32.4%)	
Number of patients with creatinine levels <177μmol/L at 5-years	15/37 (40.5%)	20/37 (54.0%)	NS
Graft survival	16/37 (43%)	23/37 (68.2%)	0.08
Patient survival	31/37 (83.7%)	32/37 (86.5%)	NS
Return to dialysis at 10-year follow-up	18/37 (48.6%)	9/37 (24%)	0.02

NS = not significant

A 2009 case series reported on the use of the LifePort® device for the preservation of donor kidneys from 27 non-beating heart donors (level IV intervention evidence) (Fieux et al 2009). Although kidneys were obtained from 54 donors only 31 were transplanted. Follow-up was available in 24 of these 31 transplantations. This study did not compare preservation methods but was interested in the feasibility of obtaining organs successfully from NHBD. Unlike previous studies reporting on the use of the LifePort® device, delayed graft function occurred in the majority of cases (92%) for a mean duration of 22 ± 9 days. Three patients experienced acute graft loss. For the remaining 21 patients, the mean creatinine level at 6-months was 152 ± 65 μmol/L. Despite organ donation refusal or donor ineligibility accounting for 52 per cent of organs not able to be used (63/122), using NHBD donors resulted in a 10 per cent increase in the kidney transplantation rate over a 17-month period.

In 2009, Bond et al published a systematic review on the effectiveness and cost-effectiveness of using either cold storage or machine perfusion for the storage and preservation of kidneys from deceased donors. This systematic review compared different solutions used for conventional cold storage, published and unpublished studies which compared cold storage to machine perfusion as well as two studies which compared the two machine perfusion methods. The two studies which compared the LifePort® transporter with the RM3 system were retrospective and results were only presented as abstracts and posters, and not published in the peer reviewed literature. The studies were not randomised. Outcomes including delayed graft function, graft function, patient survival, graft survival and length of hospitalisation all favoured the RM3 system over the LifePort® device.

NOVEMBER 2009 COST IMPACT

Markov modelling was used to simulate post-transplantation outcomes using data obtained from the two randomised controlled trials that were included in the systematic review by Bond et al (2009) which compared cold storage to preservation with the LifePort® device. The donor populations used in the two (ongoing) studies (European MPT trial used mainly BSD with some DCD donors and the UK pulsatile perfusion trial used all DCD donors) differed and therefore both populations were modelled separately When using data generated from the European study, machine preservation was found to be cheaper and generated more quality-adjusted life-years (QALYs) than cold storage. However, when the model was populated with data from the UK trial, cold storage was cheaper and generated more QALYs than machine preservation. This difference may be accounted for in the difference in reported patient outcomes. The UK study (unpublished) reported most patient outcomes with statistically significant differences between trial arms, whereas the European study only found that graft survival was better at 12 months post-transplant with machine perfusion (LifePort® = 98% vs cold storage = 94%, $p < 0.03$).

After conducting sensitivity analyses, the authors concluded that:

- Changes to the differential kidney storage costs between comparators have a very low impact on the overall net benefit estimates when set against the large cost, survival and QALY impacts of small differences in graft survival between comparators.

- Where differences in effectiveness exist between comparators, dialysis costs become an important factor in determining the overall net benefit level.

- Levels of DGF between comparators only become important when differences in graft survival are apparent between those patients experiencing immediate graft function (IGF) versus DGF, and are also used to predict long-term graft survival.

- The relative impact of differential changes to graft survival for patients experiencing immediate graft function as opposed to DGF depends on the relative proportion of patients experiencing each of these two outcomes (IGF versus DGF). For example, if very few patients in the model experience DGF, then graft survival changes for DGF patients have a small impact on the overall net benefit output.

NOVEMBER 2009 HEALTHPACT ACTION:

Machine perfusion for the preservation of kidneys for transplantation may not have statistically significant improved outcomes such as increased graft or patient survival when compared to conventional cold storage. However, improved graft function may

lead to better patient quality of life and result in overall savings for the health system. More research is required to ascertain the most successful source of donor organs and to report on the long-term effects of the different methods of preservation. The LifePort® device does offer portability which increases opportunities for organ exchange between states within Australia and between countries, such as Australia and New Zealand. The studies reported thus far have been a high level of evidence and it is unlikely that a higher level of evidence will be forthcoming in the near future. Jurisdictions are able to purchase this technology and will make purchasing decisions based on their needs. Therefore it is recommended that this summary be disseminated to specialists within the jurisdictions and that no further research is warranted.

