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EVALUATION OF DIRECTIONAL VACUUM-ASSISTED BREAST BIOPSY: REPORT FOR THE NATIONAL BREAST CANCER CENTRE

Final report

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Policy support is provided at all levels of the health care system by undertaking commissioned projects, through the provision of formal and informal advice as well as participation in working parties and committees.

FOREWORD

This project was commissioned by the National Breast Cancer Centre (NBCC). The objectives of the project, as set out in the call for expressions of interest, were to determine:

> The costs associated with the introduction and use of directional vacuum-assisted breast biopsy (DVA breast biopsy) in Australia; and
> Whether directional vacuum-assisted breast biopsy used for diagnostic purposes is cost-effective in Australia when compared to core biopsy.

The motivation for commissioning the project was an assessment of directional vacuum-assisted breast biopsy conducted by the Medical Services Advisory Committee (MSAC) which concluded that the procedure is safe and more effective than core biopsy. Although a cost-effectiveness analysis was not conducted as part of the MSAC study, MSAC recommended that the costs associated with the procedure be investigated and that, pending a review of costs, the procedure receive interim Medicare funding at a higher level than was previously available.

For the project reported here, data was required to be collected from both public and private sectors on the cost of introducing and using DVA breast biopsy and a cost-effectiveness analysis (CEA) conducted on the introduction and use of DVA breast biopsy with and without a prone table. The research question for the CEA was

> What is the impact on costs and number of open biopsies performed of using DVA breast biopsy compared to core biopsy for micro-calcification lesions?

It is important to note that this question specifies both the outcome the CEA (change in the number of core biopsies performed) and that the investigation was to be confined to micro-calcification lesions only.

An expert multidisciplinary working group was assembled to oversee the project.

Following collection of data an interim report was produced for the working group. As DVABB is a relatively new technology in Australia the interim report indicated that the current number of sites performing DVABB and the level of experience of users was insufficient to provide meaningful data to achieve the project aims. On the advice of the working group it was agreed to suspend the project at this juncture. The NBCC will consider repeating the survey in the future.

1. INTRODUCTION

Directional vacuum assisted (DVA) breast biopsy is a relatively new technology used to aid in the diagnosis of suspicious breast lesions including microcalcifications, masses, speculated masses, asymmetric multifocal disease and diffuse tissue (Medicare Services Advisory Committee 1999). This technology is currently used in a number of BreastScreen centers and Private clinics across Australia.

The primary advantages of DVA breast biopsy over open biopsy are:

> less invasive procedure, leading to less pain and quicker recovery time for the patient; and
> decreased chance of breast disfigurement (ref??).

The primary advantages of DVA breast biopsy over core biopsy are:

> the 'vacuum chamber actively draws tissue into the collection chamber ... rather than relying on tissue recoil to fall on the collection chamber' (Vargas, Agbunag et al. 2000, p. 375)
> larger and better quality samples {Vargas, 2000 #24}and {Wong, 2000 #23};
> the ability to obtain multiple specimens without having to remove and reinsert the needle (this is due to the directional capability of DVA technology) {Vargas, 2000 #24}and {Trevathan-Ramirez, 1998 #1}; and
> the potential to remove all microcalcifications (Trevathan-Ramirez 1998).

There is currently very little international evidence and no published Australian evidence on the cost-effectiveness of DVA breast biopsy technology. In an effort to fill this gap CHERE was commissioned by iSource – The National Breast Cancer Centre - to evaluate the cost-effectiveness of DVA breast biopsy technology in the diagnosis of microcalcifications. In this study, DVA and core breast biopsy technologies were compared in terms of both costs and effectiveness.

This report presents:

> results from an international literature review on the effectiveness and cost-effectiveness of DVA breast biopsy;
> information on the collection of data on DVA and core biopsy, including survey procedure and response rates;
> an investigation of the effectiveness data; and
> a discussion based on the available data.

2. INTERNATIONAL LITERATURE REVIEW OF DVA BREAST BIOPSY TECHNOLOGY

The aim of this literature review was to identify studies which had evaluated either the effectiveness or cost effectiveness of DVA breast biopsy technology. A search was conducted using the Medline and Embase databases. The search for articles on the 'effectiveness' of DVA breast biopsy technology was restricted to the years 1998-2002 while the search for articles on the 'cost effectiveness' of DVA breast biopsy technology was limited to the years 1995-2002. The literature review was also limited to studies which evaluated the effectiveness of DVA breast biopsy under stereotactic guidance. Studies which evaluated vacuum assisted breast biopsy under the guidance of ultrasound were excluded as it is known that the type of guidance used, particularly in the detection microcalcifications, impacts directly on the accuracy of tissue retrieval and hence, diagnostic accuracy (Vargas, Agbunag et al. 2000) and (Lattanzio, Guerrieri et al. 2001).

2.1 Main findings from the literature review of DVA breast biopsy

Eighteen studies were found to have evaluated the effectiveness of DVA breast biopsy techniques. Randomised control trials are generally recognised as 'the study type of choice when the objective is to evaluate the effectiveness of a treatment or procedure (Dawson and Trapp 2001, p.304) . No studies identified in this search were randomised control trials. The studies identified consisted of prospective observational studies and retrospective reviews. These types of studies provide weaker levels of evidence than a randomised control trial.

Furthermore, the results of all studies are not directly comparable because of different study design features including;

> 'effectiveness' was measured in a number of different ways, including successful sampling, accuracy of diagnosis, surgical procedure/s spared and re-biopsy rates;
> confirmation of diagnoses was not measured in the same way across all studies;
> the type of lesions biopsied differs between studies; and
> the length of follow up differed.

These factors should be kept in mind when reviewing the results presented in this section. Study characteristics including effectiveness measured employed, diagnosis confirmation method/s and follow up period (where applicable) have been summarised in Appendix A.

2.1.1 Effectiveness of the DVA breast biopsy systems

DVA breast biopsy techniques appear to be an effective breast biopsy technique in terms of tissue sampling, diagnostic accuracy and sparing surgical procedures (particularly when an 11 gauge needle is used) (see Table 1). A further advantage of DVA breast biopsy is the low complication rates associated with the procedure, particularly when the procedure is done in the prone position. However, there has been little replication of available studies. This may be due to the broad range of possible effectiveness measures available for us in this context as well as the diverse range of lesions which this procedure can be used to diagnose.

Table 1. Summary of 'effectiveness' estimates for DVA breast biopsy

EFFECTIVENESS MEASURE	RANGE OF VALUES OBTAINED FROM REVIEW
Successful sampling	All lesions (8, 11and/or 14) gauge: 96.4 -100% Calcification: 96.3 - 100%
Diagnostic accuracy	All lesions 11 and/or 14 gauge: 80 – 100% Benign lesions: 99% Non- benign lesions: 95% Calcifications 11 gauge: 98% Calcifications 14 gauge: 91%
Sensitivity	All lesions 11 gauge: 87.5% Breast carcinoma 8 and 11 gauge: 88 -98%
Diagnostic underestimation	Calcification: 16.3% Cancer: 9.5% Masses: 1.6% Ductal carcinoma in situ: 0 -18%
Surgical procedure spared	11 gauge: 76.6% 14 gauge: 35.3% 11 and 14 gauge: 46%
Complication rate	Approximately 1- 4% prone unit Approximately 5% upright unit

Velanovich et al (1999) directly compared the results of DVA breast biopsy with core needle biopsy, advanced breast biopsy instrumentation (ABBI) and wire localised biopsy for women with suspicious mammograms. The results of this study showed that DVA performed well when compared with other forms of breast biopsy (see Table 2). Although the performance of ABBI was found to be better than DVA and core biopsy, not all women will meet the criteria identified by the authors for use of ABBI, which includes:

> breast thickness greater than 30mm thick when compressed;
> lesion less than or equal to 1cm in diameter; and
> lesion must be greater than or equal to 1 cm from the chest wall and skin.

Patient criteria for core and DVA breast biopsy was identical and less stringent than patient criteria for ABBI. Therefore, core biopsy appears to be a more useful comparator than ABBI for DVA breast biopsy. When DVA breast biopsy was compared with core biopsy in this study, DVA was found to be the more effective option.

Table 2. Summary of effectiveness results for alternative breast biopsy techniques*

EFFECTIVENESS MEASURE	DVA	CORE BIOPSY	ABBI
	%	%	%
Technical success	96.4	94.3	98.7
Sensitivity	87.5	87.5	100
Specificity	100	98.6	100
Discordant result/need for rebiopsy	23.2	25.7	7.5

* Figures in this table have been taken from the study by Velanovich et al (1999)

2.1.2 Accuracy of 11 versus 14 gauge needle

DVA breast biopsy has typically been undertaken with either a 14 or 11 gauge needle. The specimen obtained through the use of an 11 gauge needle is much larger than that obtained with a 14 gauge needle, at approximately 95mg vs. 18mg respectively (Gray, Benson et al. 1999). Therefore, it can be hypothesized that, due to the larger size of sample collected, a breast biopsy undertaken with an 11 gauge needle should reduce the rate of sampling error and hence reduce the diagnostic error rate. Three studies were found to have compared the results of DVA breast biopsy undertaken with 11 gauge and 14 gauge needles. The results of these studies are presented in Table 3. (See Appendix 1 for a more detailed presentation of study features.) Based on the results from the limited number of studies available, the use of an 11 gauge needle appears to be more effective than a 14 gauge needle when effectiveness is defined in terms of successful sampling, diagnostic accuracy and surgical procedures avoided.

Table 3. Comparison of results from 11 and 14 gauge DVA breast biopsy studies

AUTHOR	'EFFECTIVENESS' RESULTS
Liberman, Gougoutas et al (2001)	% surgical procedure avoided 11 gauge: 76.6% % surgical procedure avoided 14 gauge: 35.5%
Berg, Arnoldus et al (2001)	Accuracy 11 gauge: 98% Accuracy 14 gauge: 91%
Nisbet et al (1999)	Successful sampling 11 gauge: 86% Successful sampling 14 gauge: 62%

2.1.3 Upright versus prone units

DVA breast biopsy techniques can be used with the patient in either an upright or prone position. The advantages of undertaking DVA breast biopsy in the prone position, as opposed to the upright position include:

- reduced incidence of vasovagal reactions (Georgian-Smith, D'Orsi et al. 2002);
- reduced likelihood of patient movement throughout the procedure; and
- quicker examination completion (Bassett, Winchester et al. 1997)

However, the upright unit is cheaper and requires less space than a dedicated prone biopsy table (Nisbet, Borthwick-Clarke et al. 2000).

Three studies were found to have evaluated the effectiveness of DVA breast biopsy when conducted with an upright unit (See Table 4). As a range of different needle gauges (8, 11 and 14 gauge) were used in these studies care must be taken when comparing results.

Table 4. Summary of DVA breast biopsy effectiveness with an upright unit

AUTHOR	DVA NEEDLE GAUGE	STUDY POPULATION	RESULTS
Georgian –Smith, D'Orsi et al (2001)	8 and 11 gauge	N= 180 biopsies in 174 patients N=156 (11 gauge) N= 24 (8 gauge)	- Successful sampling in 98% - Discordant results: 4% (4 cases benign at core biopsy were malignant at surgical pathology and 2 malignant cases were underestimated)
Ohsumi et al (2001)	11 and 14 gauge	N=88 lesions in 86 patients N= 85 (11 gauge) N= 3 (14 gauge)	- With surgical diagnosis: 80% accuracy (5 lesions underdiagnosed, 1 lesion 1 lesion overdiagnosed) - All benign lesions followed up without event.
Nisbet et al (1999)	11 and 14 gauge	N= 21 (14 gauge) N= 21 (11 gauge)	- Successful sampling 11 gauge: 86% - Successful sampling 14 gauge: 62%

Overall, successful sampling was estimated to have occurred in approximately 62-86% of cases (Georgian-Smith et al 2000 and Nisbet et al 1999). When results obtained with a 14 gauge needle are excluded the range is considerably smaller, with successful sampling estimated to have occurred in 86-98% of cases (Georgian-Smith et al 2000 and Nisbet et al 1999). Discordant results were estimated to occur in approximately 4-20% of cases. Georgian–Smith et al (2001) found that in their sample (N=180) 4 cases which were diagnosed as benign at the time of core biopsy were found to be malignant when surgical pathology was undertaken. Two malignant cases were also found to be underestimated (Georgian-Smith 2001). The types of lesion/s diagnosed in this study were not specified. Ohshumi et al (2001) found that within their sample (N=88) 5 lesions were under diagnosed and 1 lesion was over diagnosed.

The results of these studies, in terms of sampling success and diagnostic accuracy, appear to be similar to the results found for DVA breast biopsy when conducted on a prone table. However, at this stage, due to the limited number of studies available it is difficult to draw strong conclusions about the relative effectiveness of biopsies undertaken using an upright unit compared with those undertaken using a prone table.

2.1.4 Total vs. partial lesion removal

Only a handful of studies have sought to assess the relative effectiveness of partial lesion removal versus total lesion removal, and the evidence that does exist is conflicting. In studies conducted by Philpotts et al (2000) and Liberman, Smolkin et al (1998) it was found that diagnostic accuracy improved from 84% and 98% respectively when the lesion was only partially removed, to 100% with complete lesion removal. However, Liberman, Kaplan et al (2002) found that 'complete excision rather than sampling of the mammographic target yielded no significant differences in the frequency of sparing surgery, atypical ductal hyperplasia underestimates, rebiopsy or complications (p.679)'. These studies suggest that further investigation is warranted to determine whether there is a significant difference in 'effectiveness' between partial and complete lesion removal, and whether there are certain types or sizes of lesions where complete lesion removal may be recommended over partial lesion removal or vice versa.

2.1.5 Reasons for errors in DVA breast biopsy

Although sampling error rates for DVA breast biopsy technology are small they do exist. The primary reasons for errors in tissue retrieval were summarised by Heywang-Kobrunner et al 1998, (p381) and are outlined below:

> miscalculation of lesion depth due to identification of different structures on the ±15- stereotaxic views for error in the depth calculation due to slight accuracy in the stereotaxic planning on the ±15- view;
> deviation of the needle within dense tissue;
> patient movement;
> high elasticity of certain tissues which may be pushed forward instead of being penetrated by the needle; and
> acquisition of nonrepresentative tissue due to discontiguous growth of certain malignancies (ie. sampling error), for example in situ carcinomas and some lobular carcinomas.