NOVEMBER 2009 NUMBER OF INCLUDED STUDIES

Level IV intervention evidence	3
Level III-3 intervention evidence	1
Level III-1 intervention evidence	1

NOVEMBER 2009 REFERENCES:

Bond, M., Pitt, M. et al (2009). 'The effectiveness and cost-effectiveness of methods of storing donated kidneys from deceased donors: a systematic review and economic model', *Health Technol Assess,* 13 (38), iii-iv, xi-xiv, 1-156.

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PRIORITISING SUMMARY (2008)

REGISTER ID: **000091**

NAME OF TECHNOLOGY: **LIFEPORT® KIDNEY TRANSPORTER**

PURPOSE AND TARGET GROUP: **PORTABLE DONOR KIDNEY TRANSPORTER/ PERFUSER**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

☐	Yet to emerge	☐	Established
☐	Experimental	☐	Established *but* changed indication or modification of technique
☒	Investigational	☐	Should be taken out of use
☐	Nearly established		

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☐	Yes	ARTG number
☒	No	
☐	Not applicable	

The LifePort® device was given US Food and Drug Administration approval in 2003 and received the European CE mark in 2004 (Dove 2007).

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Russia	✓		
Netherlands	✓		

IMPACT SUMMARY:

Organ Recovery Systems markets the LifePort® kidney transporter with the aim of providing machine perfusion to ensure the viability of kidneys which need to be transported from one location to another. This technology would be made available through specialist transplant hospitals for patients who require kidney transplantation.

2008 BACKGROUND

Kidney transplantation is both cost-effective and an ideal treatment option for patients with end-stage renal failure. However the number of patients on the transplant waiting list outweighs the number of organs available. A number of ways of increasing the donor pool available have been examined including the use of non-beating heart donors and increasing the use of related, or unrelated donors. The deprivation of

oxygen and nutrients caused by ischaemia may lead to permanent damage, therefore preservation of kidney viability between retrieval and implantation is important. Tp preserve function two strategies have been used: cold storage (CS) and machine perfusion (MP). Damage is reduced during CS by slowing the metabolic rate. The kidney is flushed through with a perfusion or preservation fluid and then kept on ice. MP uses a machine to pump a cold perfusion solution through the kidney, and provides oxygen and nutrients, allowing the kidney to continue metabolism. During the 1970s, the majority of kidneys made available for transplantation would have undergone MP, however several studies found that there was no clear clinical benefit gained from the use of the more expensive and labour intensive MP and CS became the system of choice in kidney transplantation during the 1980s. However, MP may result in a reduced rate of delayed graft function (the delay in normal renal function post-transplantation). Although delayed graft function is observed in 23-33 per cent of kidneys transplanted from beating heart donors, it is more common following transplantation from non-beating heart donors. Delayed graft function is associated with poorer long term outcomes and requires short-term dialysis (Wight et al 2003).

The LifePort® device is a portable machine perfusion unit that is designed to contain and perfuse a transplantable kidney under cold and asceptic conditions (Figure 1). Although relatively compact (dimensions 61x37x36cm) the unit weighs 20.4 kg and would therefore require two people to transport it. The unit can be used for up to 24 hours before battery replacement and ice replenishment is required. The LifePort® device may have the potential to increase the number of organs able to be transplanted by increasing the viability of transported kidneys (Organ Recovery Systems 2003).

Figure 1 The LifePort® kidney transporter (Medgadget 2005)

2008 Clinical Need and Burden of Disease

The waiting list for kidney transplantation has slightly decreased from 1,488 in 2003 to 1,388 in 2007. This corresponds to a slight increase in the number of kidney transplantations performed, up from 325 in 2003 to 342 in 2007. However, in New

Zealand the number of patients awaiting kidney transplantation has increased markedly from 370 in 2003 to 559 in 2007. The number of kidney transplantation procedures performed has remained almost static with 67 in 2003 and 65 in 2007. In Australia during 2007 there were 198 kidney donors with 349 kidneys transplanted. In New Zealand during the same period there were 38 kidney donors with 65 kidneys transplanted. A number of organs are sent and retrieved between Australian States and New Zealand each year (Table 7), indicating the need for ideal transportation conditions of organs. Although no kidneys were transplanted in Australia from New Zealand donors during 2006-2007, since 1989 a total of 21 kidneys have been exchanged and transplanted. Patient and graft survival rates are shown in Figure 2 (ANZOD 2008).