Heywang-Kobrunner et al (1998) believe that to limit the number of errors the radiologist should 'undertake a critical review of all results of percutaneous biopsy together with imaging findings ie. whenever imaging findings were considered suspicious and disagreed with a benign histology or cytology, a repeat or open biopsy remained necessary (p.381).'

2.1.6 The role of experience in technical success

One study was identified which evaluated the impact of a radiologists experience on the technical success rate and false negative rate of stereotactic DVA breast biopsy. The study found that the technical success rate (using an 11 gauge needle) was significantly lower in the first five cases that were undertaken than subsequent cases and this finding was also true when the technical success of the first 15 cases was compared to subsequent cases (see table 5). For biopsies undertaken with both 11 and 14 gauge needles the learning curve was found to be steeper for microcalcifications than for mass lesions, but overall the authors concluded that the learning curve for stereotactic breast biopsy is relatively short. It should be noted that as academic radiologists who specialised in breast imaging participated in this study and hence, the generalisability of results to different settings may be limited.

Table 5. Learning curves for stereotactic breast biopsy

	FIRST 5 CASES VS. SUBSEQUENT CASES	FIRST 15 CASES VS. SUBSEQUENT CASES
11 gauge needle		
- Technical success rate	85% (17/20) vs 96.3%(310/322)	90% (54/60) vs 96.5% (273/283)
- False-negative rate	N/A	7.4% (2/27) vs. 0% (0/85)
14 gauge needle		
- Technical success rate	N/A	91.7% (55/60) vs. 97.9% (92/94)
- False negative rate	N/A	4.8% (1/21) vs. 0% (0/31)

2.2 Cost effectiveness of DVA breast biopsy techniques – literature review findings

In a true cost effectiveness study the relative costs of two interventions are weighed up against the relative effectiveness of the interventions. Based on this definition no true cost effectiveness studies evaluating DVA breast biopsy were identified in this literature search. At this stage there is no information on the cost effectiveness of DVA breast biopsy technology.

However, two studies were identified which included costings associated with DVA breast biopsy. The main features of these studies are outlined in Table 6 (see next page). In these studies DVA was found to result in savings of between $264 (A$360) - $334 (A$445) per diagnosis. However, a number of study limitations have been identified which should be kept in mind when reviewing these results. The main limitation of the study by Liberman and Sama (2000) was the retrospective nature of the study which makes it less likely to be able to capture all costs associated with the procedures evaluated. The study by Liberman, Gougatas et al (2001) was limited by the fact that the study groups was not randomised, data collection was not blinded and the costs included in this study were not well reported. At best, these studies provide us with some information on the relative costs associated with DVA and core biopsy.

Table 6. Main study features of DVA breast biopsy cost effectiveness evaluation

Author	Liberman and Sama (2000)	Liberman, Gougoutas et al. (2001)
DVA specifications	- 11 gauge - prone table	- 11 and 14 gauge - prone table
Comparator	Surgical biopsies	Surgical biopsies
Intervention type	Diagnosis	Diagnosis
Lesion type	Non-palpable lesions	Calcifications highly suggestive of malignancy
Effectiveness measure	Surgical biopsies obviated	Surgical procedures spared
Study population	N= 200 (154 with calcification lesions)	N= 17 (14 gauge) N= 47 (11 gauge)
Results	Surgical biopsies obviated: - Total : 76% (151/200) - Microcalcifications: 73% (112/154) Mean adjusted direct cost savings per diagnosis $264 (ie. a 20% decrease in the cost per diagnosis.)	Surgical procedure spared: - 11 gauge: 76.6% (36/47) - 14 gauge: 38.1% (16/42) Cost savings of $334 per diagnosis (ie. 20% decrease in the cost per diagnosis)

3. INVESTIGATION OF THE EFFECTIVENESS DATA

This section presents the results from data collection for this study. In this round of data collection we were primarily interested in collecting information on the effectiveness of DVA and core biopsy in the diagnosis of microcalcifications. Effectiveness in this study was defined as 'the number of open biopsies avoided'.

3.1 Data retrieval

3.1.1 Data retrieval: Survey 1

Twenty five centres known to have DVA technology available for breast biopsy were surveyed to obtain information on the effectiveness of both DVA and core biopsy. One additional centre was included in the sample after it had indicated that DVA breast biopsy technology was used in their centre (This centre was initially surveyed for information on core biopsy only). Of the 26 centres surveyed, 15 surveys were returned, 5 centres indicated they were unable to complete the survey (typically because they had not used the technology in the study period or had not used it for microcalcifications), 5 centres failed to return any calls and 1 centre has indicated that it will complete the survey but has not responded to a request for a date by which they will return the survey.

Of the 15 surveys that were returned 3 surveys could not be used in calculating effectiveness as the appropriate section was not complete. In the first survey, this section had not been attempted at all and as there were no details about which centre this survey belonged to it could not be followed up. In the second survey blank spaces were left in a number of boxes and it was unclear whether this represented non-completion or zeros. A follow-up phone call was made to this centre to clarify their results. It was found that this centre does not perform the 'initial' screening of women and the centre does not manage the treatment of women if a repeat biopsy is needed. Therefore, as the information contained in this survey was not consistent with the requirements of this study, data from this centre were excluded from the sample. In the third survey, the respondent indicated that the effectiveness section had been completed for all biopsies not just microcalcifications (as was specified in the question). An enquiry was made about whether this centre had data available for microcalcifications only, but to date there no response has been received. Therefore, overall 12 surveys were used to obtain information on the effectiveness of DVA biopsy (Centres 1-12).

3.1.2 Data retrieval: Survey 2

Six centres which did not have DVA technology but undertake core biopsies were also surveyed to provide additional information on the effectiveness of core biopsy. Responses were received from 5 of the 6 centres. One centre indicated that they were not able to complete the survey, leaving 4 additional surveys to use (Centres 13-16). Nine centres which had previously completed the survey for DVA biopsy also provided information on the effectiveness of core biopsy (Centres 2-8 and 11-12). Therefore, a total of 13 survey responses were obtained regarding the effectiveness of core biopsy.

3.2 Maximising response rates to surveys

Two surveys were sent out in the first round of data collection. Survey 1 was sent to 25 centres known to have DVA breast biopsy technology, to collect information on both DVA and core biopsy. Survey 2 was sent out to 6 centres which were believed to undertake core biopsy only, to collect additional information on core biopsy. Both surveys were accompanied by a letter from the National Breast Cancer Centre (NBCC) which briefly explained who was involved in the study and asked centres to participate. A letter from CHERE which briefly explained the project and CHERE's role in the project was also sent out with each survey.

To improve the response rate, reminder letters were sent to all centres which had not responded to either CHERE or the NBCC by the due date. After what was considered to be a reasonable period, follow up calls were made to centres which had still not responded or had indicated that they needed more time to complete the survey. Centres were once again given what was thought to be a reasonable period to respond, and following this, centres which had indicated that they would return their survey but had not done so and centres which had not returned calls were phoned again. The timing of calls varied, depending on how a centre had responded previously, whether the centre had indicated it needed more time and/or specified how much more time was needed.

It appears that the centres surveyed understood that the data requested was for microcalcifications only as;

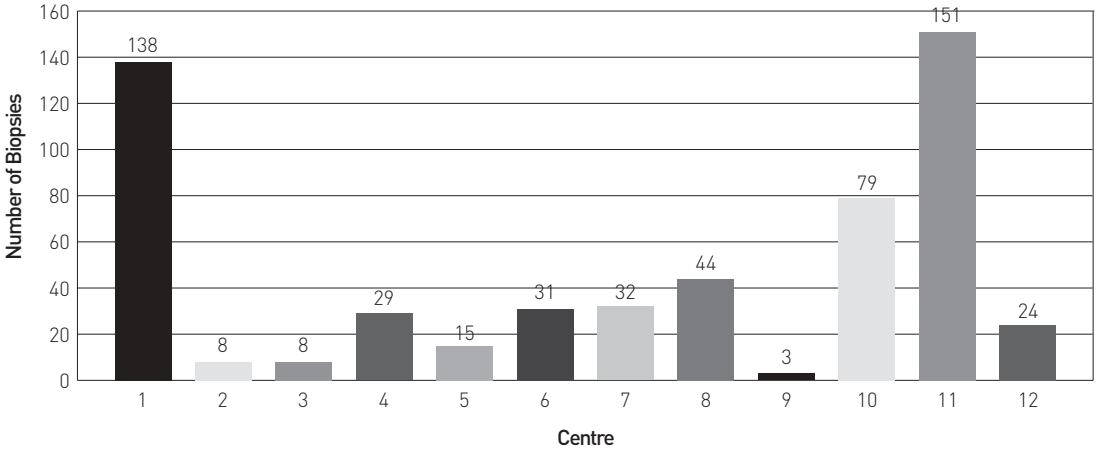
- the cover letter provided by CHERE indicated that the study was for the diagnosis of microcalcifications only;
- all effectiveness questions in the survey specifically referred to microcalcifications, with 'microcalcifications' or 'microcalcifications only' typed in bold to highlight this; and perhaps most importantly
- individuals from a number of centres who contacted us indicated that it would be difficult and/or more time consuming to retrieve the information on microcalcifications only (hence their request for more time). This indicates that it was clear to centres that microcalcifications were the lesion of interest.

3.3 Sample characteristics of the biopsy data

The data were examined to investigate the representativeness and reliability of the sample. It should be noted that not all centres that performed DVA breast biopsy also performed core biopsy, and vice versa. Therefore, to identify which procedures individual centres undertook, each centre was assigned a number (from 1-17) and these numbers were used as X-axis labels in Figures 1 and 2 below to indicate which centres undertook the procedure of interest. Therefore, centres can be identified as using DVA and core biopsy if their number is present in both Figures 1 and 2 (eg. Centre 2). Centres which used either DVA or core biopsy only are represented in the appropriate figures (eg. Centre 1 undertook DVA biopsy only and Centre 12 undertook core biopsy only.)

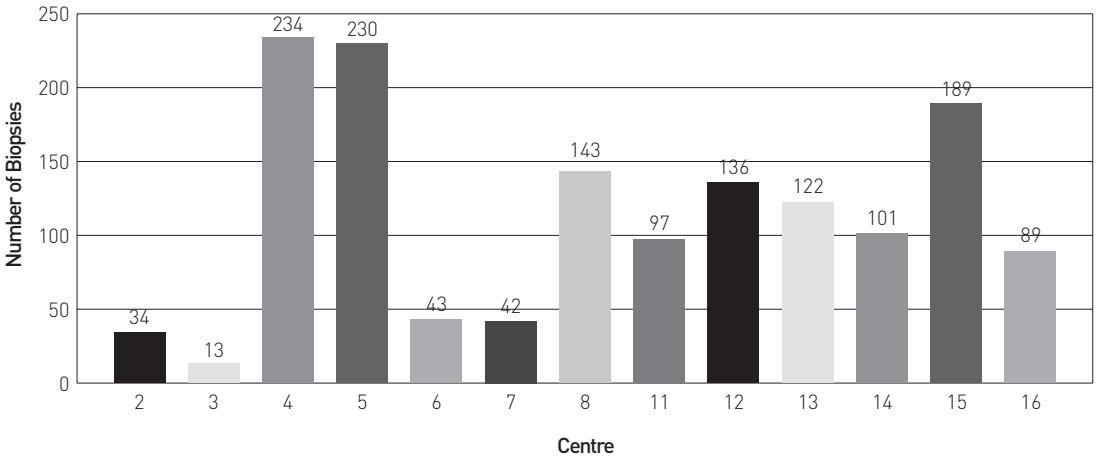
The data for DVA breast biopsy was examined first. An important characteristic of the sample data is the wide variation in the number of DVA breast biopsies performed across centres in 2001; figures ranged from 3 -151 (see Figure 1). In some centres, DVA breast biopsy technology does not appear to have been widely used, ie. less than 10 DVA breast biopsies were performed in some centres throughout 2001. This is of concern as Liberman, Benton et al (2001) found that a learning curve exists for DVA breast biopsy technology, with 'significantly higher technical success rates and lower false-negative rates' observed after the first 15 cases of DVA breast biopsy. Three of the centres in our sample had performed fewer than 15 DVA breast biopsies and therefore, in light of the evidence from Liberman, Benton et al (2001) we are less confident about the effectiveness results for these centres. If these centres are excluded our sample becomes smaller, and would be based on the results from 9 centres.

Figure 1. Number of DVA biopsies performed by centre



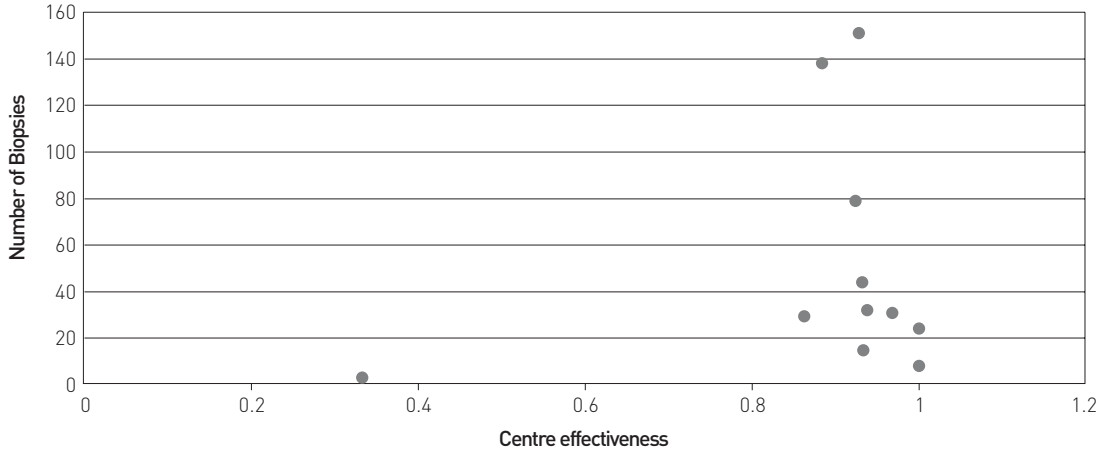
The data for core breast biopsy were also examined. Almost all centres in the sample had performed a reasonable number of core biopsies over the study period, with only one centre performing a relatively low number of biopsies (N=13) (see Figure 2).This data point was not excluded from the sample as core biopsy has been used in practice for a sufficiently long period and, it therefore seems reasonable to assume that 'learning' would have taken place in this centre.