Table 7 Exchange of kidneys between Sates and New Zealand 2007, 2006 (ANZOD 2008)

	NZ	Q'land	NSW	ACT	Vic	Tas	SA	NT	WA
Sent	0, 0	9, 19	12, 20	2, 6	7, 17	2, 14	6, 11	6, 4	7, 11
Received	0, 0	8, 9	19, 35		7, 29		11, 22		6, 7

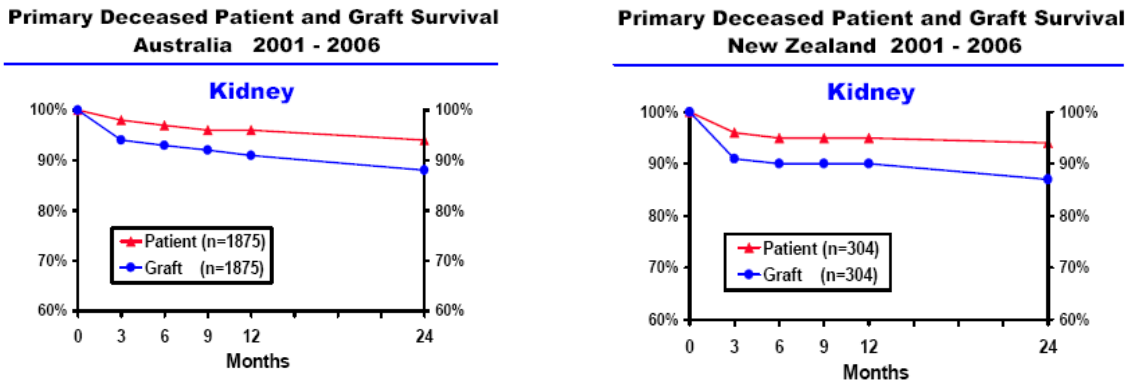

Figure 2 Patient and graft survival rates for Australia and New Zealand (ANZOD 2008)

2008 DIFFUSION

There is no evidence that the LifePort® machine perfusion device is in use in Australia.

2008 COMPARATORS

Cold storage or conventional machine perfusion would be used to maintain and preserve viability between retrieval and transplantation of the donated kidney (Wight et al 2003).

2008 SAFETY AND EFFECTIVENESS ISSUES

A recent study conducted by the same author attempted to transplant 44 kidneys from 22 non-beating heart donors. Each pair of kidneys from one donor were divided by the type of preservation with one kidney preserved using conventional cold storage whilst

the other was preserved using the LifePort® machine perfusion device (level III-1 intervention evidence). The characteristics of the recipients are summarised in Table 8.

Table 8 Recipient characteristics

	Control cold storage (n=17)	LifePort® machine perfusion (n=21)
Male	7	10
Female	10	11
Age (years)	37.9 ± 10.2	45.2 ± 9.5
Waiting list time (years)	4.2 ± 3.7	5.2 ± 3.3
Haemodialysis	11	16
Peritoneal dialysis	6	5
Glomerulonephritis	12	16
Pyelonephritis	4	4
Other diseases	1	2

Five kidneys that were to be transplanted into the cold storage group were deemed to be non-viable and discarded as was one kidney in the LifePort® group. Viability was assessed during biopsy and degenerative changes observed resulted in the kidneys being discarded. Early clinical outcomes are summarised in Table 9 (time not stated explicitly however follow-up creatinine levels were measured at 90 days).

Table 9 Comparison of early post-transplant outcomes

	Control cold storage (n=17)	LifePort® machine perfusion (n=21)	p value
Immediate function	3 (18%)	10 (48%)	<0.001
Delayed graft function	14 (82%)	11 (52%)	<0.001
Haemodialysis/ 30 days	4.9 ± 3.6	2.3 ± 2.6	<0.05
Creatinine day 1	820.7 ± 112.0	700.9 ± 227.3	<0.1
Creatinine day 21	376.9 ± 106.0	213.0 ± 137.3	<0.001
Creatinine day 90	177.0 ± 26.8	139.7 ± 32.0	<0.001
Hospital stay (days)	43.8 ± 10.2	29.3 ± 8.3	<0.0001
Acute rejection	4	1	
Primary non-function transplant	3	0	
Surgical complications	3	1	

There were significant differences between cold storage and the LifePort® machine perfusion patients in all reported outcome categories. Thirty per cent more kidneys in

the machine perfusion group experienced immediate function (p<0.001) and there was a significant reduction in the number of kidneys with delayed graft function (p<0.001). There were no non-functioning transplants in the LifePort® group compared to three in the cold storage group (Reznik et al 2008).