Figure 2. Number of core biopsies undertaken by centre

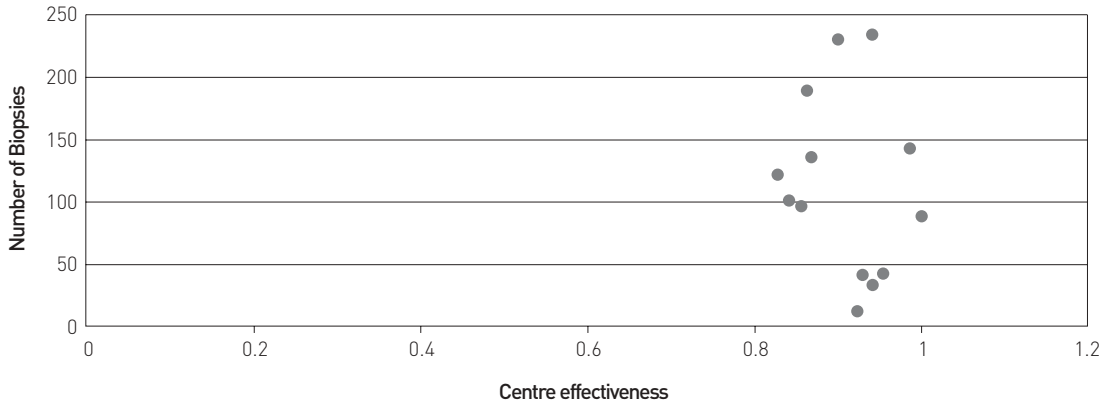


The relationship between the number of DVA biopsies undertaken in a centre and the level of effectiveness was also investigated. Effectiveness in this study was defined as the number of open biopsies avoided (sometimes referred to as the pre-operative diagnosis rate). When the number of biopsies was plotted against the level of individual centre effectiveness it can be seen that most of the results are clustered towards the right hand side of the scale, with effectiveness levels of greater than 80%, regardless of the number of DVA biopsies performed (see graph 1). However, there is one data point which appears to be very different to the rest of the data. This data point represents a centre where only three DVA breast biopsies were undertaken, which subsequently resulted in 2 open biopsies being performed. Therefore, effectiveness for this individual centre was measured at 33% - a markedly different result to the rest of the sample. However, there do not appear to be any grounds for excluding these data from the sample. When the number of core biopsies is plotted against effectiveness there do not appear to be any obvious outliers (see graph 2).

Graph 1. Relationship between number of DVA biopsies performed and centre effectiveness



Graph 2. Relationship between number of core biopsies performed and centre effectiveness



In the initial project proposal CHERE proposed that additional centres would be contacted if the data for core biopsy were insufficient. However, this was not thought to be necessary as the data collected on core biopsies appeared to be sufficient, primarily because the total sample size was relatively large. All centres - except one - which completed this section of the survey had performed over 30 core biopsies, and the effectiveness results from the centres surveyed were consistent, that is there were no obvious outliers or 'odd' results.

3.4 Alternative measures of effectiveness and results

In this study effectiveness is measured as the number of open biopsies avoided. Different methods for calculating the level of effectiveness, the appropriateness of different methods and results obtained from each method are outlined below.

3.4.1 Effectiveness based on total number of biopsies

Effectiveness can be calculated by adding the total number of DVA's, core biopsies and open biopsies performed across all centres and calculating the relevant measures of effectiveness. In our sample the total number of DVA breast biopsies performed in 2001 was 562. Of these biopsies, 46 open biopsies were subsequently performed. The total number of core biopsies performed in our sample was 1,483 and 142 open biopsies were subsequently performed. Effectiveness measures based on this methodology are presented in Table 2.

Table 2. Effectiveness based on totals

SAMPLE	EFFECTIVENESS (%)
DVA breast biopsy	
- All centres included	91.8
- 'Under 15' biopsies excluded	91.9
Core biopsy	90.4

3.4.2 Effectiveness based on average centre effectiveness

Alternatively, effectiveness can be measured by calculating the level of effectiveness for each centre and from this, calculating an overall average measure of effectiveness across the sample. Results using this methodology are shown in Table 3.

Table 3. Effectiveness based on centre effectiveness

SAMPLE	EFFECTIVENESS (%)
DVA breast biopsy	
- All centres included	89.2
- 'Under 15' biopsies only included	93.0
Core biopsy	91.0

An important aspect of this methodology is that each centre contributes equally to the measure of effectiveness. This is an important limitation of this method as, for example, a centre which performed 3 DVA breast biopsies is allocated the same weight as a centre which performed 138 biopsies. Furthermore, as the effectiveness of the technology appears to be a function of experience (Liberman, Benton et al 2001) this measure does not appear to be adequate. Therefore, a weighted measure of effectiveness would be more appropriate.

3.4.3 Weighted effectiveness

The preferred measure of effectiveness is one that weights the level of effectiveness achieved by each centre according to the number of DVA or core biopsies that were performed in that centre, relative to the total number performed in the whole sample. This methodology is the most appropriate to use because it takes into account the wide variation in the number of biopsies performed across centres. Weighted effectiveness results are presented in Table 4.

Table 4. Weighted effectiveness

SAMPLE	EFFECTIVENESS (%)
DVA breast biopsy	
- All centres included	91.8
- 'Under 15' biopsies only included	91.9
Core biopsy	90.4

When effectiveness measures are calculated using the preferred methodology (weighted effectiveness) and the most appropriate sample of centres (under 15 biopsies and incomplete data excluded) DVA biopsy (91.9%) is found to be only slightly more effective than core biopsy (90.4%). This finding seems to hold no matter what method is used to calculate effectiveness.

4. DISCUSSION

The effectiveness results outlined in Section 3 indicate that there is no real difference in the effectiveness of DVA and core biopsy and this has implications for the study. A cost-effectiveness analysis is only justified if differences exist in both the costs and effectiveness of two health care interventions. As this is not the case here, a cost effectiveness analysis would be inappropriate. Rather, a cost-minimisation analysis (which assumes equal effectiveness across technologies) would be the appropriate analysis to undertake. The aim of a cost minimisation analysis is to cost each procedure – in this case DVA and core biopsy- to establish which procedure is least costly, the magnitude of cost differences between the two procedures, and to determine what aspects of the procedures drive cost differences.

Based on survey results and expert opinion, it appears that the major driver of cost differences between DVA and core biopsy is the cost of the biopsy equipment (ie. the Mammotome and Bard Biopsy gun) and associated equipment consumables (eg. biopsy needle). The number and type of staff required to perform the procedures, staff time, patient consumables and pathology associated with both procedures appear to be very similar and would not affect relative costs. Therefore, as it is clear which resources are the primary drivers of cost differences between the procedures, a formal cost minimisation is also unnecessary as it would be unlikely to produce additional understanding of differences in costs between the two procedures. The members of the NBCC project team agreed that the formal costing component of this study would not proceed.

It may be too early to undertake a cost-effectiveness study of the type attempted here (ie. where effectiveness is based on a sample of centres utilising the technology for a particular reason) as the diffusion and application of DVA technology in Australia appears to be in its early stages. In these circumstances a randomised controlled trial (RCT) is the preferred study design. Data obtained in an RCT on the effectiveness of both DVA and core biopsy could be used in a cost-effectiveness analysis, either in tandem with the RCT or as a separate, subsequent study. An appropriately conducted RCT would not be affected by the low level of diffusion and would be able to deal with factors such as level of experience of centres, patient characteristics (to ensure a random sample) and other environmental factors which could not be controlled for in this study. This option is suggested for consideration by the NBCC project team.

LIST OF APPENDICES

APPENDIX 1

Table 1. Summary of DVA breast biopsy diagnostic effectiveness literature

AUTHOR	DVA SPECIFICATIONS	LESION TYPE	STUDY POPULATION	EFFECTIVENESS MEASURE	RESULTS
(Liberman, Kaplan et al. 2002)	-11 gauge - prone table	Solitary lesions	N= 788 (466 lesions excised and 322 sampled)	Medical records, mammographic and histologic findings reviewed. Clinical follow up data obtained.	Complete excision: - Discordance: 0.2% - DCIS underestimates: 6.8% Sampling: - Discordance: 2.5% - DCIS underestimates: 20%
(Liberman, Gougoutas et al. 2001)	-11 and 14 gauge - prone table	Calcifications highly suggestive of malignancy	- 11 gauge (n=47) -14 gauge (n=17)	Medical records reviewed to determine number of surgical procedures spared.	Surgical procedure avoided : - 11 gauge: 76.6% - 14 gauge: 35.3%
(Berg, Arnoldus et al. 2001)	- 11 and 14 gauge - prone table	Amorphous calcifications not clearly stable for at least 5 years and not in a diffuse scattered distribution	-11 gauge (n=102) - 14 gauge (n=11)	Mammographic follow up at 6, 12 and 24 months when no excision. Odds ratios calculated	- Calcification retrieved from all biopsies - Accuracy 11 gauge: 98% - Accuracy 14 gauge: 91% - Surgical procedure avoided (11 & 14 gauge): 46% (57/123)
(Lai, Burrowes et al. 2001)	- 11 gauge - prone table	Suspicious lesions	N=315 biopsies with adequate follow-up	Follow up 6 month mammogram	- Accuracy rate for benign and non benign lesions: 97.9% (2 misses) - Accuracy rate for benign lesions: 99% - Accuracy rate for non benign lesions: 95%
(Brem, Schoonjans et al. 2001)	-11gauge and 8 gauge -prone table	Non-palpable breast lesions	-N=69 (11 gauge) - N= 35 (8 gauge)	Surgical pathologic results of 104 breast carcinomas reviewed.	Underestimation of invasive carcinoma of DCIS lesion: - < 30mm (11 gauge): 3% - > 30 mm (11 gauge): 43% - < 30 mm (8 gauge): 0% - > 30 mm (8 gauge): 17% Sensitivity for diagnosis of breast carcinoma: - 11 gauge: 89% - 8 gauge: 96%

Table 1. Summary of DVA breast biopsy diagnostic effectiveness literature (continued)

AUTHOR	DVA SPECIFICATIONS	LESION TYPE	STUDY POPULATION	EFFECTIVENESS MEASURE	RESULTS
(Georgian-Smith, D'Orsi et al. 2002)	- 8 and 11 gauge - upright mammographic unit	Not specified	N= 180 biopsies in 174 patients N= 156 (11 gauge) & 24 (8 gauge)	Surgical excision or mammographic follow up. Follow up occurred in 147 cases	- Successful sampling in 98% - Discordant results: 4% (4 cases benign at core biopsy were malignant at surgical pathology and 2 malignant cases were underestimated)
(Ohsumi, Takashima et al. 2001)	- 11 and 14 gauge - upright mammographic unit	Non palpable breast lesions: 70 with microcalcif-ications, 8 masses without calcifications, 10 with masses and calcifications	N=88 lesions in 86 patients N= 85 (11 gauge) N= 3 (14 gauge)	Surgical diagnosis for malignant or ADH cases. Follow up and mammography for benign cases.	- With surgical diagnosis: 80% accuracy (5 lesions underdiagnosed, 1 lesion overdiagnosed) - All benign lesions followed up without event.
(Cangiarella, Waisman et al. 2001)	- 11 gauge - prone table	Indeterminate mammary microcalcifications without evidence of mammographic density or mass	N= 160 biopsies in 142 patients	Excisional biopsy specimens assessed and submitted for histologic evaluation. Patients with benign diagnosis had 6 month follow up mammogram.	- Patients who were followed up (67%) showed no change in cluster development or new areas of calcification or densities. - Underestimation rate for carcinoma: 20% (2/10) - 8.3% (1/12) of cases diagnosed with intraductal carcinoma showed an invasive component on follow up.
(Brem, Schoonjans et al. 2001)	- 11 gauge - prone table	Suspicious breast lesions which resulted in diagnosis of invasive breast carcinoma	N= 56 lesions surgically excised lesions	Pathology of DVA and surgically excised tissue of 56 carcinomas as well as imaging findings correlated.	- Sensitivity for diagnosis of invasion in breast cancer: 88% - 12.5 % of carcinomas completely excised
(Cangiarella, Gross et al. 2000)	- 11 gauge - prone table	Indeterminate microcalcification (not associated with a mass or density)	N=298	Incidence of positive margins determined in cases where surgical excision was recommended.	- Calcification detected in 99.7% of cases. - Mammotome biopsy facilitates fewer surgical procedures to achieve negative margins (69% had single surgical procedure)
(Beck, Gotz et al. 2000)	- 11 gauge - vacuum biopsy gun - prone table	Mammographically indeterminate lesions	N=594 lesions in 560 patients	All borderline, DCIS or invasive carcinoma cases reexision performed. All patients followed up 6-12 months.	- Accuracy: 100% (N=117) - Complete removal in 95% of cases with microcalcifications <1cm and 46% of masses <1cm. - For lesion >1 complete removal was not attempted.

Table 1. Summary of DVA breast biopsy diagnostic effectiveness literature (continued)

AUTHOR	DVA SPECIFICATIONS	LESION TYPE	STUDY POPULATION	EFFECTIVENESS MEASURE	RESULTS
(Philpotts, Lee et al. 2000)	- 11 gauge - prone table	Retrospective review to identify cases of atypical ductal hyperplasia, ductal carcinoma in situ, or invasive diseases	N= 178	Accuracy defined as those where histologic diagnosis from excisional biopsy was the same or at a lower stage than DVA biopsy.	- Overall rate of accuracy: 90.5% - Rate of underestimation for cancer: 9.5% - Underestimation rate for calcification: 16.3% - Underestimation rate for masses: 1.6% - Underestimation rate for ductal carcinoma in situ: 18% - No underestimation when entire lesion removed
(Velanovich, Lewis et al. 1999)	- 11 gauge - Lorad table	Mass, asymmetry or clustered microcalcifications	N= 107	- Technical success: if enough tissue had been removed to produce pathologic diagnosis - True positive and false positive confirmed at subsequent lumpectomy or mastectomy. - True negative confirmed by subsequent excisional biopsy, 6 month mammogram or follow up clinical examination.	- Technical success: 96.4% - Sensitivity (true positive): 87.5% - Specificity (true negative): 100% - Rebiopsy rate: 20-25%
(Gray, Benson et al. 1999)	- 11 gauge - prone table	Suspicious calcifications or small foci densities	N= 148 lesions in 141 patients	Post biopsy mammogram obtained. For benign findings 6 month follow up.	- No cases of false negative biopsies - 1 patient with diagnosis of ductal carcinoma upgraded to invasive ductal carcinoma
(Nisbet, Borthwick-Clarke et al. 2000)	- 11 gauge and 14 gauge - upright mammographic unit	Small clusters of indeterminate calcifications	N= 21 (14 gauge) N= 21 (11 gauge)	Successful sampling of calcifications	- Successful sampling 11 gauge: 86% - Successful sampling 14 gauge: 62%
(Klem, Jacobs et al. 1999)	- 11 gauge - Lorad table	Microcalcifications or mass	N= 316 biopsies in 279 patients	Diagnosis checked against pathology of open procedures	- Specificity: 99.5% - Sensitivity: 90%