An earlier small scale study was reported by the same author. A total of 14 kidneys from seven non-beating heart donors were transplanted into 14 recipients. One kidney from each donor was preserved using conventional cold storage whilst the other was preserved using the LifePort® machine perfusion device (level III-1 intervention evidence). The average warm ischaemia time (time between declaration of death to time cold perfusion began) was 25.5 ± 13 minutes. The average cold perfusion time was the same in both groups at 18 ± 6 hours. Unfortunately the results of this initial study were omitted in the published paper. The evaluators contacted the author who is yet to respond (Reznik et al 2006).

COST IMPACT

Organ Recovery Systems quote the current price of the LifePort® Kidney Transporter, Continuous Flow and the Pulsatile Flow as US$20,160 and €14,400, equating to approximately A$25,000. The LifePort® device requires the use of several disposable, one use only, consumables which may be purchase separately or as a pack. The Perfusion Pack consists of LifePort Perfusion Circuit (closed system with in-line filter and pressure sensor), SealRing™ 7x20 cannula, and sterile drape and costs US$620 or €440 (Organ Recovery Systems 2003).

No economic studies evaluating the use of the LifePort® device were identified, however if the LifePort® was capable of maximising the number of viable kidneys able to be transported and transplanted, this may have a potential economic impact considering factors including survival of patients on waiting lists and the ongoing need for dialysis. In addition, the LifePort® device may increase the donor pool by salvaging previously rejected kidneys from deceased donors, which may have an economic impact (Dove 2007).

A systematic review conducted in the United Kingdom examined the clinical and cost-effectiveness of MP compared to CS as a means of preserving kidneys to be transplanted and donated from beating and non-beating heart donors. It has been suggested that MP may reduce delayed graft function and increase the size of the donor pool by extending the criteria for donor recruitment. A reduction in delayed graft function would be considered a cost saving. The meta-analysis suggests that the use of MP compared to CS is associated with a relative risk of delayed graft function of 0.804 (95%CI [0.672, 0.961]). There was no evidence indicating that this effect would be different in kidneys obtained from either beating or non-beating heart donors. One year graft survival data showed no significant effect, however the included studies were underpowered. The published economic evidence was considered to be poor and it was considered unlikely in the UK that complete cost

recovery from the use of MP would be gained from a reduction in delayed graft function. However, a baseline analysis indicated that in the long-term MP would be expected to be cheaper and more effective than CS for both beating and non-beating heart donors (Wight et al 2003).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

There is an ethical imperative to increase the number of potential organs available for donation to patients on the transplantation waiting list.

OTHER ISSUES

A large multi-centre European study with 338 participants was due to conclude in 2007. When the results of this study are due to be published is unknown despite contacting the primary investigator and Organ Recovery Systems. A large multi-centre European study investigating the efficacy and cost-effectiveness of machine versus static (CS) preservation in 600 patients was due to be finalised in November 2006. No results have been reported. Two other studies are currently underway. A randomised controlled trial in the United Kingdom began in August 2006 and is looking at outcomes from non-beating heart donor kidneys. The remaining study which also commenced in August 2006 in Brazil, expects to run for 24 months and recruit 148 patients (Organ Recovery Systems 2003).

SUMMARY OF FINDINGS

The LifePort® appears to be effective in increasing the donor pool for kidney transplantation to enable the use of beating and non-beating heart donors. Only one small scale study was assessed, comparing the use of two different preservation methods on kidneys received from the same donor. Significant differences in viability were observed when the LifePort® was used compared to conventional cold storage. The portability of the LifePort® may result in a larger number of transplants being achieved between states and New Zealand.

HEALTHPACT ACTION:

Based on the good quality, albeit small evidence base and the obvious benefits to the patient of receiving a viable, functioning kidney transplant, and the possibility of increasing the number of organs exchanged between countries and states, HealthPACT recommended that this technology be monitored.

NUMBER OF INCLUDED STUDIES

Total number of studies	
Level III-1 intervention evidence	2

REFERENCES:

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SEARCH CRITERIA TO BE USED:

Graft Survival/*physiology
*Kidney
Kidney Transplantation/*physiology
Organ Preservation/*methods
Perfusion/*methods
*Tissue Donors
Kidney Transplantation/*instrumentation
Reperfusion Injury/*prevention & control
Tissue Donors