Table 1. Summary of DVA breast biopsy diagnostic effectiveness literature (continued)

AUTHOR	DVA SPECIFICATIONS	LESION TYPE	STUDY POPULATION	EFFECTIVENESS MEASURE	RESULTS
(Zannis and Aliano 1998)	- 11 gauge and 14 gauge - prone table	Breast lesions	N=72	6 month mammogram follow-up for benign lesions for 33 of 56 patients	- Successful sampling: 100% - False negatives: 0% - No underestimation
(Heywang-Kobrunner, Schaumloffel et al. 1998)	- Mammotome gun - prone table	Indeterminate (N=230), suspicious (N=26) and malignant (N=5) lesions	N=261 lesions in 236 patients	- Demonstration of complete or partial removal - Re-excision of malignant (n=45) and borderline lesions (N=6) - Radiologic-histologic correlation - 6 month mammogram follow-up (N=129)	- Specificity (accuracy): 100% - Sensitivity: 99% (2 cases (1%) where stereotaxic depth was incorrect) - In borderline lesions, in situ carcinoma, and invasive carcinomas no change in diagnosis with re-exision or mastectomy - Complete removal of lesion (although not a goal of the study) possible in 96%of microcalcifications occupying space <1cm and 19/20 for densities >1cm - No relevant side effects
(Liberman, Smolkin et al. 1998)	- 11 gauge - prone table	Calcific lesions	N=112 lesions in 80 patients	Medical records, histologic findings, mammograms reviewed. Surgery used to identify underestimation.	Histologic underestimation: 2% No calcification retrieved: 5% No underestimation when all calcification removed. Repeat biopsy: 17%

APPENDIX 2

Study background

This aim of this study is to assess the cost-effectiveness of stereotactic vacuum assisted breast biopsy in the diagnosis of microcalcifications. In this study the cost-effectiveness of vacuum assisted (mammotome) breast biopsy will be compared against stereotactic core biopsy. Therefore, the information in this questionnaire focuses on **stereotactic vacuum assisted breast biopsy** (mammotome) and **stereotactic core biopsy** in the diagnosis of microcalcifications.

General questions for vacuum assisted breast biopsy cost effectiveness study

1. How long has your service had vacuum assisted (mammotome) breast biopsy equipment?

_____

2. How many vacuum assisted (mammotome) breast biopsy systems does your service have?

_____

3. Does your service have a prone table? If not, what type of stereotactic unit do you use for vacuum assisted (mammotome) breast biopsies?

_____

4. What gauge needle do you use for vacuum assisted (mammotome) breast biopsy?

_____

Procedure

The information in this section relates to **DIAGNOSTIC** procedures only.

The information required in this section refers to activities undertaken in your service **between January and December 2001**.

1. In 2001 how many women were screened through your service?

_____

2. In 2001, of all the women screened at your service how many were recalled for investigation of a **micro-calcification**?

_____

3. In 2001, of all women with a detected micro-calcification abnormality, how many went on to have the initial investigation of the micro-calcification performed by:

   - stereotactic vacuum assisted (mammotome) breast biopsy: _____
   - stereotactic core biopsy: _____
   - other (please specify): _____

   _____

   _____

Please complete for stereotactic assessment of microcalcifications only

TYPE OF PROCEDURE	DEFINITIVE OUTCOME		INADEQUATE/INDETERMINATE/ SUSPICIOUS (CODES 3 & 4)			TOTAL
	NORMAL OR BENIGN (CODE 1 & 2)	MALIGNANT (CODE 5)	RE-BIOPSY – STEREO CORE	RE-BIOPSY – STEREO MAMMO-TONE	OPEN BIOPSY	
Stereo-tactic core biopsy						
Stereo-tactic vacuum assisted						

c) Of all woman who had a vacuum assisted (mammotome) breast biopsy, how many had Micromark clips inserted?

d) How many Micromark clips in total were inserted in your clinic in 2001?

Staff required for procedures

In Table 1, please specify all staff needed to undertake stereotactic core and vacuum assisted (mammotome) breast biopsy. Please include staff and time involved in 'setting up' for each procedure.

→ **Column 1:** List all the staff required per core biopsy and vacuum assisted (mammotome) breast biopsy (eg. procedures nurse, radiographer, radiologist, counsellor).

→ **Column 2:** Number of staff required.

→ **Column 3:** Level of staff qualification (if required).

→ **Column 4:** Estimate of staff time required by each staff member per procedure.

Table 1. Staff required for stereotactic core biopsy and vacuum assisted (mammotome) breast biopsy.

STAFF REQUIRED (MINUTES)	NUMBER OF STAFF	LEVEL OF QUALIFICATION	STAFF TIME REQUIRED
STEREOTACTIC CORE BIOPSY			
Radiologist/surgeon			
Radiographer			
Counsellor			
Other			
STEREOTACTIC VACUUM ASSISTED (MAMMOTOME) BREAST BIOPSY			
Radiologist/Surgeon			
Radiographer			
Counsellor			
Other			

1 Did staff need to be specifically trained to use the vacuum assisted (mammotome) breast biopsy system? If YES, how much time was involved in training?

General questions about the vacuum assisted (mammotome) breast biopsy and stereotactic core biopsy

1 Estimate the total time taken to perform a:

- Stereotactic core biopsy: _____
- Stereotactic vacuum assisted (mammotome) breast biopsy: _____

2 Specify all routine pathology tests undertaken for those women who have stereotactic vacuum assisted (mammotome) breast biopsy.

3 Specify all routine pathology tests undertaken for those women who have a stereotactic core biopsy.

4 Please outline all patient consumables (eg. gloves, bandages anaesthetic etc), machine consumables (eg. needle, saline, syringe) and patient non-disposables (eg. forceps, instrument pack etc.) associated with vacuum assisted (mammotome) breast biopsy and stereotactic core biopsy in Table 2 (see next page).

Instructions for filling out the Table 2 are as follows:

→ **Column 1:** A preliminary list of consumables associated with vacuum assisted (mammotome) breast biopsy is provided.

→ **Column 2:** Indicate how many of these items are used per procedure. If you do not use an item listed indicate this with N/A.

→ If your service uses items not listed, list them under 'other' at the end of the table.

→ **Column 3:** Indicate whether the item listed is disposable (D) or non-disposable (ND)

→ **Column 4:** List all consumables used for each stereotactic core biopsy.

→ **Column 5:** Indicate the number of items used per stereotactic core biopsy

→ **Column 6:** Indicate whether the item is disposable (D) or non-disposable (ND)

Table 2. Consumables associated with stereotactic core and vacuum assisted (mammotome) breast biopsy

VACUUM ASSISTED (MAMMOTOME) BREAST BIOPSY CONSUMABLES	NUMBER OF ITEMS USED PER PROCEDURE	DISPOSABLE OR NON-DISPOSABLE (D OR ND)	CORE BREAST BIOPSY CONSUMABLES	NUMBER OF ITEMS USED PER PROCEDURE	DISPOSABLE OR NON-DISPOSABLE (D OR ND)
Bag, specimen					
Bandage (specify size)					
Container, specimen					
Dressing, wound op site (specify size)					
Forms (please specify eg. consent, pathology) - - -					
Freezer bag					
Gauze swab, sterile (specify size)					
Gloves - Powderless, non sterile - Sterile, surgeon					
Ice pack, disposable					
Lignocaine with 105 adrenaline, 5ml					
Lignocaine, 1%, 5ml					
Pamphlets (specify type, eg. info) - - -					
Protowel					
Needle (specify size)					
Micromark slide					

Table 2. Consumables associated with stereotactic core and vacuum assisted (mammotome) breast biopsy (continued)

VACUUM ASSISTED (MAMMOTOME) BREAST BIOPSY CONSUMABLES	NUMBER OF ITEMS USED PER PROCEDURE	DISPOSABLE OR NON-DISPOSABLE (D OR ND)	CORE BREAST BIOPSY CONSUMABLES	NUMBER OF ITEMS USED PER PROCEDURE	DISPOSABLE OR NON-DISPOSABLE (D OR ND)
Needle guide					
Scalpel, disposable (specify size)					
Steri-strip (specify size)					
Syringe, leur lok, 5ml					
Underpad					
Wipe, alcohol					
X-ray clip position (specify size)					
X-ray specimen (specify size)					
Forceps, sterile					
Instrument pack					
Needle, Mammotome (specify gauge)					
Saline, sterile 10ml					
Syringe, slip, 10 ml					
Other					

If more room is required please continue on back of this page.

Thank you for completing this survey.
Please return it to CHERE in the reply-paid envelope.

APPENDIX 3 – REMINDER LETTER

22 October 2002

Dear Director,

Recently you received a request from the National Breast Cancer Centre and the Centre for Health Economics Research and Evaluation (CHERE) to fill out a survey which sought information on the use of vacuum assisted breast biopsy in your centre. The information collected from this survey is to be used in a study to assess the cost effectiveness of vacuum assisted breast biopsy. If you have already returned your survey please ignore this letter.

If you have not returned your survey, either because you did not receive this survey, were unable to complete the survey for some reason, or simply need more time to complete the survey could you please let either Marion Haas (02) 9351 0908 or Lorraine Ivancic (02) 9351 0919 know. Your cooperation is greatly appreciated.

Yours sincerely,

Marion Haas

Deputy Director CHERE

APPENDIX 4

Study background

This aim of this study is to assess the cost-effectiveness of stereotactic vacuum assisted breast biopsy in the diagnosis of microcalcifications. In this study the cost-effectiveness of vacuum assisted (mammotome) breast biopsy will be compared against standard stereotactic core biopsy.

The information in this questionnaire relates to standard stereotactic core biopsy (ie. exclude any vacuum assisted procedures) in the diagnosis of microcalcifications.

Procedure: Standard stereotactic core biopsy

The information required in this section refers to activities undertaken in your service between January and December 2001.

1. In 2001 how many women were screened through your service?

   _____

2. In 2001, of all the women screened at your service how many were recalled for investigation of a **micro-calcification**?

   _____

3. In 2001, of all women with a detected micro-calcification abnormality, how many went on to have the initial investigation of the micro-calcification performed by:

   - standard stereotactic core biopsy: _____
   - other (please specify): _____

Please complete for standard stereotactic assessment of microcalcifications only

TYPE OF PROCEDURE	DEFINITIVE OUTCOME		INADEQUATE/INTEDERMINITE/ SUSPICIOUS (CODES 3 & 4)		TOTAL
	NORMAL OR BENIGN (CODE 1&2)	MALIGNANT (CODE 5)	RE-BIOPSY – STEREO CORE	OPEN BIOPSY	
Stereo-tactic core biopsy					

Staff required for procedures

In Table 1 (see next page) specify all staff needed to undertake standard stereotactic core biopsy. Please include staff and time involved in 'setting up' for each procedure.

→ **Column 1:** List all the staff required per core biopsy (eg. procedures nurse, radiographer, radiologist, counsellor).

→ **Column 2:** Number of staff required.

→ **Column 3:** Level of staff qualification (if required).

→ **Column 4:** Estimate of staff time required by each staff member per procedure.

Table 1. Staff required for standard stereotactic core biopsy breast biopsy

STAFF REQUIRED	NUMBER OF STAFF	LEVEL OF QUALIFICATION	STAFF TIME REQUIRED (MINUTES)
Radiologist/surgeon			
Radiographer			
Counsellor			
Other			

1. Did staff need to be specifically trained to undertake standard core biopsies? If YES, how much time was involved in training?

General questions on standard stereotactic core biopsy

1. Estimate the total time taken to perform a standard stereotactic core biopsy (in minutes).

2. Specify all routine pathology tests undertaken for those women who have a standard stereotactic core biopsy.

3. All patient consumables (eg. gloves, bandages anaesthetic etc), machine consumables (eg. needle, saline, syringe) and patient non-disposables (eg. forceps, instrument pack etc.) associated with standard stereotactic core biopsy are to be outlined in Table 2 (see next page). Instructions for filling out the table are as follows:

→ **Column 1:** A preliminary list of consumables associated with standard stereotactic core biopsy is provided.

→ **Column 1:** Indicate how many of these items are used per procedure. If you do not use an item listed indicate this with N/A.

If your service uses items not listed, list them under 'other' at the end of the table.

→ **Column 1:** Indicate whether the item listed is disposable (D) or non-disposable (ND)

Table 2. Consumables associated with standard stereotactic core biopsy

STEREOTACTIC STANDARD CORE BIOPSY CONSUMABLES	NUMBER OF ITEMS USED PER PROCEDURE	DISPOSABLE OR NON-DISPOSABLE (D OR ND)
Bag, specimen		
Bandage (specify size)		
Container, specimen		
Dressing, wound op site (specify size)		
Forms (please specify type eg. consent, pathology etc.)		
-		
-		
-		
Freezer bag		
Gauze swab, sterile (specify size)		
Gloves - Powderless, non sterile - Sterile, surgeon		
Ice pack, disposable		
Lignocaine with 105 adrenaline, 5ml		
Lignocaine, 1%, 5ml		
Needle (specify size)		
Pamphlets (please specify type, eg. information etc) - - -		
Protowel		
Scalpel, disposable (specify size)		
Steri-strip (specify size)		
Syringe, leur lok, 5ml		
Underpad		
Wipe, alcohol		
X-ray specimen (specify size)		
Forceps, sterile		
Instrument pack		
Other		

If more room is required please continue on back of this page.

Thank you for completing this survey.
Please return it to CHERE in the reply-paid envelope

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